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DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service

7 CFR Part 930


Tart Cherries Grown in the States of Michigan, et al.; Revision of Exemption Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule implementing a recommendation from the Cherry Industry Administrative Board (Board) that revised the exemption provisions under the marketing order for tart cherries grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin (order). The Board locally administers the order and is comprised of growers and handlers operating within the production area. The interim rule changed the number of years that new market development and market expansion projects are eligible for handler diversion credit from one year to three years. The interim rule also revised the composition of the subcommittee which reviews exemption requests. These changes are intended to encourage handlers to participate in new market and market expansion activities to facilitate sales and help ensure impartiality during the review process.

DATES: Effective April 19, 2016.

FOR FURTHER INFORMATION CONTACT: Jennie M. Varela, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: Jennie.Varela@ams.usda.gov or Christian.Nissen@ams.usda.gov.

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: http://www.ams.usda.gov/rules-regulations/moa/small-businesses; or by contacting Antoinette Carter, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Antoinette.Carter@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This final rule is issued under Marketing Order No. 930, as amended (7 CFR part 930), regulating the handling of tart cherries grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin, hereinafter referred to as the “order.” The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.”

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This final rule continues in effect the provisions of the interim rule that revised the exemption provisions prescribed under the order. The interim rule changed the number of years that new market development and market expansion projects are eligible for handler diversion credit from one year to three years. The interim rule also revised the composition of the subcommittee which reviews exemption requests. These changes are intended to encourage the use of new market development and market expansion activities to facilitate sales and help ensure impartiality during the review process. These changes were unanimously recommended by the Board at its meeting on June 25, 2015.

Section 930.59 of the order authorizes handler diversion. When volume regulation is in effect, handlers may fulfill any restricted percentage requirement in full or in part by acquiring diversion certificates or by voluntarily diverting cherries or cherry products in a program approved by the Board, rather than placing cherries in an inventory reserve.

Section 930.159 of the order’s administrative rules specifies methods of handler diversion, including using cherries or cherry products for exempt purposes prescribed under § 930.162. Section 930.162 establishes the terms and conditions of exemption that must be satisfied for handlers to receive diversion certificates for exempt uses. Section 930.162(b) defines the activities which qualify for exemptions under new market development and market expansion and the period for which they are eligible for diversion credit. New market development and market expansion activities include, but are not limited to, sales of cherries into markets that are not yet commercially established, product line extensions, or segmentation of markets along geographic or other definable characteristics.

Section 930.162(d) establishes a Board-appointed subcommittee to review the applications for exemption or renewal of exemption and to either approve or deny the exemption. Prior to this change, this section specified that the subcommittee consist of three members, including the Board manager, or a Board member acting in the manager’s stead, the public member, and one industry person who is not on the Board.

The order provides for the use of volume regulation to stabilize prices and improve grower returns during periods of oversupply. At the beginning of each season, the Board examines production and sales data to determine whether a volume regulation is necessary and, if so, announces free and restricted percentages to limit the volume of tart cherries on the market. Free percentage cherries can be used to supply any available market, including domestic markets for pie filling, water packed, and frozen tart cherries. Restricted percentage cherries can be placed in reserve or be used to earn diversion credits as prescribed in §§ 930.159 and 930.162 of the order’s administrative rules. These activities include, in part, the development of new products, new market development and market expansion, the development of export markets, and charitable contributions.

In 2012, the Board made a series of changes to the volume control
provisions to facilitate the marketing of tart cherries and to help lower restrictions during seasons when volume control is implemented. One of these changes was to decrease the number of years that new market development and market expansion projects are eligible for handler diversion credit from three years to one year. The Board thought this decrease would continue to encourage new market development and market expansion projects while reducing the impact these credits had on volume restriction calculations. At that time, new market and market expansion sales were not included in the average sales figure used to determine optimum supply for volume regulation. The Board anticipated the change would shift more volume to sales, helping to reduce the calculated surplus and lower the restricted percentage.

In revisiting this change, the Board recognized that the underlying rationale for having reduced the duration of diversion credit for new market development and market expansion was no longer an issue. Since that change, the method for calculating average sales for the purpose of volume regulation has been adjusted so that only export sales are excluded from the average sales calculation. Consequently, all sales from market development and market expansion activities are now included as sales when calculating a restriction. Therefore, increasing the number of years new market development and market expansion projects are eligible to receive diversion credit from one year to three years will not significantly impact the calculations for free and restricted percentages.

Further, since limiting these activities to one year, participation in new market development and market expansion activities has dropped dramatically. In years prior to changing from three years to one year, applications for new market activities numbered around 20 to 25 a season. During the 2014–15 season, the first season with volume regulation under the one-year limitation, applications dropped to eight. Handlers stated that it was not worth the time and effort to develop one of these projects if the benefit was only for a single year. It was reported that the shortened time frame did not allow handlers to recoup the resources needed to establish one of these projects.

The Board affirmed its support for new market development and market expansion diversion credit programs. Accordingly, the Board voted unanimously to change the exemption provisions applicable to handler diversion activities by increasing the number of years that new market development and market expansion activities are eligible for diversion credit back to three years. The Board also noted that projects approved for the 2014–15 season would be allowed to continue and be subject to the new three-year cycle.

This action also continues in effect a revision to the composition of the subcommittee appointed to review exemption applications. The subcommittee was formed to assist Board staff members in reviewing and granting exemptions. The subcommittee reviews applications to use restricted cherries for activities related to new product development, new market development and market expansion, the development of export markets, and for experimental purposes. Prior to this change, the previous provisions (§ 930.162(d)) stated that the subcommittee consists of the manager of the Board or a Board member acting in their stead, the public member, and one industry member who is not on the Board. The Board recommended changing the composition of the subcommittee to help ensure impartiality so that no one affiliated with a handler was part of the review process.

Consequently, the Board recommended revising the subcommittee to consist of three members, all of whom are not affiliated with a handler but have industry knowledge. One of these members shall be the public member or the alternate public member, if available to serve. The subcommittee will also include a similarly qualified alternate should one of the other members be unable to serve.

The Board made several other recommendations for changes to the regulations under the order at its June 25, 2015, meeting. These changes are being considered under a separate action.

**Final Regulatory Flexibility Analysis**

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 600 producers of tart cherries in the regulated area and approximately 40 handlers of tart cherries who are subject to regulation under the order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $750,000 and small agricultural service firms have been defined as those having annual receipts of less than $7,500,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service and Board data, the average annual grower price for tart cherries during the 2014–15 season was $0.35 per pound, and total utilization was around 300 million pounds. Therefore, average receipts for tart cherry producers were around $175,800, well below the SBA threshold for small producers. In 2014, The Food Institute estimated an f.o.b. price of $0.96 per pound for frozen tart cherries, which make up the majority of processed tart cherries. Using this data, average annual grower receipts were about $6.9 million, which is also below the SBA threshold for small agricultural service firms. Assuming a normal distribution, the majority of producers and handlers of tart cherries may be classified as small entities.

This final rule continues in effect the action that revised § 930.162 of the regulations regarding exemptions by changing the number of years that new market development and market expansion projects are eligible for handler diversion credit from one year to three years. This rule also continues in effect the revision to the composition of the subcommittee which reviews exemption requests. These changes are intended to encourage the use of new market development and market expansion activities to facilitate sales and to help ensure impartiality during the review process. The authority for these actions is provided in § 930.59 of the order.

It is not anticipated that this action will impose additional costs on handlers or growers, regardless of size. Rather, this should help handlers receive better returns on their new market development and market expansion projects by providing additional time for the handlers to receive diversion credit for those activities. This should provide more opportunity for them to recoup the time and resources required to establish these projects.

In addition, changing the number of years that these projects are eligible for
that duplicate, overlap, or conflict with this final rule. Further, the public comment received concerning the proposal did not address the initial regulatory flexibility analysis.

In addition, the Board’s meeting was widely publicized throughout the tart cherry industry, and all interested persons were invited to attend and participate in Board deliberations on all issues. Like all Board meetings, the June 25, 2015, meeting was a public meeting, and all entities, both large and small, were able to express views on this issue. An interim rule concerning this action was published in the Federal Register on November 5, 2015, (80 FR 68424) and was effective November 6, 2015. Copies of the rule were sent via email to all Board members and tart cherry handlers. Finally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending January 4, 2016, was provided to allow interested persons to respond to the proposal.

One comment was received during the comment period in response to the interim rule. The commenter, a producer, supported part of the action but offered an alternative to the membership of the subcommittee. The commenter supported the expansion of handler diversion credits for new market development and market expansion projects from one year to three years. The commenter agreed with the Board’s finding that it will encourage growth in the industry. Regarding the change to the membership of the approval subcommittee, the commenter suggested that membership should be further modified to include cherry growers that are not also handlers. However, the Board’s intent in making the revision to the subcommittee requirements was, in part, to ensure impartiality. Consequently, the Board recommended that the subcommittee be composed of members who are not affiliated with any handler. Even growers who are not handlers themselves have a business relationship with the handlers to which they sell.

The additional points in the comment were not relevant to the interim rule. Accordingly, no changes will be made to the interim rule, based on the comment received. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule, without change. To view the interim rule and the comment that was received, go to: http://www.regulations.gov/#/docketDetail?D=AMS-FV-15-0046.

This action also affirms information contained in the interim rule concerning Executive Orders 12866, 12988, 13175, and 13563; the Paperwork Reduction Act (44 U.S.C. Chapter 35); and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the Federal Register (80 FR 68424, November 5, 2015) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 930
Marketing agreements, Reporting and recordkeeping requirements, Tart cherries.

Accordingly, the interim rule that amended 7 CFR part 930 and that was published at 80 FR 68424 on November 5, 2015, is adopted as a final rule, without change.

Dated: April 12, 2016.
Elanor Starmer, Administrator, Agricultural Marketing Service.

[FR Doc. 2016–08834 Filed 4–15–16; 8:45 am]
BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service

7 CFR Part 1290
[Document No. AMS–TM–16–0004]
RIN 0581–AC59

Specialty Crop Block Grant Program Regulation; Removal of a Final Rule

AGENCY: Agricultural Marketing Service.

ACTION: Final rule; removal.

SUMMARY: The Agricultural Marketing Service (AMS) is rescinding and removing from the Code of Federal Regulations 7 CFR part 1290 entitled “Specialty Crop Block Grant Program” (SCBGP) in its entirety. This regulation implemented the SCBGP for the fiscal years 2006 to 2008 and is now obsolete.

DATES: Effective April 19, 2016.

FOR FURTHER INFORMATION CONTACT: Trista Etzig, Grants Division Director; Telephone: (202) 720–8356; email: Trista.Etzig@ams.usda.gov.

SUPPLEMENTARY INFORMATION: SCBGP is authorized under the Specialty Crop Competitiveness Act of 2004 (7 U.S.C. 1621 note).

AMS published 7 CFR part 1290, as a Final rule, in the Federal Register on September 11, 2006 (71 FR 53307), to establish regulations for SCBGP. SCBGP is a noncompetitive grant program that...
makes funds available to eligible entities for projects to solely enhance the competitiveness of specialty crops. The rule established SCBGP eligibility and application requirements, review and approval processes, and grant administration procedures for SCBGP for the fiscal years 2006 to 2008. The grant agreements that 7 CFR part 1290 affected have expired and the regulations are now obsolete. Therefore, the AMS is rescinding and removing the regulation implementing the SCBGP from 2006 to 2008 in its entirety.

**List of Subjects in 7 CFR Part 1290**
- Agriculture, Reporting and recordkeeping requirements, Specialty crop block grants.

**PART 1290—[REMOVED AND RESERVED]**

For the reasons set forth in the preamble, under the authority of 7 U.S.C. 1621 note, 7 CFR part 1290 is removed.

- Dated: April 12, 2016.
- Elanor Starmer, Administrator, Agricultural Marketing Service.
- [FR Doc. 2016–08832 Filed 4–15–16; 8:45 am]

**DEPARTMENT OF ENERGY**

**10 CFR Part 430**


**RIN 1904–AD02**

Energy Conservation Program for Consumer Products and Certain Commercial and Industrial Equipment: Determination of Portable Air Conditioners as a Covered Consumer Product

**GENCY:** Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Final determination.

**SUMMARY:** The U.S. Department of Energy (DOE) is classifying portable air conditioners (ACs) as a covered product under the Energy Policy and Conservation Act (EPCA), as amended. This classification is based on DOE’s determination that portable ACs are a type of consumer product that meets the requisite criteria specified in EPCA. Specifically, DOE has determined that classifying portable ACs as a covered product is necessary or appropriate to carry out the purposes of EPCA, and that average U.S. household energy use by portable ACs is likely to exceed 100 kilowatt-hours (kWh) per year.

**DATES:** This rule is effective May 18, 2016.

**ADDRESSES:** This rulemaking can be identified by docket number EERE–2013–BT–STD–0033 and/or Regulatory Information Number (RIN) 1904–AD02.

- **Docket:** The docket, which includes Federal Register notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index may not be publicly available, such as those containing information that is exempt from public disclosure.

- A link to the docket Web page can be found at: https://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx#ruleid/76. This Web page will contain a link to the docket for this notice on the www.regulations.gov site. The www.regulations.gov Web page contains simple instructions on how to access all documents, including public comments, in the docket.

- For further information on how to review the docket, contact Ms. Brenda Edwards at (202) 586–2945 or by email: Brenda.Edwards@ee.doe.gov.


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I. Statutory Authority


1 EPCA authorizes the Secretary of Energy to classify additional types of consumer products not otherwise specified in Part A as covered products. For a type of consumer product to be classified as a covered product, the Secretary must determine that:

1. Classifying the product as a covered product is necessary for the purposes of EPCA; and
2. The average annual per-household energy use by products of such type is likely to exceed 100 kilowatt-hours (kWh) per year. (42 U.S.C. 6292(b)(1))

For the Secretary to prescribe an energy conservation standard pursuant to 42 U.S.C. 6295(o) and (p) for covered products added pursuant to 42 U.S.C. 6292(b)(1), he must also determine that:

1. The average household energy use of the products has exceeded 150 kWh per household for a 12-month period;
2. The aggregate 12-month energy use of the products has exceeded 4.2 terawatt-hours (TWh);
3. Substantial improvement in energy efficiency is technologically feasible; and
4. Application of a labeling rule under 42 U.S.C. 6294 is unlikely to be sufficient to induce manufacturers to produce, and consumers and other persons to purchase, covered products of such type (or class) that achieve the maximum energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(l)(1))

Portable ACs are movable units typically designed to provide 8,000–14,000 British thermal units (Btu) per hour (hr) of cooling capacity2 for a single room. In contrast to room ACs, a covered product that provides...

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1 For editorial reasons, upon codification in the U.S. Code, Part B was re-designated Part A.
2 As rated according to current industry test methods.
consumers with a similar function, portable ACs are not permanently installed on the wall or in a window. DOE has determined that portable ACs meet the statutory requirements under 42 U.S.C. 6292(b)(1), and therefore classifies portable ACs as a covered product. Separately, DOE is conducting rulemakings to consider test procedures and energy conservation standards for portable ACs. DOE will determine if portable ACs satisfy the provisions of 42 U.S.C. 6295(l)(1) during the course of the energy conservation standards rulemaking.

II. Current Rulemaking Process

DOE has not previously conducted an energy conservation standards rulemaking for portable ACs. On July 5, 2013, DOE published in the Federal Register a notice of proposed determination of coverage (NOPD) in which it tentatively determined that portable ACs satisfy the provisions of 42 U.S.C. 6292(b)(1). 78 FR 40403. After considering public comments on the NOPD (see sections III and IV of this notice), DOE is issuing this final determination of coverage for portable ACs and is evaluating in separate rulemakings both test procedures and energy conservation standards for portable ACs.

With respect to the test procedure rulemaking, DOE initially published a notice of data availability (NODA) on May 9, 2014, in which it discussed various industry test procedures and presented results from its investigative testing. 79 FR 26639. In the NODA, DOE evaluated existing methodologies and alternate approaches adapted from these methodologies that could be incorporated in a future DOE test procedure for portable ACs.

After reviewing comments and information received on the NODA, DOE published a test procedure notice of proposed rulemaking (NOPR) on February 27, 2015, in which it proposed to establish test procedures for portable ACs that would ensure the test procedure is repeatable and with certain modifications to ensure the test procedures would be repeatable and representative. Based on comments from interested parties on the NOPR, DOE subsequently published a supplemental notice of proposed rulemaking (SNOPR) on November 27, 2015, in which it proposed revisions to the test procedure proposed in the NOPR to improve repeatability, reduce test burden, and ensure that the test procedure is representative of typical consumer usage. 80 FR 74020.

With respect to the energy conservation standards rulemaking, DOE published a notice of public meeting and notice of availability of a preliminary technical support document (TSD) for portable ACs on February 27, 2015, 80 FR 10628. The TSD describes the details of DOE's preliminary analysis. DOE held a public meeting to discuss and receive comments on the preliminary analysis it conducted. The meeting covered the analytical framework, models, and tools that DOE used to evaluate potential standards; the results of preliminary analyses performed by DOE for this product; the energy conservation standard levels derived from these analyses that DOE could consider for this product; and other issues relevant to the development of energy conservation standards for portable ACs.

After considering comments and information submitted on the preliminary analysis, DOE expects to complete a full analysis of both the burdens and benefits of potential energy conservation standards in a NOPR, pursuant to 42 U.S.C. 6295(o). Because DOE is classifying portable ACs as a covered product under 42 U.S.C. 6292(b)(1), DOE will also consider as part of any energy conservation standard NOPR whether portable ACs satisfy the requirements of 42 U.S.C. 6295(l)(1). After the publication of the standards NOPR, DOE will afford interested parties an opportunity during a period of not less than 60 days to provide oral and written comment. After receiving and considering the comments on the NOPR and not less than 90 days after the publication of the NOPR, DOE will issue the final rule prescribing any new energy conservation standards for portable ACs.

III. Product Definition

In the NOPD, DOE proposed the following definition of “portable air conditioner” to determine the potential scope of which products would potentially be regulated as a covered product. The proposed definition also provided clarity for interested parties with respect to the test procedure and energy conservation standards rulemakings as DOE continued its analyses. DOE initially proposed that a portable AC was:

A consumer product, other than a “packaged terminal air conditioner,” which is powered by a single phase electric current and which is an encased assembly designed as a portable unit that may rest on the floor or other elevated surface for the purpose of providing delivery of conditioned air to an enclosed space. It includes a prime source of refrigeration and may include a means for ventilating and heating.

78 FR 40403, 40404 (July 5, 2013).

DOE noted that this proposed definition would be mutually exclusive to the current definition for a room AC, which is “designed as a unit for mounting in a window or through the wall.” (10 CFR 430.2) Id.

In response to the NOPD, DOE received several comments from interested parties regarding the kinds of products that would be included under the proposed definition of a portable AC. DOE addressed these comments in the test procedure NOPR and proposed a revised definition to further refine the definition and exclude other similar products. Specifically, DOE proposed the definition:

An encased assembly, other than a “packaged terminal air conditioner,” “room air conditioner,” or “dehumidifier,” designed as a portable unit for delivering cooled, conditioned air to an enclosed space, that is powered by single-phase electric current, which may rest on the floor or other elevated surface. It includes a source of refrigeration and may include additional means for air circulation and heating.


DOE received multiple comments from interested parties in response to the proposed definition in the test procedure NOPR, focusing on the distinction between portable ACs intended for consumer versus commercial applications.

DENSO Products and Services Americas, Inc. (DENSO) noted that portable ACs are used in both residential and commercial settings, and that the typical distinction between the two settings is the use of single-phase versus three-phase power. However, DENSO expressed concern about the proposed definition because some portable ACs with single-phase power may be used in commercial or industrial applications. (DENSO, TP Public Meeting Transcript, No. 13 at pp. 21–22) 3

3 A notation in the form “DENSO, TP Public Meeting Transcript, No. 13 at pp. 21–22” identifies an oral comment that DOE received on March 18, 2015 during the Test Procedure NOPR public meeting, was recorded in the public meeting transcript in the docket for the test procedure rulemaking (Docket No. EERE–2014–BT–TP–0014). This particular notation refers to a comment (1) made by DENSO Products and Services Americas, Inc. (DENSO) during the public meeting; (2) recorded in document number 13, which is the

Continued
Oceanaire and the National Association of Manufacturers (NAM) supported the exclusion of commercial portable ACs from coverage, given the limited size of the industry and small number of units produced. These commenters stated that requiring additional testing would have a significant negative impact on this niche market. According to Oceanaire and DENSO, annual shipments of commercial portable ACs are only 15,000, as compared to the 973,700 annual shipments of consumer portable ACs in the United States that DOE estimated in its preliminary analysis for portable AC energy conservation standards. (Oceanaire, No. 10 at p. 3; NAM, No. 17 at pp. 1, 3; DENSO, TP NOPR No. 14 at p. 4)4

To identify products that are commonly referred to as portable ACs but that it contends should be excluded from coverage as consumer products, Oceanaire referred to NAM’s definition of a commercial portable AC and the following characteristics it believes are common to commercial portable ACs: (1) A minimum evaporator inlet air flow of 265 cubic feet per minute (CFM) and minimum condenser air flow of 500 CFM at standard temperature, pressure, and rated voltage; (2) a minimum refrigerant charge of 14 ounces per unit; (3) an internal condensate tank of a minimum 2-gallon capacity or a condensate pump capable of a minimum 15-foot head pressure; and (4) a minimum weight of 110 pounds. Oceanaire also stated that cooling capacities of commercial portable ACs typically range up to 65,000 Btu/hr.

A number of commenters asserted that the installation locations, operating conditions, use cases, and necessary product construction for commercial portable ACs are substantially different than those for consumer portable ACs. Oceanaire, NAM, and DENSO cited examples of permanent installations for commercial portable ACs, including steel mills, auto repair shops, cosmetics and food processing facilities, and other environments that are subject to extreme temperature, humidity, and corrosive conditions. Oceanaire further noted that commercial portable ACs are also used to address temporary or emergency short-term conditions, and are purchased by rental companies that provide temporary service to a variety of businesses. Oceanaire described the construction of commercial portable ACs as having 18 gauge and thicker steel cabinetry and support structures to meet the needs of commercial and industrial customers, and according to Oceanaire, such portable ACs have an average lifetime of 10 years. (Oceanaire, TP NOPR No. 10 at p. 2; NAM, TP NOPR No. 17 at pp. 2–3; DENSO, TP NOPR No. 14 at p. 1)

For the aforementioned reasons, Oceanaire and NAM stated that they believe that commercial portable ACs do not qualify under the provisions of EPCA as a covered product. (Oceanaire, TP NOPR No. 10 at p. 2; NAM, TP NOPR No. 17 at p. 3)

In the test procedure NOPR, DOE stated that portable ACs are not currently a covered product, and did not propose to classify commercial portable ACs as a covered product. Rather, consistent with the authority under EPCA to classify additional types of “consumer product” not otherwise specified in Part A as covered products, DOE proposed to classify “portable ACs” as a covered product.

EPCA defines “consumer product” as any article of a type that consumes, or is designed to consume, energy and which, to any significant extent, is distributed in commerce for personal use or consumption by individuals. (42 U.S.C. 6291(1)) EPCA further specifies that the definition of a consumer product applies “without regard to whether the product is in fact distributed in commerce for personal use or consumption by an individual.” (42 U.S.C. 6291(1)[B]) Under the definition of “portable air conditioner” proposed by DOE, portable ACs clearly meet EPCA’s definition of “consumer product.”

Although the definition of consumer product does not depend on whether the product is, in fact, distributed in commerce for personal use or consumption by an individual, DOE has proposed a definition of “portable air conditioner” that excludes units that could normally not be used in a residential setting by limiting the definition to include only portable ACs powered by single-phase electric current. As such, a product that requires three-phase power, a characteristic that is not appropriate for consumer products, would not be covered under DOE’s definition. Consequently, any product with single-phase power that otherwise meets the definition of a portable AC would be considered by DOE to be a portable AC regardless of the manufacturer-intended application or installation location.

Moreover, air flow rates, refrigerant charge, condensate handling system, and product weight are not attributes that inherently determine suitability for consumer use. For example, DOE identified multiple portable ACs marketed as consumer products with evaporator air flow rates greater than 265 CFM, the threshold suggested by Oceanaire and NAM, and rugged construction with correspondingly higher weight that may be desirable in some residential applications such as garages or temporary attic cooling. Further, a portable AC that meets the single-phase power requirement in the portable AC definition would not meet certain minimum thresholds for some of the product attributes in NAM’s definition of a commercial portable AC, such that the power requirement would have the same effect as if the definition were to specifically include those thresholds.

For these reasons, DOE is establishing in 10 CFR 430.2 the definition of “portable air conditioner” proposed in the test procedure NOPR with minor editorial revisions that do not modify the intent or scope of the definition:

A portable encased assembly, other than a “packaged terminal air conditioner,” “room air conditioner,” or “dehumidifier,” that delivers cooled, conditioned air to an enclosed space, and is powered by single-phase electric current. It includes a source of refrigeration and may include additional means for air circulation and heating.

IV. Evaluation of Portable ACs as a Covered Product Subject to Energy Conservation Standards

The following sections describe DOE’s determination that portable ACs fulfill the criteria for being added as a covered product pursuant to 42 U.S.C. 6292(b)(1). As stated previously, DOE may classify a type of consumer product as a covered product if (1) classifying products of such type as covered products is necessary and appropriate to carry out the purposes of EPCA; and (2) the average annual per-household energy use by products of such type is likely to exceed 100 kWh (or its Btu equivalent) per year.

A. Coverage Necessary or Appropriate To Carry Out Purposes of EPCA

DOE tentatively concluded in the NOPD that coverage of portable ACs is necessary or appropriate to carry out the purposes of EPCA. With such include: (1) To conserve energy supplies through energy conservation programs, and,
where necessary, the regulation of certain energy uses; and (2) to provide for improved energy efficiency of motor vehicles, major appliances, and certain other consumer products. (42 U.S.C. 6201) In the NOPD, DOE presented the results of its initial analysis, which suggested that the aggregate energy use of portable ACs has been increasing as these units have become popular in recent years. DOE estimated, based on market studies, that 973.7 thousand units shipped in North America in 2012, with a projected growth to 1743.7 thousand units by 2018, representing nearly 80-percent growth over 6 years.5 DOE notes that the number of entries in the California Energy Commission’s product database for “spot air conditioners”6 increased from 295 in August 2013 to 442 in October 2015, suggesting that DOE’s initial estimate of significant growth in this product category is reasonable. DOE stated in the NOPD that coverage of portable ACs would enable the conservation of energy supplies through both labeling programs and the regulation of portable AC efficiency. DOE also asserted that there is significant variation in the annual energy consumption of different models currently available, such that technologies exist to reduce the energy consumption of portable ACs. 78 FR 40403, 40404 (Jul. 5, 2013).

The Appliance Standards Awareness Project (ASAP), Alliance to Save Energy (ASE), American Council for an Energy-Efficient Economy (ACEEE), Consumers Union (CU), and Northwest Energy Efficiency Alliance (NEEA) (hereinafter the “Joint Commenters”) and AHAM supported DOE’s proposed determination that classifying portable ACs as a covered product is necessary or appropriate to carry out the purposes of EPCA. (AHAM, No. 6 at pp. 1–2; Joint Commenters, No. 4 at p. 2) The Joint Commenters further recommended that DOE classify portable ACs as a covered product to enable subsequent development of test procedures and consideration of energy conservation standards for portable ACs because: (1) Shipments are growing; (2) portable ACs have high per-unit energy use; and (3) competing products (such as room ACs) are currently covered. (Joint Commenters, No. 4 at p. 2)

DOE, therefore, reaffirms its tentative conclusion in the NOPD and determines that classifying portable ACs as a covered product is necessary and appropriate to carry out the purposes of EPCA. In consideration of the potential for improved energy efficiency of portable ACs and associated national energy savings, DOE has developed a proposed test procedure in a recent rulemaking that would establish Appendix CC, and is currently addressing potential energy conservation standards for portable ACs in a standards rulemaking.

B. Average Household Energy Use

In the NOPD, DOE estimated the average household portable AC energy use of portable ACs. DOE based its calculations on a review of the current market and a comparison to room AC energy use, and determined that the typical rated energy efficiency ratio (EER) of portable ACs is approximately 9.5, with a large available range (approximately 8.2–14.3), and that typical cooling capacities range from 8,000–14,000 Btu/hr. DOE further estimated average per-household annual electricity consumption of a portable AC, based on a typical unit with EER 9.5, to be approximately 650 kWh/yr (750 kWh/yr for EER 8.2, and 400 kWh/yr for EER 14.3). DOE also noted that one set of laboratory tests7 measured the cooling capacity of units to be half of manufacturers’ reported values, suggesting that in-field energy use is much larger than the rated value would imply. Therefore, DOE tentatively determined in the NOPD that the average annual per-household energy use for portable ACs is very likely to exceed 100 kWh/yr, satisfying the criterion of 42 U.S.C. 6292(b)(1)(B) required for classification of portable ACs as a covered product under Part A of Title III of the EPCA, as amended. 78 FR 40403, 40404–40405.

AHAM agreed with the result of DOE’s estimate of portable AC annual energy use, although it did not agree with DOE’s methodology. Specifically, AHAM suggested that the usage profiles of portable ACs differ from those for room ACs, which were the basis for DOE’s analysis. AHAM stated its belief that portable ACs are used for a shorter period of time because some consumers may use them to supplement conditioned air in a particular space or area of a room instead of as the primary means of cooling. Nevertheless, AHAM stated that it does not believe that these differences would change the determination that per-household energy use for portable ACs is likely to exceed 100 kWh/yr. (AHAM, No. 6 at pp. 2–3) The California IOUs stated that DOE’s estimate of annual energy use for a typical portable AC unit is significant and comparable to the per-unit energy use of many major household appliances. (California IOUs, No. 5 at p. 3) DOE solicited, but did not receive, portable AC usage data in both the test procedure and energy conservation standards rulemakings. DOE agrees, however, that the potential differences between portable AC and room AC usage would not change DOE’s initial determination that portable ACs meet the threshold per-household energy use, particularly because DOE’s estimates were at least a factor of four greater than the 100 kWh/yr requirement. Therefore, DOE determines here that average annual per-household energy use by portable ACs is likely to exceed 100 kWh (or its Btu equivalent) per year.

Accordingly, DOE has determined that portable ACs meet the statutory requirements under 42 U.S.C. 6292(b)(1), and therefore classifies portable ACs as a covered product. DOE amends the definition of covered product in 10 CFR 430.2 to reflect this determination.

V. Procedural Issues and Regulatory Review

DOE has reviewed this final determination of coverage for portable ACs under the following executive orders and acts.

A. Review Under Executive Order 12866

The Office of Management and Budget (OMB) has determined that coverage determination rulemakings do not constitute “significant regulatory actions” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this final action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the OMB.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement

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6 California regulations define “spot air conditioner” as “an air conditioner that discharges cool air into a space and discharges rejected heat back into that space, where there is no physical boundary separating the discharges.” This definition is distinct from the regulations’ definition of “room air conditioner” as “a factory-encased air conditioner that is designed: (1) As a unit for mounting in a window, through a wall, or as a console, and (2) for delivery without ducts of conditioned air to an enclosed space.” (California Code of Regulations, Title 20: Division 2; Chapter 4, Article 4, Section 1602(c) and (d)) Entries in the CEC database listed as spot ACs include varying configurations of portable ACs, including those that reject heat outside the conditioned space, as well as products that would not meet DOE’s definition of portable AC because they operate on three-phase power.


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Fairness Act of 1996) requires preparation of a regulatory flexibility analysis for any rule that, by law, must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. A regulatory flexibility analysis examines the impact of the rule on small entities and considers alternative ways of reducing negative effects. Also, as required by E.O. 13272, “Proper Consideration of Small Entities in Agency Rulemaking” 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003 to ensure that the potential impact of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990 (Feb. 19, 2003). DOE makes its procedures and policies available on the Office of the General Counsel’s Web site at http://energy.gov/gc/office-general-counsel.

DOE reviewed this final determination under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. This final determination sets no standards; it only positively determines that future standards may be warranted and should be explored in an energy conservation standards and test procedure rulemaking. Economic impacts on small entities would be considered in the context of such rulemakings. On the basis of the foregoing, DOE certifies that the determination has no significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this final determination. DOE will transmit this certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

This final determination, which concludes that portable ACs meet the criteria for a covered product for which the Secretary may prescribe an energy conservation standard pursuant to 42 U.S.C. 6295(o) and (p), imposes no new information or record-keeping requirements. Accordingly, the OMB clearance is not required under the Paperwork Reduction Act. (44 U.S.C. 3501 et seq.)

D. Review Under the National Environmental Policy Act of 1969

In this notice, DOE positively determines that portable ACs meet the criteria for classification as covered products and that future standards may be warranted to regulate their energy use. Should DOE pursue that option, the relevant environmental impacts would be explored as part of that rulemaking. As a result, DOE has determined that this action falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and DOE’s implementing regulations at 10 CFR part 1021. Specifically, this action establishes a class of products (portable ACs) for which energy conservation standards would be appropriate. However, this action does not establish energy conservation standards, and, therefore, does not result in any environmental impacts. Thus, this action is covered by Categorical Exclusion A6 “Procedural rulemakings” under 10 CFR part 1021, subpart D. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order (E.O.) 13132, “Federalism” 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to assess carefully the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in developing regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process that it will follow in developing such regulations. 65 FR 13735 (Mar. 14, 2000). DOE has examined this final determination and concludes that it does not preempt State law or have substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the product that is the subject of this final determination. States can petition DOE for exemption from such preemption to the extent permitted, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) No further action is required by E.O. 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, “Civil Justice Reform” 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the duty to: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation specifies the following: (1) The preemptive effect, if any; (2) any effect on existing Federal law or regulation; (3) a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) the retroactive effect, if any; (5) definitions of key terms; and (6) other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of E.O. 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether these standards are met, or whether it is unreasonable to meet one or more of them. DOE completed the required review and determined that, to the extent permitted by law, this final determination meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4, codified at 2 U.S.C. 1501 et seq.) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and tribal governments and the private sector. For regulatory actions likely to result in a rule that may cause expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any 1 year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a) and (b)) UMRA requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and tribal governments on a proposed “significant intergovernmental mandate.” UMRA also requires an agency plan for giving notice and opportunity for timely input.
to small governments that may be potentially affected before establishing any requirement that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA, 62 FR 12820 (Mar. 18, 1997). (This policy also is available at http://energy.gov/office/general-counsel). DOE reviewed this final determination pursuant to these existing authorities and its policy statement and determined that the rule contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of $100 million or more in any year, so the UMRA requirements do not apply.

\section*{H. Review Under the Treasury and General Government Appropriations Act of 1999}

Section 654 of the Treasury and General Government Appropriations Act of 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final determination does not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

\section*{I. Review Under Executive Order 12630}

Pursuant to E.O. 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights” 53 FR 8859 (Mar. 15, 1988), DOE determined that this final determination does not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

\section*{J. Review Under the Treasury and General Government Appropriations Act of 2001}

The Treasury and General Government Appropriation Act of 2001 (44 U.S.C. 3516, note) requires agencies to review most disseminations of information they make to the public under guidelines established by each agency pursuant to general guidelines issued by the OMB. The OMB’s guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final determination under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

\section*{K. Review Under Executive Order 13211}

E.O. 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A “significant energy action” is defined as any action by an agency that promulgates a final rule or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under E.O. 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of the Office of Information and Regulatory Affairs (OIRA) as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the proposal is implemented, and of reasonable alternatives to the proposed action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that this regulatory action establishing certain definitions and determining that portable ACs meet the criteria for a covered product for which the Secretary may prescribe an energy conservation standard pursuant to 42 U.S.C. 6295(o) and (p) does not have a significant adverse effect on the supply, distribution, or use of energy. This action is also not a significant regulatory action for purposes of E.O. 12866, and the OIRA Administrator has not designated this final determination as a significant energy action under E.O. 12866 or any successor order. Therefore, this final determination is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

\section*{L. Review Under the Information Quality Bulletin for Peer Review}

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal government, including influential scientific information related to agency regulatory actions. The purpose of the Bulletin is to enhance the quality and credibility of the Government’s scientific information. DOE has determined that the analyses conducted for the regulatory action discussed in this document do not constitute “influential scientific information,” which the Bulletin defines as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.” 70 FR 2667 (Jan. 14, 2005). The analyses were subject to pre-dissemination review prior to issuance of this rulemaking.

DOE will determine the appropriate level of review that would apply to any future rulemaking to establish energy conservation standards for portable ACs.

\section*{VI. Approval of the Office of the Secretary}

The Secretary of Energy has approved publication of this final determination.

\section*{List of Subjects in 10 CFR Part 430}

Administrative practice and procedure, Confidential business information, Energy conservation, Reporting and recordkeeping requirements.

Issued in Washington, DC, on April 11, 2016.

David Friedman,
Principal Deputy Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE amends part 430 of chapter II of title 10, Code of Federal Regulations as set forth below:

\section*{PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS}

\subsection*{§430.2 Definitions.}

* * * * *

\textbf{Covered product} means a consumer product—

(1) Of a type specified in section 322 of the Act, or

(2) That is a ceiling fan, ceiling fan light kit, medium base compact fluorescent lamp, dehumidifier, battery charger, external power supply, torche, or portable air conditioner.

* * * * *

\textbf{Portable air conditioner} means a portable encased assembly, other than a “packaged terminal air conditioner,” “room air conditioner,” or
“dehumidifier,” that delivers cooled, conditioned air to an enclosed space, and is powered by single-phase electric current. It includes a source of refrigeration and may include additional means for air circulation and heating.

I. Background

SUPPLEMENTARY INFORMATION:

FOR FURTHER INFORMATION CONTACT:

For the convenience of the affected parties and the public, the text of the Orders follows below in its entirety. You may access these Orders and the Summary Instructions and Guidance concerning the content and format of reports required by the Orders and the rule.

II. Orders, Summary Instructions and Guidance

For the convenience of the affected parties and the public, the text of the Orders follows below in its entirety. You may access these Orders and the Summary Instructions and Guidance concerning the content and format of reports required by the Orders and the rule.

To accompany this Order and dated March 2, 2016, with Appendices 1 through 12 thereto, Summary Instructions and Guidance, prescribe for the regulated entities the scenarios to be used for stress testing. The Summary Instructions and Guidance also provides to the regulated entities advice necessary to absorb losses as a result of adverse economic conditions; and supplemented on February 4, 2016; and supplemented on February 4, 2016.

Whereas, section 1314 of the Safety and Soundness Act, 12 U.S.C. 4514(a) authorizes the Director of FHFA to require regulated entities, by general or specific order, to submit such reports on their management, activities, and operation as the Director considers appropriate.

Now Therefore, it is hereby Ordered as follows:

Each regulated entity shall report to FHFA and to the Board of Governors of the Federal Reserve System the results of the stress testing as required by 12 CFR 1238, in the form and with the content described therein and in the Summary Instructions and Guidance, with Appendices 1 through 12 thereto, accompanying this Order and dated March 2, 2016.

It Is So Ordered, this the 2nd day of March, 2016.

This Order is effective immediately.

Signed at Washington, DC, this 2nd day of March, 2016.

Melvin L. Watt, Director, Federal Housing Finance Agency.

Dated: April 12, 2016.

Melvin L. Watt, Director, Federal Housing Finance Agency.

BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 524, 529, 556, and 558

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January and February 2016. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being
amended to reflect changes of sponsorship of applications that occurred in January and February. 

DATES: This rule is effective April 18, 2016.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January and February 2016, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOIA Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/Centers/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.

II. Changes of Sponsorship

Also, FDA is amending the regulations to reflect the approval of several minor supplemental applications that revised classes of food-producing animals in indications and in food safety warnings for decoquinate producing animals in indications and in applications that revised classes of food-several minor supplemental regulations to reflect the approval of FDA is amending the animal drug

<table>
<thead>
<tr>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>Action</th>
<th>21 CFR section</th>
<th>FOIA summary</th>
<th>NEPA review</th>
</tr>
</thead>
<tbody>
<tr>
<td>141–444 ...</td>
<td>Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW United Kingdom.</td>
<td>ZYCORTAL Suspension (desoxycorticosterone pivalate injectable suspension).</td>
<td>Original approval for use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison’s disease).</td>
<td>522.535</td>
<td>yes ..........</td>
<td>CE.1,2</td>
</tr>
<tr>
<td>141–448 ...</td>
<td>Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601.</td>
<td>THYRO–TABS CANINE (levothyroxine sodium tablets).</td>
<td>Original approval for replacement therapy for diminished thyroid function in dogs.</td>
<td>520.1248</td>
<td>yes ..........</td>
<td>CE.1,2</td>
</tr>
<tr>
<td>141–452 ...</td>
<td>Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.</td>
<td>SIMPARICA (sarolaner) Chewables.</td>
<td>Original approval for killing adult fleas, and for the treatment and prevention of flea infestations and the treatment and control of tick infestations in dogs.</td>
<td>520.2086</td>
<td>yes ..........</td>
<td>CE.1,2</td>
</tr>
<tr>
<td>141–263 ...</td>
<td>Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.</td>
<td>CERENIA (maropitant citrate) Injectable Solution.</td>
<td>Supplemental approval providing for intravenous administration in dogs and cats.</td>
<td>522.1315</td>
<td>yes ..........</td>
<td>CE.1,2</td>
</tr>
<tr>
<td>141–449 ...</td>
<td>Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.</td>
<td>SAFE–GUARD AquaSol (fenbendazole oral suspension) Suspension Concentrate.</td>
<td>Supplemental approval for the treatment and control of certain nematode worms in swine, except for nursing piglets; and of a revised tolerance in swine liver.</td>
<td>520.905a,</td>
<td>yes ..........</td>
<td>EA/FONSI.3</td>
</tr>
<tr>
<td>200–600 ...</td>
<td>ECO LLC, 344 Nassau St., Princeton, NJ 08540.</td>
<td>WORMX (pyrantel pamoate) Flavored Tablets.</td>
<td>Original approval as a generic copy of NADA 139–191.</td>
<td>520.2041</td>
<td>yes ..........</td>
<td>CE.1,2</td>
</tr>
</tbody>
</table>

1 The Agency has determined that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not have a significant effect on the human environment.

2 CE granted under 21 CFR 25.33(d)(1).

3 The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

III. Changes of Sponsorship

Also, FDA is amending the regulations to reflect the approval of several minor supplemental applications that revised classes of food-producing animals in indications and in food safety warnings for decoquinate producing animals in indications and in applications that revised classes of food-several minor supplemental regulations to reflect the approval of

Table 1—Original and Supplemental NADAs and ANADAs Approved During January and February 2016

<table>
<thead>
<tr>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>Action</th>
<th>21 CFR section</th>
</tr>
</thead>
<tbody>
<tr>
<td>006–391 ...</td>
<td>S.O. (sulfaquinoxaline) 40% Medicated Feed</td>
<td></td>
<td>558.586</td>
<td></td>
</tr>
<tr>
<td>006–677 ...</td>
<td>S.O. (sulfaquinoxaline) 20% Solution</td>
<td></td>
<td>520.2325a</td>
<td></td>
</tr>
<tr>
<td>007–087 ...</td>
<td>Sulfaquinoxaline Solubilized</td>
<td></td>
<td>520.2325a</td>
<td></td>
</tr>
</tbody>
</table>

Mission, KS 66201 has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria:
FDA has also noticed that in §558.355 (21 CFR 558.355) use of bacitracin methylenedisalicylate at 100 to 200 grams/ton in combination with monensin in broiler and replacement chicken feeds was codified in error for NADA 141–140 (66 FR 13236, March 5, 2001). At this time, §558.355 is amended by removing paragraphs (f)(1)(xxx) and (f)(4)(v). In addition, paragraph (f)(4)(iv), a remnant of a previous technical amendment (79 FR 10963, February 27, 2014), is also being removed. We have also noticed that certain paragraphs describing approved conditions of use were removed in error from §558.355 during codification of a supplemental application to NADA 138–456 that increased the dose range for monensin used in combination with bacitracin methylenedisalicylate in broiler chicken feed (57 FR 6554, February 26, 1992). At this time, §558.355 is amended by adding paragraphs (f)(1)(xxiv)(a) and (b). These actions are being taken to improve the accuracy of the regulations.

FDA has noticed that in error we removed the approved conditions of use for gleetferron, an injectable iron used to prevent anemia in young piglets. At this time, 21 CFR 522.1055 is being added. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of “rule” in 5 U.S.C. 553(a) because it is a rule of “particular applicability.” Therefore, it is not subject to the

List of Subjects

21 CFR Parts 520, 522, 524, and 529
Animal drugs.
21 CFR Part 556
Animal drugs, Food.
21 CFR Part 558
Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, 524, 529, 556, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS

1. The authority citation for part 520 continues to read as follows:

§ 520.100 [Amended]
2. In § 520.100, remove and reserve paragraph (b)(3).
3. In § 520.441, revise paragraph (b)(1), remove paragraph (b)(2); redesignate paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3); and revise newly redesignated paragraph (b)(2).
The revisions read as follows:

§ 520.441 Chlorotetracycline powder.
(b) * * * * * * * * * * * *
(1) Nos. 000010, 016592, 054771, and 069254 for use as in paragraph (d) of this section.
(2) No. 066104 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (d)(4)(iv) of this section.

4. In § 520.905a, in paragraph (a), remove “paragraph (e)(5)” and in its place add “paragraphs (e)(5) and (6)”; and add paragraph (e)(6) to read as follows:

§ 520.905a Fenbendazole suspension.
(e) * * * * * * *
(6) Swine, except for nursing piglets—(i) * * *

§ 520.1263c Lincomycin powder.
(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter as follows:
(1) No. 016592 for use as in paragraph (d) of this section.
(2) Nos. 054771, 066104, and 066123 for use as in paragraphs (d)(1) and (d)(2) of this section.

§ 520.1484 [Amended]
8. In § 520.1484, in paragraph (b)(2), remove “054771” and in its place add “016592”.
§ 520.1660d [Amended]
9. In § 520.1660d, in paragraph (b)(2), remove “054771” and in its place add “016592”; and in paragraph (b)(3), remove “054628” and in its place add “066104”.

§ 520.1696b [Amended]
10. In § 520.1696b, in paragraph (b), in numerical order add “016592”.

§ 520.1705 [Amended]
11. In § 520.1705, in paragraph (a), remove “pergolide mesylate” and in its place add “pergolide (as pergolide mesylate)”.

§ 520.2041 [Amended]
12. In § 520.2041, in paragraph (b), remove “Nos. 017135 and 051311” and in its place add “Nos. 017135, 051311, and 069167”.
13. Add § 520.2086 to read as follows:

§ 520.2086 Sarolaner.
(a) Specifications. Each chewable tablet contains 5, 10, 20, 40, 80, or 120 milligrams (mg) sarolaner.
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
(c) Conditions of use in dogs—(1) Amount. Administer orally once a month at the recommended minimum dosage of 0.9 mg/lb (2 mg/kg).
(2) Indications for use. Kills adult flies, and for the treatment and prevention of flea infestations (Ctenocephalides felis), and the treatment and control of tick infestations (Amblyomma americanum (lone star tick), Amblyomma maculatum (Gulf Coast tick), Dermacentor variabilis (American dog tick), and Rhipicephalus sanguineus (brown dog tick)) for 1 month in dogs 6 months of age or older and weighing 2.8 pounds or more.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2123c [Amended]
14. In § 520.2123c, in paragraph (b), remove “000859” and in its place add “016592”.

§ 520.2218 [Amended]
15. In § 520.2218, in paragraph (b), remove “054771” and in its place add “016592”.

§ 520.2220a [Amended]
16. In § 520.2220a, in paragraph (b)(1), remove “000859” and in its place add “016592”.

§ 520.2260b [Amended]
17. In § 520.2260b, in paragraph (f)(1), remove “000859” and in its place add “016592”.

§ 520.2325a [Amended]
18. In § 520.2325a, in paragraph (a)(1), remove “000859” and in its place add “016592”; and in paragraph (a)(3), remove “No. 054771” and in its place add “Nos. 016592 and 054771”.

§ 520.2345d, in paragraph (b)(2), remove “054628” and in its place add “066104” in paragraph (b)(3),
remove “No. 054771” and in its place add “Nos. 016592 and 054771”; and revise the first sentence in paragraph (d)(1)(iii) and paragraph (d)(2)(iii) to read as follows:

§ 520.2345d Tetracycline powder.

* * * * *

(d) * * * *

(1) * * * *

(iii) Limitations. Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for No. 066104 and within 5 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.* * *

(ii) Limitations. Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for No. 066104 and within 4 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. * * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

20. The authority citation for part 522 continues to read as follows:


21. Revise §522.535 to read as follows:

§ 522.535 Desoxycorticosterone.

(a) Specifications. Each milliliter of suspension contains 25 milligrams (mg) of desoxycorticosterone pivalate.

(b) Sponsors. See sponsor numbers in §510.600(c) of this chapter.

(1) No. 043264 for use as in paragraphs (c)(1)(i), (c)(2)(i), and (c)(3) of this section.

(2) No. 058198 for use as in paragraphs (c)(1)(i), (c)(2)(ii), and (c)(3) of this section.

(c) Conditions of use—(1) Amount. (i) Administer an initial dose of 2.2 mg/kilogram (1 mg/lb) of body weight by subcutaneous injection. Subsequent dosages should be individualized according to label instructions based on patient response to therapy.

(ii) Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(2) Indications for use—(i) For use as replacement therapy for mineralocorticoid deficiency in dogs

with primary hypoadrenocorticism (Addison’s Disease).

(ii) For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.540 [Amended]

22. In §522.540, in paragraphs (a)(2)(i) and (d)(2)(i), remove “000859” and in its place add “016592”.

§ 522.1044 [Amended]

23. In §522.1044, in paragraph (b)(4), remove “000859” and in its place add “016592”.

24. Add §522.1055 to read as follows:

§ 522.1055 Gleetoferron.

(a) Specifications. Each milliliter contains the equivalent of 200 milligrams (mg) of elemental iron as gletoferron (complex of ferric hydroxide and dextran glucoheptonic acid).

(b) Sponsor. See No. 059120 in §510.600(c) of this chapter.

(c) Conditions of use. It is used in young piglets as follows:

(1) Amounts and indications for use—(i) Administer 200 mg of elemental iron intramuscularly on or before 3 days of age for prevention of iron deficiency anemia.

(ii) Administer 200 mg of elemental iron intramuscularly for treatment of iron deficiency anemia.

(2) [Reserved]

§ 522.1182 [Amended]

25. In §522.1182, in paragraph (b)(6), remove “000859” and in its place add “016592”; and remove paragraph (b)(8).

§ 522.1315 [Amended]

26. In §522.1315, in paragraphs (c)(1)(i) and (c)(2)(i), remove “subcutaneous injection” and in its place add “subcutaneous or intravenous injection”.

§ 522.1660a [Amended]

27. In §522.1660a, in paragraph (b), remove “000859” and in its place add “016592”.

§ 522.1662a [Amended]

28. In §522.1662a, in paragraphs (b)(2) and (i)(2), remove “000859” and in its place add “016592”.

§ 522.1696a [Amended]

29. In §522.1696a, in paragraph (b)(2), remove “000859” and in its place add “016592”.

§ 522.1696b [Amended]

30. In §522.1696b, in paragraph (b)(1), remove “000859” and in its place add “016592”.

§ 522.2120 [Amended]

31. In §522.2120, in paragraph (b), remove “000859” and in its place add “016592”.

§ 522.2220 [Amended]

32. In §522.2220, in paragraph (b)(3), remove “000859” and in its place add “016592”.

§ 522.2615 [Amended]

33. In §522.2615, in paragraph (b), remove “000859” and in its place add “016592”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

34. The authority citation for part 524 continues to read as follows:


§ 524.1193 [Amended]

35. In paragraph (b)(2) of §524.1193, remove “000859” and in its place add “016592”.

§ 524.1484k [Amended]

36. In §524.1484k, revise the section heading to read: Neomycin and prednisolone suspension.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

37. The authority citation for part 529 continues to read as follows:


§ 529.1660 [Amended]

38. In §529.1660, in paragraph (b)(2), remove “048164, 054771, and 061623” and in its place add “054771, 061623, and 069254”.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

39. The authority citation for part 556 continues to read as follows:


40. In §556.275, in paragraph (b)(2)(i), remove “6 ppm” and in its place add “3.2 ppm”; redesignate paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and add new paragraph (b)(3) and paragraph (c) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *
(3) Chickens—(i) Liver (the target tissue). The tolerance for fenbendazole sulfone (the marker residue) is 5.2 ppm.

(ii) [Reserved]

(c) Related conditions of use. See §§ 520.905a, 520.905c, 520.905d, 520.905e, and 558.258 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

41. The authority citation for part 558 continues to read as follows:


§ 558.195 [Amended]

42. Amend § 558.195 as follows:

(a) In paragraph (b)(1), remove “Do not feed to laying chickens.” and in its place add “Do not feed to laying hens producing eggs for human consumption.”;

(b) In the table in paragraphs (e)(1)(i), in the “Indications for use” column, remove “Do not feed to laying hens producing eggs for human consumption.”;

(c) In the table in paragraphs (e)(3)(i)1. and (e)(3)(iii)1., in the “Limitations” column, remove “Do not feed to sheep producing milk for food.” and in its place add “Do not feed to sheep producing milk for human consumption.”;

(d) In the table in paragraphs (e)(3)(ii)1. and (e)(3)(iii)1. in the “Limitations” column, remove “Do not feed to cows producing milk for food.” and in its place add “Do not feed to cows producing milk for human consumption.”;

(e) In paragraph (d)(1)(xxvi)(b), remove “Chlortetracycline as provided by Nos. 016592; bacitracin methylene disalicylate as provided by No. 054771; chlortetracycline as provided by Nos. 054771 and 016592; oxytetracycline as provided by Nos. 054771 and 016592 in § 510.600(c) of this chapter.” and in its place add “Chlortetracycline as provided by Nos. 054771 and 016592; oxytetracycline as provided by Nos. 054771 and 016592 in § 510.600(c) of this chapter.”;

(f) In paragraph (d)(1)(xxvii)(b), remove “Salinomycin as provided by Nos. 016592; bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.” and in its place add “Salinomycin as provided by Nos. 016592; bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.”;

43. In § 558.340, redesignate paragraph (b)(3) as paragraph (b)(2) and redesignate paragraph (b)(2) as paragraph (b)(3);

44. Amend § 558.355, revise paragraph (f)(1)(xxv); and revise paragraph (f)(1)(xxv) introductory text and remove and reserve paragraphs (f)(1)(xxx), (f)(4)(iv), and (f)(4)(v).

The provisions read as follows:

§ 558.355 Monensin.

(f) * * * *

(1) * * * *

(xxiv) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 4 to 50 grams.

(2) Limitations. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylene disalicylate provided by No. 054771 in § 510.600(c) of this chapter.

(xi) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams.

§ 558.515 [Amended]

45. In § 558.515, in the table in paragraph (d), in the entry for “30 (0.0033 pct)”, in the first entry under the “Indications for use” column, remove “For broiler and fryer chickens:” and in its place add “Broiler chickens:” and in the first entry under the “Limitations” column, remove “Do not feed to layers:” and in its place add “Do not feed to chickens producing eggs for food.”

§ 558.550 [Amended]

46. Amend § 558.550 as follows:

(a) In paragraph (b)(1), remove “054771” and in its place add “016592”;

(b) Remove paragraph (b)(2) and redesignate paragraph (b)(3) as paragraph (b)(2);

(c) In paragraph (d)(1)(xxvii)(c), remove “Chlortetracycline as provided by Nos. 054771 and 069254; salinomycin as provided by Nos. 054771 and 016592 in § 510.600(c) of this chapter.” and in its place add “Chlortetracycline as provided by Nos. 054771 and 069254; salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.”;

(d) In paragraph (d)(1)(xx)(C) and (xxi)(C), remove “Salinomycin as provided by Nos. 054771 and 069254; bambermycins by No. 016592 in § 510.600(c) of this chapter.” and in its place add “Salinomycin and bambermycins as provided by Nos. 054771 and 016592; bambermycins by No. 016592 in § 510.600(c) of this chapter.”;

§ 558.586 [Amended]

47. In § 558.586, in paragraph (b), remove “000859” and in its place add “016592”.

Dated: April 12, 2016.

Tracey Forfa,
Acting Director, Center for Veterinary Medicine.

[FR Doc. 2016–08827 Filed 4–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0650]

Cardiovascular Devices;
Reclassification of External Pacemaker Pulse Generator Devices;
Reclassification of Pacing System Analyzers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify external pacemaker pulse generator (EPPC) devices, which are currently preamendments class III devices (regulated under product code
FDA has classified most devices into class II (special controls) and to reclassify pacing system analyzers (PSAs) into class II (special controls) based on new information and subject to premarket notification. This final order also creates a separate classification regulation for PSAs and places single and dual chamber PSAs, which are currently classified with EPPG devices, and triple chamber PSAs (TCPSPs), which are currently postamendments class III devices, into that new classification regulation.

DATES: This order is effective April 18, 2016.

FOR FURTHER INFORMATION CONTACT: Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1652, Silver Spring, MD 20903, 301–796–6351, hina.pinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities


Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as postamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A postamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a postamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a premarket approval application (PMA) until FDA issues a final order under section 513(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device under that section from rulemaking to an administrative order. Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon “new information.” FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify an eligible device type. The term “new information,” as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos Co. v. United States Department of Health, Education, and Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1979); Upjohn v. Finch, 432 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see Bell, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F. Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in “medical science” (Upjohn, 422 F.2d at 951). Whether data before the Agency are old or new data, the “new information” to support reclassification under section 513(e) must be “valid scientific evidence,” as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Manufacturers Assoc. v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986)). FDA relies upon “valid scientific evidence” in the reclassification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360(c)).

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order to reclassify a device under that section. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act and (3) consideration of comments to a public docket. FDA published a proposed order to reclassify EPPG and PSA devices in the Federal Register of September 15, 2014 (79 FR 54927) (the “proposed order”). On September 11, 2013, FDA held a meeting of a device classification panel described in section 513(b) to discuss reclassification of EPPG and PSA devices (the “2013 Panel”). FDA
has also received and considered comments on the proposed order as discussed in section III. Therefore, FDA has satisfied the requirements for issuing a final order under section 513(e)(1) of the FD&C Act.

II. Regulatory History of the Devices

As noted in the proposed order, on March 9, 1979, the Agency published a proposed rule for the classification of EPPG devices into class III (44 FR 13284). FDA subsequently published a final rule classifying EPPG devices into class III under § 870.3600 (21 CFR 870.3600) after receiving no comments on the March 9, 1979, proposed rule (45 FR 7904, February 5, 1980). In 1987, FDA published a final rule to codify language clarifying that no effective date had been established for the requirement for premarket approval for EPPG devices (52 FR 17732, May 11, 1987). In 2009, FDA published an order (the “515(i) Order”) requiring manufacturers of remaining class III devices for which regulations requiring PMAs had not been issued, including EPPGs, to submit a summary of information concerning those devices by August 7, 2009 (74 FR 16214, April 9, 2009). On October 17, 2011, FDA published a proposed rule proposing the reclassification of EPPG devices from class III to class II (76 FR 64214), which the Agency subsequently withdrew on September 15, 2014 (79 FR 54927). FDA withdrew the proposed rule in response to the new process for reclassifications under section 513(e) of the FD&C Act, as amended by FDASIA, and new information, including new information discussed during the 2013 Panel meeting.

Single and dual chamber PSAs have historically been classified with EPPG devices. Single and dual chamber PSAs combine the functionality of a single or dual chamber EPPG, which is currently a class III device, and the functionality of a pacemaker electrode function tester, which is regulated as a class II device under § 870.3720 (21 CFR 870.3720). Single and dual chamber PSA devices have been found substantially equivalent to EPPG devices through the 510(k) process. TCPSA devices have not been determined to be substantially equivalent to a predicate device through the 510(k) process and, because TCPSAs were not on the market before May 28, 1976, TCPSAs have been reviewed through the PMA process as postamendments class III devices. This order creates a new classification regulation for single, dual, and triple chamber PSA devices, which combine the functionality of an EPPG and the functionality of a pacemaker electrode function tester.

As discussed in the proposed order, FDA considered the available information on these devices (EPPG and PSA devices) and concluded that reclassifying these devices to class II, subject to the identified special controls, would provide reasonable assurance of their safety and effectiveness. As required by section 513(e)(1) of the FD&C Act, FDA convened a meeting of a device classification panel described in section 513(b) of the FD&C Act to discuss whether EPPG and PSA devices should be reclassified or remain in class III on September 11, 2013 (78 FR 49272). The reclassification of EPPG and PSA devices was supported by the 2013 Panel. The 2013 Panel recommended that EPPG devices (including single and dual chamber PSAs) be reclassified to class II with special controls when intended for cardiac rate control or prophylactic arrhythmia prevention. In addition, the 2013 Panel agreed that EPPG devices are life-supporting and, per § 860.93 (21 CFR 860.93), explained that its rationale for recommending that EPPG devices be reclassified to class II was based on the proposed special controls FDA presented, which the 2013 Panel believed were adequate (along with general controls) to mitigate the risks of the device.

The 2013 Panel also recommended that TCPSA devices be reclassified to class II with special controls when intended for use during the pulse generator implant procedure. The 2013 Panel acknowledged that TCPSA devices are life-supporting devices and provided the following rationale per § 860.93 for recommending that TCPSA devices be reclassified to class II: (1) These devices are used only during the implant procedure where backup monitoring is continuous, hazards can be recognized and treated immediately, and where there is a reasonable expectation that users are adequately trained; (2) these devices are not intended to provide the long-term hemodynamic benefit of biventricular pacing or cardiac resynchronization therapy; and (3) the recommended special controls will mitigate the health risks associated with the device. The 2013 Panel transcript and other meeting materials are available on FDA’s Web site (Ref. 1). Since the 2013 Panel meeting, FDA has not become aware of new information that would provide a basis for a device classification panel to make a different recommendation or different findings.

III. Public Comments in Response to the Proposed Order

In response to the September 15, 2014, proposed order to reclassify EPPG and PSA devices (79 FR 54927), FDA received two comments. FDA previously received three sets of comments on the October 17, 2011, proposed rule to reclassify EPPG devices that was subsequently withdrawn (79 FR 54927). The Agency has considered all of these comments in drafting this final order.

The comments and FDA’s responses to the comments are summarized in this section. Certain comments are grouped together under a single number because the subject matter of the comments is similar. The number assigned to each comment is purely for organizational purposes and does not signify the comment’s value or importance or the order in which it was submitted.

(Comment 1) Four comments suggested that EPPG devices are life-sustaining and should be subject to premarket approval to provide better assurance of safety and effectiveness; as such, the comments asserted that EPPG devices should remain in class III. Further, one comment indicated that the proposed special controls are not sufficient to mitigate the risks associated with EPPG devices. Three other comments also discussed the risks associated with these devices and the need for adequate mitigation through premarket approval.

(Remote 1) These comments were considered by FDA in drafting this final order. Per 21 CFR 860.3(c)(3), a device is in class III if two conditions are met: (1) Insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness; or (2) that application of special controls described in 21 CFR 860.3(c)(2) would provide such assurance, and (2) the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury. FDA has concluded that for EPPG devices, special controls will provide reasonable assurance of safety and effectiveness to appropriately mitigate risks to health. Therefore, these life-supporting devices can be reclassified into class II. As discussed in section II, the 2013 Panel agreed with FDA’s recommendation of class II for EPPG and TCPSA devices.

EPPG devices are therapeutic devices designed to be used temporarily and in a controlled clinical setting. The expected presence of clinical support...
and physician monitoring mitigates many potential complications. Specifically, EPPG devices are used exclusively in hospital environments with the patients supervised by qualified medical personnel. The environment of care for EPPG devices includes resuscitation equipment, hospital level monitoring of heart rhythm, and patient vital status by other devices with alarm functions. The special controls require labeling for EPPG devices to “clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use.” Further, the non-clinical performance testing and labeling special controls appropriately mitigate the risks for EPPG devices by helping to ensure adequate device performance/pacing, as well as proper maintenance of the device.

(Comment 2) Three comments referenced the number of medical device reports (MDRs) associated with EPPG devices and suggested that MDR data support keeping EPPG devices in class III. Two of those comments also discussed the number of MDR reports for malfunctions associated with EPPG devices and suggested that this shows the performance standards that have been developed and used to support EPPG marketing applications are insufficient to provide reasonable assurance of safety and effectiveness. (Response 2) Increased premarket regulatory requirements cannot be assumed to result in fewer MDRs, nor are MDRs necessarily an indicator of poor device performance. FDA performed multiple analyses of MDRs for EPPG devices in the Manufacturer and User Facility Device Experience (MAUDE) database. The Agency’s analysis of the available data shows that over 85 percent of reports had either no patient involvement or no known consequences to the patient. These types of malfunction reports were generally discovered during routine servicing, which may be anticipated for reusable electrical devices. FDA’s MDR analyses were conducted multiple times during the reclassification process and showed trends of increased reporting, but with an associated sharp decline in the relative number of death and injury reports over the last several years (i.e., the increased reporting was largely for device malfunctions). FDA believes these trends are indicative of tighter adherence to MDR requirements and a related change in reporting practices rather than a change in device performance. FDA’s detailed review of MDRs for EPPG devices also did not suggest design or functional issues that would be decreased by requiring premarket approval for EPPG devices. FDA also reviewed device recalls for EPPGs over the past 15 years and did not find evidence indicating the need for class III premarket approval regulation of these devices. FDA presented its analysis of MDR and recall data to the 2013 Panel that ultimately recommended reclassification of EPPG devices from class III to class II (special controls). The 2013 Panel identified no new or different risks for EPPG devices based on that information. Therefore, FDA believes that the identified special controls provide adequate mitigation of the health risks posed by the EPPG device.

(Comment 3) One comment suggested that EPPG devices remain in class III and require PMAs because FDA failed to identify new information on which to base the reclassification recommendation, specifically noting: (1) Performance standards developed in support of PMAs are not publicly available, and (2) information submitted in response to the 515(i) Order that was not publicly available in the Agency’s analysis of risks to health for EPPG devices.

(Response 3) FDA’s presentation to the 2013 Panel included a summary of the available safety and effectiveness information for EPPG devices, including FDA’s analysis of adverse event reports from FDA’s MAUDE database and available literature. The 2013 Panel agreed with FDA’s conclusion that the available scientific evidence is adequate to support reasonable assurance of the safety and effectiveness of EPPG devices and to reclassify EPPG devices to class II. While the 2013 Panel agreed with the identified risks to health presented at the September 11, 2013, meeting, it recommended that FDA consider rewording some of the language for clarity and also to ensure that certain hazards, such as asynchronous pacing and arrhythmia induction, are included in the risks to health. FDA agreed with the 2013 Panel’s recommendations and modified the risks to health accordingly as outlined in section V of the 2014 proposed order. The Agency identified in the proposed order special controls, including non-clinical performance testing data and labeling that, together with general controls (including prescription use), would provide reasonable assurance of the safety and effectiveness of EPPG devices. Since the 2013 Panel, FDA has not become aware of new information that would provide a basis for a different recommendation or finding for these devices. Information submitted in response to the 2009 515(i) Order that FDA used in its reclassification determination was incorporated in what the Agency presented to the 2013 Panel (see Ref. 1). In addition, that information was listed in the September 15, 2014, proposed order and is publicly available through other sources. The information presented to the 2013 Panel and discussed in the 2014 proposed order also identified and provided information regarding the two recognized consensus standards that address various aspects of design and performance of EPPG devices (IEC 60601–1 and IEC 60601–2–31). The information provided by these consensus standards is particularly important as design control measures and aided in forming part of the basis for FDA’s reclassification determination. Therefore, the information that forms the basis for FDA’s reclassification determination has been made publicly available.

(Comment 4) One comment suggested that PSA devices remain in class III because the special controls rely heavily on labeling to mitigate risks, and expressed doubt that labeling would be sufficient to protect the health of patients.

(Response 4) It should be noted that labeling is not the only mitigation that is proposed to reasonably assure safety and effectiveness of PSAs. Further, neither FDA nor the 2013 Panel believed that clinical performance testing was necessary to provide reasonable assurance of safety or effectiveness. The environment of care for PSAs is limited to the surgical implant suite, which must have backup pacing, defibrillation and resuscitation equipment, and capabilities including intensive care level monitoring of heart rhythm and patient vital signs. Therefore, FDA believes that the non-clinical performance testing and labeling special controls, in addition to general controls, can be established to mitigate the identified risks and provide reasonable assurance of the safety and effectiveness of PSA devices when indicated for use during the implant procedure of pacemakers and defibrillators for the evaluation of the placement and integrity of pacing leads to determine the appropriate pacing parameters for the implanted device. Furthermore, the 2013 Panel agreed that the special controls would mitigate the health risks associated with the PSA devices.

IV. The Final Order

Based on the information discussed in the preamble to the proposed order (79 FR 54927, September 15, 2014), the comments received, a review of the
MAUDE database and recall data, a review of current scientific literature, and the 2013 Panel deliberations (see the 2013 Panel transcript [Ref. 1]). FDA concludes that special controls, in conjunction with general controls, will provide reasonable assurance of the safety and effectiveness of EPPG and PSA devices. Under sections 513(e) and 513(f) of the FD&C Act, FDA is adopting its findings, as published in the preamble to the proposed order. FDA is issuing this final order to reclassify EPPG devices from class III to class II (special controls), as well as to create a separate classification regulation for PSA devices and reclassify PSA devices into class II (special controls). As noted in the proposed order, FDA is also making a slight modification to the identification for EPPG devices in §870.3600 to clarify that these are prescription devices.

Following the effective date of this final order, firms marketing an EPPG or PSA device must comply with the applicable mitigation measures set forth in the modified special controls. Manufacturers of EPPG or PSA devices that have not been legally marketed prior to the effective date of this final order, or models (if any) that have been marketed but are required to submit a new 510(k) under 21 CFR 807.81(a)(3) because the device is about to be significantly changed or modified, must obtain 510(k) clearance and demonstrate compliance with the special controls included in this final order, before marketing the new or changed device. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of EPPG and PSA devices for their intended uses, and therefore, these device types are not exempt from premarket notification requirements.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231: the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously promulgated regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, pursuant to section 513(e)(1)(A)(ii) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in §870.3600 related to the classification of EPPG devices as class III devices, and codifying the reclassification of EPPG and PSA devices into class II (special controls).

VIII. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:


2. Section 870.3600 is revised to read as follows:

§870.3600 External pacemaker pulse generator.

(a) Identification. An external pacemaker pulse generator (EPPG) is a prescription device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart’s intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

(b) Classification. Class II (special controls). The special controls for this device are:

1. Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

2. Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

3. Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

4. Appropriate software verification, validation, and hazard analysis must be performed.
§ 870.3605 Pacing system analyzer.

(a) Identification. A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3660). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g., data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the EPPG device. The markings should identify positive (+) and negative (−) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching); and

(v) Appropriate electromagnetic compatibility information must be included.

3. In Subpart D, add § 870.3605 to read as follows:

§ 870.3605 Pacing system analyzer.

(a) Identification. A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3660). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient’s pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g., data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the PSA. The markings should identify positive (+) and negative (−) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals. Triple chamber devices should clearly identify atrial, right ventricular, and left ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching);

(v) Labeling must limit the use of external pacing to the implant procedure; and

(vi) Appropriate electromagnetic compatibility information must be included.

Dated: April 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–08898 Filed 4–15–16; 8:45 am]

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DEPARTMENT OF LABOR
Occupational Safety and Health Administration

29 CFR Part 1987
[Docket Number: OSHA–2011–0859]
RIN 1218–AC58

Procedures for Handling Retaliation Complaints Under Section 402 of the FDA Food Safety Modernization Act

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: This document provides the final text of regulations governing the employee protection (retaliation or whistleblower) provision found at section 402 of the FDA Food Safety Modernization Act (FSMA), which added section 1012 to the Federal Food, Drug, and Cosmetic Act. An interim final rule governing these provisions and requesting public comment was published in the Federal Register on February 13, 2014. Two comments were received that were responsive to the rule. This rule responds to those comments and establishes the final procedures and time frames for the handling of retaliation complaints under FSMA, including procedures and time frames for employee complaints to the Occupational Safety and Health Administration (OSHA), investigations by OSHA, appeals of OSHA determinations to an administrative law judge (ALJ) for a hearing de novo, hearings by ALJs, review of ALJ decisions by the Administrative Review Board (ARB) (acting on behalf of the Secretary of Labor), and judicial review of the Secretary’s final decision.

DATES: This final rule is effective on April 18, 2016.

FOR FURTHER INFORMATION CONTACT: Cleveland Fairchild, Program Analyst, Directorate of Whistleblower Protection Programs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–4618, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2199. This is not a toll-free number. Email: OSHA.DWPP@dol.gov. This Federal Register publication is available in alternative formats. The alternative formats available are: Large print, electronic file on computer disk (Word Perfect, ASCII, Mates with Duxbury Braille System), and audiotape.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (Pub. L. 111–353, 124 Stat. 3885), was signed into law on January 4, 2011. Section 402 of the FDA Food Safety Modernization Act amended the Federal Food, Drug, and Cosmetic Act (FD&C) to add section 1012, 21 U.S.C. 399d, which provides protection to employees against retaliation by an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food for engaging in certain protected activities. Section 1012 protects employees against retaliation because they provided or are about to provide to their employer, the
Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of, any provision of the FD&C or any order, rule, regulation, standard, or ban under the FD&C; testified or are about to testify in a proceeding concerning such violation; assisted or participated, or are about to assist or participate, in such a proceeding; or objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of any provision of the FD&C or any order, rule, regulation, standard, or ban under the FD&C.

Section 1012 became effective upon enactment on January 4, 2011. Although the Food and Drug Administration of the U.S. Department of Health and Human Services (FDA) generally administers the FD&C, the Secretary of Labor is responsible for enforcing the employee protection provision set forth in section 1012 of the FD&C. These rules establish procedures for the handling of whistleblower complaints under section 1012 of the FD&C. Throughout this rule, FSMA refers to section 402 of the FDA Food Safety Modernization Act, codified as section 1012 of the Federal Food, Drug and Cosmetic Act. See 21 U.S.C. 399d.

II. Summary of Statutory Procedures

FSMA’s whistleblower provisions include procedures that allow a covered employee to file, within 180 days of the alleged retaliation, a complaint with the Secretary of Labor (Secretary). Upon receipt of the complaint, the Secretary must provide written notice to the person or persons named in the complaint alleged to have violated the FSMA (respondent) of the filing of the complaint, the allegations contained in the complaint, the substance of the evidence supporting the complaint, and the rights afforded the respondent throughout the investigation. The Secretary must then, within 60 days of receipt of the complaint, afford the complainant and respondent an opportunity to submit a response and meet with the investigator to present statements from witnesses, and conduct an investigation.

The statute provides that the Secretary may conduct an investigation only if the complainant has made a prima facie showing that the protected activity was a contributing factor in the adverse action alleged in the complaint and the respondent has not demonstrated through clear and convincing evidence, that it would have taken the same adverse action in the absence of that activity (see section 1987.104 for a summary of the investigation process). OSHA interprets the prima facie case requirement as allowing the complainant to meet this burden through the complaint as supplemented by interviews of the complainant.

After investigating a complaint, the Secretary will issue written findings. If, as a result of the investigation, the Secretary finds there is reasonable cause to believe that retaliation has occurred, the Secretary must notify the respondent of those findings, along with a preliminary order that requires the respondent to, where appropriate: Take affirmative action to abate the violation; reinstate the complainant to his or her former position together with the compensation of that position (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and provide compensatory damages to the complainant, as well as all costs and expenses (including attorney fees and expert witness fees) reasonably incurred by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

The complainant and the respondent then have 30 days after the date of the Secretary’s notification in which to file objections to the findings and/or preliminary order and request a hearing before an administrative law judge (ALJ) at the Department of Labor. The filing of objections under FSMA will stay any remedy in the preliminary order except for preliminary reinstatement. If a hearing before an ALJ is not requested within 30 days, the preliminary order becomes final and is not subject to judicial review.

If a hearing is held, the statute requires the hearing to be conducted “expeditiously.” The Secretary then has 120 days after the conclusion of any hearing in which to issue a final order, which may provide appropriate relief or deny the complaint. Until the Secretary’s final order is issued, the Secretary, the complainant, and the respondent may enter into a settlement agreement that terminates the proceeding. Where the Secretary has determined that a violation has occurred, the Secretary, where appropriate, will assess against the respondent a sum equal to the total amount of all costs and expenses, including attorney and expert witness fees, reasonably incurred by the complainant for, or in connection with, the bringing of the complaint upon which the Secretary issued the order. The Secretary may also award a prevailing employer reasonable attorney fees, not exceeding $1,000, if the Secretary finds that the complaint is frivolous or has been brought in bad faith.

Within 60 days of the issuance of the final order, any person adversely affected or aggrieved by the Secretary’s final order may file an appeal with the United States Court of Appeals for the circuit in which the violation allegedly occurred or the circuit where the complainant resided on the date of the violation.

FSMA permits the employee to seek de novo review of the complaint by a United States district court in the event that the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination. The court will have jurisdiction over the action without regard to the amount in controversy, and the case will be tried before a jury at the request of either party.

FSMA also provides that nothing therein preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprimand, retaliation, or any other manner of discrimination provided by Federal or State law. Finally, FSMA states that nothing therein shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement, and the rights and remedies in FSMA may not be waived by any agreement, policy, form, or condition of employment.

III. Summary and Discussion of Regulatory Provisions

On February 13, 2014, OSHA published in the Federal Register an interim final rule (IFR) establishing rules governing the whistleblower provisions of 402 of the FDA Food Safety Modernization Act. 79 FR 8619. OSHA provided the public an opportunity to comment on the IFR by April 14, 2014.

In response, OSHA received comments that were responsive to the rule from two organizations. Comments were received from the Roll Law Group (Roll), on behalf of Paramount Farming Company LLC, Paramount Farms International LLC, Pom Wonderful LLC, and Paramount Citrus Holdings LLC, and; Kalijarvi, Chuzi, Newman & Fitch, P.C. (Kalijarvi). OSHA also received one comment that was not responsive to the rule.

OSHA has reviewed and considered the comments and now adopts this final rule with minor revisions. The following discussion addresses the
comments and OSHA’s responses. The provisions in the IFR are adopted and continued in this final rule, unless otherwise noted below. The regulatory provisions in this part have been written and organized to be consistent with other whistleblower regulations promulgated by OSHA to the extent possible within the bounds of the statutory language of FSMA. Responsibility for receiving and investigating complaints under FSMA has been delegated to the Assistant Secretary for Occupational Safety and Health (Assistant Secretary). Secretary of Labor’s Order No. 1–2012 (Jan. 18, 2012), 77 FR 3912 (Jan. 25, 2012). Hearings on determinations by the Assistant Secretary are conducted by the Office of Administrative Law Judges, and appeals from decisions by ALJs are decided by the ARB. Secretary of Labor’s Order No. 2–2012 (Oct. 19, 2012), 77 FR 69378 (Nov. 16, 2012).

General Comments

Roll commented that OSHA should “ensure that the rules not only protect employee rights and promote food safety, but uphold equality and fairly address the concerns of both parties involved in these types of matters.” OSHA agrees, and notes that its procedures are designed to ensure a fair process for both parties.

Kalijarvi commented that “Congress passed the FSMA to protect people from getting sick and dying. When Congress passes a law to accomplish a remedial purpose, that purpose should be central to decisions about interpretation and application of the law.” Kalijarvi elaborated that decisions under FSMA should be made with an eye towards furthering the statute’s remedial purpose. In addition, Kalijarvi commented that OSHA’s discussion of the reasonable belief doctrine serves as a helpful reminder that “a complainant’s whistleblower activity will be protected when it is based on a reasonable belief that any provision of the FD&C, or any order, rule, regulation, standard, or ban under the FD&C, has been violated.” OSHA believes that, generally, support for the remedial nature of the FSMA is found in the statute itself.

Subpart A—Complaints, Investigations, Findings and Preliminary Orders

Section 1987.100 Purpose and Scope

This section describes the purpose of the regulations implementing FSMA and provides an overview of the procedures covered by these regulations. No comments were received on this section, and no changes were made to it.

Section 1987.101 Definitions

This section includes general definitions from the FD&C, which are applicable to the whistleblower provisions of FSMA. The FD&C states that the term “person” includes an individual, partnership, corporation, and association. See 21 U.S.C. 321(e). The FD&C also defines the term “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” See 21 U.S.C. 321(f). No comments were received on this section, and no changes were made to it.

Section 1987.102 Obligations and Prohibited Acts

This section describes the activities that are protected under FSMA, and the conduct that is prohibited in response to any protected activities. Under FSMA, an entity engaged in the manufacture, processing, packaging, transporting, distribution, reception, holding, or importation of food may not retaliate against an employee because the employee “provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this chapter or any order, rule, regulation, standard, or ban under this chapter.” 21 U.S.C. 399d(a)(1). FSMA also protects employees who testify, assist or participate in proceedings concerning such violations. See 21 U.S.C. 399d(a)(2) and (3). Finally, FSMA prohibits retaliation because an employee “objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this chapter, or any order, rule, regulation, standard, or ban under this chapter.” 21 U.S.C. 399d(a)(4). References to “this chapter” refer to the FD&C, which is chapter 9 of title 21. 21 U.S.C. 301 et seq. Although an entity must therefore be engaged in the manufacture, processing, packaging, transporting, distribution, reception, holding, or importation of food in order to be covered by FSMA, a complainant’s whistleblower activity will be protected when it is based on a reasonable belief that any provision of the FD&C, or any order, rule, regulation, standard, or ban under the FD&C, has been violated.

In order to have a “reasonable belief” under FSMA, a complainant must have both a subjective, good faith belief and an objectively reasonable belief that the complained-of conduct violated the FD&C or any order, rule, regulation, standard, or ban under the FD&C. See Sylvester v. Parexel Int’l LLC, ARB No. 07–123, 2011 WL 2165854, at * 11–12 (ARB May 25, 2011) (discussing the reasonable belief standard under analogous language in the Sarbanes-Oxley Act whistleblower provision for employees, 18 U.S.C. 1514A). The requirement that the complainant have a subjective, good faith belief is satisfied so long as the complainant actually believed that the conduct complained of violated the relevant law. See id. The objective “reasonableness” of a complainant’s belief is typically determined “based on the knowledge available to a reasonable person in the same factual circumstances with the same training and experience as the aggrieved employee.” Id. at *12 (internal quotation marks and citation omitted). However, the complainant need not show that the conduct complained of constituted an actual violation of law. Pursuant to this standard, an employee’s whistleblower activity is protected where it is based on a reasonable, but mistaken, belief that a violation of the relevant law has occurred. Id. at * 13.

No comments were received on this section, and no changes were made to it.

Section 1987.103 Filing of Retaliation Complaint

This section explains the requirements for filing a retaliation complaint under FSMA. According to section 1012(b)(1) of the FD&C, a complaint must be filed within 180 days of when the alleged violation occurs. Under Delaware State College v. Ricks, 449 U.S. 250, 258 (1980), this is considered to be when the retaliatory decision has been both made and communicated to the complainant. In other words, the limitations period commences once the employee is aware or reasonably should be aware of the employer’s decision to take an adverse action. See Equal Emp’t Opportunity Comm’n v. United Parcel Serv., Inc., 249 F.3d 557, 561–62 (6th Cir. 2001). The time for filing a complaint may be tolled for reasons warranted by applicable case law. For example, OSHA may consider the time for filing a complaint to be tolled if a complainant mistakenly files a complaint with an agency other than OSHA within 180 days after an alleged adverse action.
Complaints filed under FSMA need not be in any particular form. They may be either oral or in writing. If the complainant is unable to file the complaint in English, OSHA will accept the complaint in any language. With the consent of the employee, complaints may be filed by any person on the employee’s behalf.

OSHA notes that a complaint of retaliation filed with OSHA under FSMA is not a formal document and need not conform to the pleading standards for complaints filed in federal district court articulated in Bell Atlantic v. Twombly, 550 U.S. 544 (2007) and Ashcroft v. Iqbal, 556 U.S. 662 (2009). See Sylvestre, 2011 WL 2165854, at *9–10 (holding whistleblower complaints filed with OSHA under analogous provisions in the Sarbanes-Oxley Act need not conform to federal court pleading standards). Rather, the complaint filed with OSHA under this section simply alerts OSHA to the existence of the alleged retaliation and the complainant’s desire that OSHA investigate the complaint. Upon receipt of the complaint, OSHA is to determine whether the “complaint, supplemented as appropriate by interviews of the complainant” alleges “the existence of facts and evidence to make a prima facie showing.” 29 CFR 1987.104(e). As explained in section 1987.104(e), if the complaint, supplemented as appropriate, contains a prima facie allegation, and the respondent does not show clear and convincing evidence that it would have taken the same action in the absence of the alleged protected activity, OSHA conducts an investigation to determine whether there is reasonable cause to believe that retaliation has occurred. See 21 U.S.C. 399d(b)(2)(A), 29 CFR 1987.104(e).

No comments were received on this section, and no changes were made to it.

Section 1987.104 Investigation

This section describes the procedures that apply to the investigation of complaints under FSMA. Paragraph (a) of this section outlines the procedures for notifying the parties and the FDA of the complaint and notifying the respondent of its rights under these regulations. Paragraph (b) describes the procedures for the respondent to submit its response to the complaint. Paragraph (c) describes OSHA’s procedures for sharing a party’s submissions during a whistleblower investigation with the other parties to the investigation. Paragraph (f) this section discusses confidentiality of information provided during investigations.

Paragraph (e) of this section sets forth the applicable burdens of proof. FSMA requires that a complainant make an initial prima facie showing that protected activity was “a contributing factor” in the adverse action alleged in the complaint, i.e., that the protected activity, alone or in combination with other factors, affected in some way the outcome of the employer’s decision. The complainant will be considered to have met the required burden if the complaint on its face, supplemented as appropriate through interviews of the complainant, alleges the existence of facts and either direct or circumstantial evidence to meet the required showing. The complainant’s burden may be satisfied, for example, if he or she shows that the adverse action took place within a temporal proximity of the protected activity, or at the first opportunity available to the respondent, giving rise to the inference that it was a contributing factor in the adverse action. See, e.g., Porter v. Cal. Dep’t of Corrs., 419 F.3d 885, 895 (9th Cir. 2005) (years between the protected activity and the retaliatory actions did not defeat a finding of a causal connection where the defendant did not have the opportunity to retaliate until he was given responsibility for making personnel decisions).

If the complainant does not make the required prima facie showing, the investigation must be discontinued and the complaint dismissed. See Trimmer v. U.S. Dep’t of Labor, 174 F.3d 1098, 1101 (10th Cir. 1999) (noting that the burden-shift is framework of the Energy Reorganization Act of 1974 (ERA), which is the same framework now applicable to FSMA, serves a “gatekeeping function” that “stem[s] frivolous complaints”). Even in cases where the complainant successfully makes a prima facie showing, the investigation must be discontinued if the employer demonstrates, by clear and convincing evidence, that it would have taken the same adverse action in the absence of the protected activity. Thus, OSHA must dismiss a complaint under FSMA and make findings of fact if either: (1) The complainant fails to meet the required burden of proof in the adverse action; or (2) the employer rebuts that showing by clear and convincing evidence that it would have taken the same adverse action absent the protected activity.

Assuming that an investigation proceeds beyond the gatekeeping phase, the statute requires OSHA to determine whether there is reasonable cause to believe that protected activity was a contributing factor in the alleged adverse action. A contributing factor is “any factor which, alone or in connection with other factors, tends to affect in any way the outcome of the decision.” Marano v. Dep’t of Justice, 2 F.3d 1137, 1140 (Fed. Cir. 1993) (internal quotation marks, emphasis and citation omitted) (discussing the Whistleblower Protection Act, 5 U.S.C. 1221(e)(1)); see also Addis v. Dep’t of Labor, 575 F.3d 688, 689–91 (7th Cir. 2009) (discussing Marano as applied to analogous whistleblower provision in the ERA); Clarke v. Navajo Express, Inc., ARB No. 09–114, 2011 WL 2614326, at *3 (ARB June 29, 2011) (discussing burdens of proof under analogous whistleblower provision in the Surface Transportation Assistance Act (STAA)).

For protected activity to be a contributing factor in the adverse action, “a complainant need not necessarily prove that the respondent’s articulated reason was a pretext in order to prevail,” because a complainant alternatively can prevail by showing that the respondent’s “ ‘reason, while true, is only one of the reasons for its conduct,”’ and that another reason was the complainant’s protected activity. See Klopfenstein v. PCC Flow Techs. Holdings, Inc., ARB No. 04–149, 2006 WL 3246904, at *13 (ARB May 31, 2006) (quoting Rachid v. Jack in the Box, Inc., 376 F.3d 305, 312 (5th Cir. 2004)) (discussing contributing factor test under the Sarbanes-Oxley whistleblower provision), aff’d sub nom. Klopfenstein v. Admin. Review Bd., U.S. Dep’t of Labor, 402 F. App’x 96 (9th Cir. 2010) WL 4746688 (5th Cir. 2010).

If OSHA finds reasonable cause to believe that the alleged protected activity was a contributing factor in the adverse action, OSHA may not order relief if the employer demonstrates by clear and convincing evidence that it would have taken the same action in the absence of the protected activity. See 21 U.S.C. 399d(b)(2)(C). The “clear and convincing evidence” standard is a higher burden of proof than a “preponderance of the evidence” standard. Clear and convincing evidence is evidence that the thing to be proved is highly probable or reasonably certain. Clarke, 2011 WL 2614326, at *3.

Paragraph (f) describes the procedures OSHA will follow prior to the issuance of findings and a preliminary order when OSHA has reasonable cause to believe that a violation has occurred.

Roll commented that this section of the IFR did not explicitly state that the respondent has the right to receive copies of the substantive evidence provided by the complainant, and Roll states that it is “essential that both
parties receive equal access to all documents throughout the entire matter.” OSHA agrees that the input of both parties in the investigation is important to ensure that OSHA reaches the proper outcome during its investigation. In fact, OSHA’s current policy is to request that each party provide the other parties with a copy of all submissions to OSHA that are pertinent to the whistleblower complaint. Where the parties do not provide each other such submissions, OSHA will ensure that each party is provided with such information after redacting the submissions as appropriate. OSHA has revised paragraph (c) to clarify these policies regarding information sharing during the course of an investigation. Further information regarding OSHA’s nonpublic disclosure and information sharing policies also may be found in the Whistleblower Investigations Manual, available at, http://www.whistleblowers.gov/regulations.html.

Roll also commented that the IFR did not provide the complainant and the respondent equal opportunity to respond to the each other’s submissions to OSHA. OSHA has revised paragraph (c) to clarify that OSHA will ensure that each party is provided with an opportunity to respond to the other party’s submissions. Apart from the changes to paragraph (c) described above, OSHA has reworded paragraphs (a) and (f) slightly to clarify the paragraphs without changing their meaning.

Section 1987.105 Issuance of Findings and Preliminary Orders

This section provides that, on the basis of information obtained in the investigation, the Secretary will issue, within 60 days of the filing of a complaint, written findings regarding whether or not there is reasonable cause to believe that the complaint has merit. If the findings are that there is reasonable cause to believe that the complaint has merit, the Assistant Secretary will order appropriate relief, including preliminary reinstatement, affirmative action to abate the violation, back pay with interest, and compensatory damages. The findings and, where appropriate, preliminary order, advise the parties of their right to file objections to the findings of the Assistant Secretary and to request a hearing. The findings and, where appropriate, preliminary order, also advise the respondent of the right to request an award of attorney fees not exceeding $1,000 from the ALJ, regardless of whether the respondent has filed objections, if the respondent alleges that the complaint was frivolous or brought in bad faith. If no objections are filed within 30 days of receipt of the findings, the findings and any preliminary order of the Assistant Secretary become the final decision and order of the Secretary. If objections are timely filed, any order of preliminary reinstatement will take effect, but the remaining provisions of the order will not take effect until administrative proceedings are completed.

As explained in the IFR, in ordering interest on back pay under FSMA, the Secretary has determined that interest due will be computed by compounding daily the Internal Revenue Service interest rate for the underpayment of taxes, which under 26 U.S.C. 6621 is generally the Federal short-term rate plus three percentage points. 79 FR 8623. The Secretary has long applied the interest rate in 26 U.S.C. 6621 to calculate interest on backpay in whistleblower cases. Doyle v. Hydro Nuclear Servs., ARB Nos. 99–041, 99–042, 00–012, 2000 WL 694384, at *14–15, 17 (ARB May 17, 2000); see also Cefalu v. Roadway Express, Inc., ARB No. 09–070, 2011 WL 1247212, at *2 (ARB Mar. 17, 2011); Pollock v. Cont’l Express, ARB Nos. 07–073, 08–051, 2010 WL 1776974, at *8 (ARB Apr. 19, 2010); Murray v. Air Ride, Inc., ARB No. 00–045, slip op. at 9 (ARB Dec. 29, 2000). Section 6621 provides the appropriate measure of compensation under FSMA and other DOL-administered whistleblower statutes because it ensures the complainant will be placed in the same position he or she would have been in if no unlawful retaliation occurred. See Ass’t Sec’y v. Double R. Trucking, Inc., ARB No. 99–061, slip op. at 5 (ARB July 16, 1999) (interest awards pursuant to § 6621 are mandatory elements of complainant’s make-whole remedy). Section 6621 provides a reasonably accurate prediction of market outcomes (which represents the loss of investment opportunity by the complainant and the employer’s benefit from use of the withheld money) and thus provides the complainant with appropriate make-whole relief. See EEOC v. Erie Cnty., 751 F.2d 79, 82 (2d Cir. 1984) ("[s]ince the goal of a suit under the [Fair Labor Standards Act] and the Equal Pay Act is to make whole the victims of the unlawful underpayment of wages, and since § 6621 has been adopted as a good indicator of the value of the use of money, it was well within" the district court’s discretion the prejudgment interest under § 6621); New Horizons for the Retarded, 283 N.L.R.B. No. 181, 1987 WL 89652, at *2 (NLRB May 28, 1987) (observing that “the short-term Federal rate [used by § 6621] is based on average market yields on marketable Federal obligations and is influenced by private economic market forces”). Similarly, as explained in the IFR, daily compounding of the interest award ensures that complainants are made whole for unlawful retaliation in violation of FSMA. 79 FR 8623.

As explained in the IFR, in ordering back pay, OSHA will require the respondent to submit the appropriate documentation to the Social Security Administration (SSA) allocating the back pay to the appropriate calendar quarters. Requiring the reporting of back pay allocation to the SSA serves the remedial purposes of FSMA by ensuring that employees subjected to retaliation are truly made whole. See 79 FR 8623; see also Don Chavas, LLC d/b/a Tortillas Don Chavas, 361 NLRB No. 10, 2014 WL 3897178, at *4–5 (NLRB Aug. 8, 2014).

Finally, as noted in the IFR, in limited circumstances, in lieu of preliminary reinstatement, OSHA may order that the complainant receive the same pay and benefits that he or she received prior to termination, but not actually return to work. See 79 FR 8623. Such “economic reinstatement” is akin to an order for front pay and frequently is employed in cases arising under section 105(c) of the Federal Mine Safety and Health Act of 1977, which protects miners from retaliation. 30 U.S.C. 815(c); see, e.g., Sec’y of Labor ex rel. York v. BR&D Enters., Inc., 23 FMSHRC 697, 2001 WL 1806020, at *1 (ALJ June 26, 2001). Front pay has been recognized as a possible remedy in cases under the whistleblower statutes enforced by OSHA in limited circumstances where reinstatement would not be appropriate. See, e.g., Luder v. Cont’l Airlines, Inc., ARB No. 10–026, 2012 WL 376755, at *11 (ARB Jan. 31, 2012), aff’d, Cont’l Airlines, Inc. v. Admin. Rev. Bd., No. 15–60012, slip op. at 8, 2016 WL 97461, at *4 (5th Cir. Jan. 7, 2016) (unpublished) (under Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, “front-pay is available when reinstatement is not possible”); Moder v. Vill. of Jackson, ARB Nos. 01–095, 02–039, 2003 WL 21499864, at *10 (ARB June 30, 2003) (under environmental whistleblower statutes, “front pay may be an appropriate substitute when the parties prove the impossibility of a productive and amicable working relationship, or the company no longer has a position for which the complainant is qualified”).
and front pay and suggested that OSHA should include specific guidelines pertaining to front pay awards. Roll noted that the IFR provided examples of situations where front pay might be appropriate, but the rules themselves do not explicitly state that front pay is an available remedy, which could be “misleading.” Further, Roll questioned whether OSHA has authority to order front pay as a remedy.

OSHA declines to adopt specific guidelines pertaining to front pay awards in these rules. As explained in the IFR, the appropriateness of “economic reinstatement” or front pay as an alternative to the default statutory remedy of reinstatement has long been recognized. OSHA believes that relevant case law more appropriately addresses the parameters for issuing an award of front pay in lieu of reinstatement. See, e.g., Luder, ARB No. 10–026, slip op. at *11. (holding that front pay must be awarded according to reasonable parameters such as the amount of the proposed award, the length of time the complainant expects to be out of work, and the applicable discount rate) (internal quotation marks and citations omitted), front pay award modified. Luder v. Cont’l Airlines, Inc., ARB No. 13–009, 2014 WL 6850012 (ARB Nov. 2014); aff’d, Cont’l Airlines, Inc. v. Admin. Review Bd., No. 15–60012, slip op. at 8, 2016 WL 974611, at *4 (5th Cir. Jan. 7, 2016) (unpublished).

Kalijarvi requested that the rule include a reference to Blackburn v. Martin, 982 F.2d 125 (4th Cir. 1992) to inform the public that emotional distress damages may be awarded without the testimony of expert witnesses. A number of ARB decisions have awarded such damages without the testimony of expert witnesses in appropriate circumstances. See e.g., Lockheed Martin Corp. v. Admin. Review Bd., 717 F.3d 1121, 1138 (10th Cir. 2013) (upholding an award of $75,000 for emotional pain and suffering without requiring the testimony of expert witnesses); Menendez v. Halliburton, Inc., ARB Nos 09–002, 09–003 2013 WL 1282255, at *11–12 (ARB Mar. 15, 2013) (upholding award of $30,000 for emotional distress and reputational harm without requiring expert testimony) aff’d sub nom. Halliburton, Inc. v. Admin. Review Bd., 771 F.3d 254 (5th Cir. 2014). OSHA believes that these cases adequately serve to notify the public that emotional distress damages may be awarded without the testimony of expert witnesses.

For these reasons, OSHA has made no changes to the text of this section.

Subpart B—Litigation

Section 1987.106 Objections to the Findings and the Preliminary Order and Requests for a Hearing

To be effective, objections to the findings of the Assistant Secretary must be in writing and must be filed with the Chief Administrative Law Judge, U.S. Department of Labor, within 30 days of receipt of the findings. The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of the filing; if the objection is filed in person, by hand-delivery or other means, the objection is filed upon receipt. The filing of objections also is considered a request for a hearing before an ALJ. Although the parties are directed to serve a copy of their objections on the other parties of record, as well as the OSHA official who issued the findings and order, the Assistant Secretary, and the U.S. Department of Labor’s Associate Solicitor for Fair Labor Standards, the failure to serve copies of the objections on the other parties of record does not affect the ALJ’s jurisdiction to hear and decide the merits of the case. See Shirani v. Calvert Cliffs Nuclear Power Plant, Inc., ARB No. 04–101, 2005 WL 2865915, at *7 (ARB Oct. 31, 2005).

The timely filing of objections stays all provisions of the preliminary order, except for the portion requiring reinstatement. A respondent may file a motion to stay the Assistant Secretary’s preliminary order of reinstatement with the Office of Administrative Law Judges. However, such a motion will be granted only based on exceptional circumstances. The Secretary believes that a stay of the Assistant Secretary’s preliminary order of reinstatement under FSMA would be appropriate only where the respondent can establish the necessary criteria for equitable injunctive relief, i.e., irreparable injury, likelihood of success on the merits, a balancing of possible harms to the parties, and the public interest favors a stay. If no timely objection to the Assistant Secretary’s findings and/or preliminary order is filed, then the Assistant Secretary’s findings and/or preliminary order become the final decision of the Secretary not subject to judicial review.

No comments were received on this section, and no changes were made to it.

Section 1987.107 Hearings

This section adopts the rules of practice and procedures for administrative hearings before the Office of Administrative Law Judges as set forth in 29 CFR part 18 subpart A. This section provides that the hearing is to commence expeditiously, except upon a showing of good cause or unless otherwise agreed to by the parties. Hearings will be conducted de novo, on the record. As noted in this section, formal rules of evidence will not apply, but rules or principles designed to assure production of the most probative evidence will be applied. The ALJ may exclude evidence that is immaterial, irrelevant, or unduly repetitious.

No comments were received on this section, and no changes were made to it.

Section 1987.108 Role of Federal Agencies

The Assistant Secretary, at his or her discretion, may participate as a party or amicus curiae at any time in the administrative proceedings under FSMA. For example, the Assistant Secretary may exercise his or her discretion to prosecute the case in the administrative proceeding before an ALJ; petition for review of a decision of an ALJ, including a decision based on a settlement agreement between the complainant and the respondent, regardless of whether the Assistant Secretary participated before the ALJ; or participate as amicus curiae before the ALJ or in the ARB proceeding. Although OSHA anticipates that ordinarily the Assistant Secretary will not participate, the Assistant Secretary may choose to do so in appropriate cases, such as cases involving important or novel legal issues, multiple employees, alleged violations that appear egregious, or where the interests of justice might require participation by the Assistant Secretary. The FDA, if interested in a proceeding, also may participate as amicus curiae at any time in the proceedings.

No comments were received on this section, though minor changes were made as needed to clarify the provision without changing its meaning.

Section 1987.109 Decision and Orders of the Administrative Law Judge

This section sets forth the requirements for the content of the decision and order of the ALJ, and includes the standard for finding a violation under FSMA. Specifically, the complainant must demonstrate (i.e., prove by a preponderance of the evidence) that the protected activity was a “contributing factor” in the adverse action. See, e.g., Allen v. Admin. Review Bd., 514 F.3d 468, 475 n.1 (5th Cir. 2008) (“The term ‘demonstrates’ [under identical burden-shifting scheme in the Sarbanes-Oxley whistleblower provision] means to prove by a
preponderance of the evidence.”). If the employee demonstrates that the alleged protected activity was a contributing factor in the adverse action, the employer, to escape liability, must demonstrate by “clear and convincing evidence” that it would have taken the same action in the absence of the protected activity. See 21 U.S.C. 399d(b)(2)(C).

Paragraph (c) of this section further provides that OSHA’s determination to dismiss the complaint without an investigation or without a complete investigation under section 1987.104 is not subject to review. Thus, section 1987.109(c) clarifies that OSHA’s determinations on whether to proceed with an investigation under FSMA and whether to make particular investigative findings are discretionary decisions not subject to review by the ALJ. The ALJ hears cases de novo and, therefore, as a general matter, may not remand cases to OSHA to conduct an investigation or make further factual findings.

Paragraph (d) notes the remedies that the ALJ may order under FSMA and, as discussed under section 1987.105 above, provides that interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily, and that the respondent will be required to submit appropriate documentation to the SSA allocating any back pay award to the appropriate calendar quarters. Paragraph (e) requires that the ALJ’s decision be served on all parties to the proceeding, OSHA, and the U.S. Department of Labor’s Associate Solicitor for Fair Labor Standards. Paragraph (e) also provides that any ALJ decision requiring reinstatement or lifting an order of reinstatement by the Assistant Secretary will be effective immediately upon receipt of the decision by the respondent. All other portions of the ALJ’s order will be effective 14 days after the date of the decision unless a timely petition for review has been filed with the ARB. If no timely petition for review is filed with the ARB, the decision of the ALJ becomes the final decision of the Secretary and is not subject to judicial review.

No comments were received on this section, and no changes were made to it.

Section 1987.110 Decision and Orders of the Administrative Review Board

Upon the issuance of the ALJ’s decision, the parties have 14 days within which to petition the ARB for review of that decision. The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of filing of the petition; if the petition is filed in person, by hand delivery or other means, the petition is considered filed upon receipt.

The appeal provisions in this part provide that an appeal to the ARB is not a matter of right but is accepted at the discretion of the ARB. The parties should identify in their petitions for review the legal conclusions or orders to which they object, or the objections may be deemed waived. The ARB has 30 days to decide whether to grant the petition for review. If the ARB does not grant the petition, the decision of the ALJ becomes the final decision of the Secretary. If a timely petition for review is filed with the ARB, any relief ordered by the ALJ, except for that portion ordering reinstatement, is inoperative while the matter is pending before the ARB. If the ARB accepts a petition for review, the ALJ’s factual determinations will be reviewed under the substantial evidence standard.

Kalijarvi submitted several comments related to this section of the rule. Kalijarvi requested the removal of the portion of the rule stating that objections not raised in the petition for review to the ARB may be considered waived. Instead, Kalijarvi requested that the provision be altered to instruct parties to identify in their petitions for review the legal conclusions or orders to which they object so that the ARB may determine whether the review presents issues worthy of full briefing. OSHA declines to revise the rule as Kalijarvi has proposed. OSHA notes that the IFR used the phrase “may” be deemed waived, indicating that the parties are not necessarily barred from subsequently raising grounds in addition to those included in the initial petition. Further, OSHA’s inclusion of this provision is not intended to limit the circumstances in which parties can add additional grounds for review as a case progresses before the ARB; rather, the rules include this provision to put the public on notice of the possible consequences of failing to specify the basis of an appeal to the ARB. OSHA recognizes that, while the ARB has held in some instances that an exception not specifically urged may be deemed waived, the ARB also has found that the rules provide for exceptions to this general rule.

Kalijarvi also requested that the deadline for filing a petition for review with the ARB be extended past 14 days, and for this section to allow explicitly for the parties to file a motion to extend the time for submitting a petition for review. Kalijarvi further requested that OSHA explain how the current text of the section furthers FSMA’s remedial purpose. OSHA declines to extend the time limit to petition for review because the shorter review period is consistent with the practices and procedures followed in OSHA’s other whistleblower programs. Furthermore, as Kalijarvi acknowledges in its comment, parties may file a motion for extension of time to appeal an ALJ’s decision, and the ARB has discretion to grant such extensions.

Kalijarvi requested that, based on exceptional circumstances, the ARB may grant a motion to stay an ALJ’s preliminary order of reinstatement under FSMA, which otherwise would be effective, while review is conducted by the ARB. The Secretary believes that a stay of an ALJ’s preliminary order of reinstatement under FSMA would be appropriate only where the respondent can establish the necessary criteria for equitable injunctive relief, i.e., irreparable injury, likelihood of success on the merits, a balancing of possible harms to the parties, and the public interest favors a stay.

If the ARB concludes that the respondent has violated the law, it will order the respondent to take appropriate affirmative action to abate the violation, including reinstatement of the complainant to that person’s former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of employment, and compensatory damages. At the request of the complainant, the ARB will assess against the respondent all costs and expenses (including attorney and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily, and the respondent will be required to submit appropriate documentation to the Social Security Administration (SSA) allocating any back pay award to the appropriate calendar quarters. If the ARB determines that the respondent has not violated the law, an order will be issued denying the complaint. If, upon
the request of the respondent, the ARB determines that a complaint was frivolous or was brought in bad faith, the ARB may award to the respondent a reasonable attorney fee, not exceeding $1,000, to be paid by the complainant.

No changes were made to this section, and other than the comments discussed above, no additional comments were received on this section.

Subpart C—Miscellaneous Provisions
Section 1987.111 Withdrawal of Complaints, Findings, Objections, and Petitions for Review: Settlement

This section provides the procedures and time periods for withdrawal of complaints, the withdrawal of findings and/or preliminary orders by the Assistant Secretary, and the withdrawal of objections to findings and/or orders. It permits complainants to withdraw their complaints orally and provides that, in such circumstances, OSHA will confirm a complainant’s desire to withdraw in writing. It also provides for approval of settlements at the investigative and adjudicative stages of the case.

Roll commented that this provision should state explicitly that settlements may be conducted in a confidential manner and outside of the administrative proceedings. Because the IFR did not plainly provide such assurances, Roll expressed concern that “the lack of confidentiality will work as a disincentive for both parties . . . [and] will ultimately lead to fewer out-of-court settlements. . . .” Roll further commented that this section should include guidelines regarding when the Secretary will approve or disapprove a settlement agreement, as well as an explanation regarding the settlement options that are available to the parties.

OSHA is not making any changes to the rule in response to this comment. This section implements FSMA’s statutory provision that “[a]ll any time before issuance of a final order, a proceeding under this subsection may be terminated on the basis of a settlement agreement entered into by the Secretary, the complainant, and the person alleged to have committed the violation.” 21 U.S.C. 399(b)(3)(A).

However, OSHA notes that the Secretary has always recognized that parties may efficiently resolve cases in negotiations between themselves. The Secretary’s policy is to approve privately negotiated settlements, provided that each settlement is reviewed by the Secretary to ensure that the terms are fair, adequate, reasonable, and consistent with the purpose and intent of the relevant whistleblower statute and the public interest. See, e.g., Macktal v. Sec’y of Labor, 923 F.2d 1150, 1154 (5th Cir. 1991) (agreeing that the Secretary may “enter into” a settlement by approving a settlement negotiated and agreed to by the parties); see also OSHA’s Whistleblower Investigations Manual, pp. 6–18 to 6–21 (Apr. 21, 2015) available at http://www.whistleblowers.gov/regulations_page.html. OSHA believes that paragraphs (d)(1) and (2) adequately explain that a settlement agreement reached between the parties will settle a pending whistleblower case so long as the agreement is reviewed and approved by OSHA, an ALJ, or the ARB. The resources listed above provide more detailed guidance on when OSHA, an ALJ or the ARB will approve or disapprove a settlement agreement, and OSHA thus believes it unnecessary to add such additional details to the regulatory text.

As to Roll’s confidentiality concerns, OSHA, an ALJ or the ARB will not approve an agreement that states or implies that any of these entities, or DOL more generally, is party to a confidentiality agreement. Moreover, as noted in paragraph (e) of this section, any settlement approved by OSHA, the ALJ, or the ARB will constitute the final order of the Secretary, and as such, an approved agreement is an official government record that is subject to applicable public disclosure rules. See, e.g., Gonzalez v. J.C. Penny Corp., Inc., ARB No. 10–148, 2012 WL 4753923, at *6 [ARB Sept. 28, 2012] (describing the public interest supporting the Secretary’s review of settlement agreements); McGuire v. B.P. Prods. N. Am., Inc., 2014–TSC–0001, slip op. at 6–11 [AL Jan. 17, 2014] (describing public disclosure interests relating to whistleblower settlements and some of the provisions that the Secretary may not approve in a whistleblower settlement). Thus, for example, while parties may negotiate the terms of a settlement agreement in confidence and may indicate to OSHA, an ALJ or the ARB that they believe a settlement contains information exempt from disclosure under the Freedom of Information Act (FOIA) and that they should receive pre-disclosure notification of a request for disclosure, the Secretary must make his own determination of whether the contents of a settlement may be withheld in response to a request from a member of the public. See, e.g., Vannoy v. Celanese Corp., ARB No. 09–118, 2013 WL 5872048, at *2 [ARB Sept. 27, 2013] (describing the application of FOIA to a whistleblower settlement).

Section 1987.112 Judicial Review

This section describes the statutory provisions for judicial review of decisions of the Secretary and requires, in cases where judicial review is sought, the ALJ or the ARB to submit the record of proceedings to the appropriate court pursuant to the rules of such court. No comments were received on this section, and no changes were made to it.

Section 1987.113 Judicial Enforcement

This section describes the Secretary’s power under FSMA to obtain judicial enforcement of orders and the terms of settlement agreements. FSMA expressly authorizes district courts to enforce orders, including preliminary orders of reinstatement, issued by the Secretary. See 21 U.S.C. 399d(b)(6) (“Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order.”).

Specifically, reinstatement orders issued at the close of OSHA’s investigation are immediately enforceable in district court pursuant to 21 U.S.C. 399d(b)(6) and (7). FSMA provides that the Secretary shall order the person who has committed a violation to reinstate the complainant to his or her former position. See 21 U.S.C. 399d(b)(3)(B)(ii). FSMA also provides that the Secretary shall accompany any reasonable cause finding that a violation occurred with a preliminary order containing the relief prescribed by subsection (b)(3)(B), which includes reinstatement where appropriate, and that any preliminary order of reinstatement shall not be stayed upon the filing of objections. See 21 U.S.C. 399d(b)(2)(B) (“The filing of such objections shall not operate to stay any reinstatement remedy contained in the preliminary order.”). Thus, under FSMA, enforceable orders include preliminary orders that contain the relief of reinstatement prescribed by 21 U.S.C. 399d(b)(3)(B). This statutory interpretation is consistent with the Secretary’s interpretation of similar language in the whistleblower provisions of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, 49 U.S.C. 42121, and Section 806 of the Corporate and Criminal Fraud Accountability Act of 2002, Title VIII of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1514A. See Brief for the Intervenor/Plaintiff-Appellee Secretary of Labor, Solis v. Tenn. Commerce Bancorp, Inc., No. 10–5602.
1987.105(a). This section refers to the Assistant Secretary's determination. "Written determination" filing of the complaint, or within 90 days of the Secretary within 210 days of the court if there has been no final decision de novo review in the appropriate district circumstances. FSMA permits a complaint filed with OSHA, under the same allegations contained in the de novo action in district court, alleging Section 1987.114 District Court Jurisdiction of Retaliation Complaints This section sets forth provisions that allow a complainant to bring an original de novo action in district court, alleging the same allegations contained in the complaint filed with OSHA, under certain circumstances. FSMA permits a complainant to file an action for de novo review in the appropriate district court if there has been no final decision of the Secretary within 210 days of the filing of the complaint, or within 90 days after receiving a written determination. "Written determination" refers to the Assistant Secretary's written findings issued at the close of OSHA's investigation under section 1987.105(a). See 21 U.S.C. 399d(b)(4). The Secretary's final decision is generally the decision of the ARB issued under section 1987.110. In other words, a complainant may file an action for de novo review in the appropriate district court in either of the following two circumstances: (1) A complainant may file a de novo action in district court within 90 days of receiving the Assistant Secretary's written findings issued under section 1987.105(a), or (2) a complainant may file a de novo action in district court if more than 210 days have passed since the filing of the complaint and the Secretary has not issued a final decision. The plain language of 21 U.S.C. 399d(b)(4), by distinguishing between actions that can be brought if the Secretary has not issued a "final decision" within 210 days and actions that can be brought within 90 days after a "written determination," supports allowing de novo actions in district court under either of the circumstances described above.

However, the Secretary believes that FSMA does not permit complainants to initiate an action in federal court after the Secretary's final decision, even if the date of the final decision is more than 210 days after the filing of the complaint or within 90 days of the complainant's receipt of the Assistant Secretary's written findings. The purpose of the "kick-out" provision is to aid the complainant in receiving a prompt decision. That goal is not implicated in a situation where the complainant already has received a final decision from the Secretary. In addition, permitting the complainant to file a new case in district court in such circumstances conflicts with the parties' right to seek judicial review of the Secretary's final decision in the court of appeals. See 21 U.S.C. 399d(b)(5)(B) (providing that an order with respect to which review could have been obtained in the court of appeals shall not be subject to judicial review in any criminal or other civil proceeding).

Under FSMA, the Assistant Secretary's written findings become the final order of the Secretary, not subject to judicial review, if no objection is filed within 30 days. See 21 U.S.C. 399d(b)(2)(B). Thus, a complainant may need to file timely objections to the Assistant Secretary's findings, as provided for in § 1987.106, in order to preserve the right to file an action in district court.

This section also requires that, within seven days after filing a complaint in district court, a complainant must provide a file-stamped copy of the complaint to OSHA, the ALJ, or the ARB, depending on where the proceeding is pending. In all cases, a copy of the complaint also must be provided to the OSHA official who issued the findings and/or preliminary order, the Assistant Secretary, and the U.S. Department of Labor's Associate Solicitor for Fair Labor Standards. This provision is necessary to notify the agency that the complainant has opted to file a complaint in district court. This provision is not a substitute for the complainant's compliance with the requirements for service of process of the district court complaint contained in the Federal Rules of Civil Procedure and the local rules of the district court where the complaint is filed. This section also incorporates the statutory provisions which allow for a jury trial at the request of either party in a district court action, and which specify the remedies and burdens of proof in a district court action.

In response to the IFR preamble's statement that the purpose of the "kick-out" provision is to aid the complainant in receiving a prompt decision, "Kalijarvi commented that the kick-out provision offers additional benefits to parties, such as an opportunity to receive a jury determination of damages. Indeed, Paragraph (a) of this section provides that an action brought under this section is entitled to trial by jury. OSHA appreciates Kalijarvi's comment, but has left the text of the rule unchanged.

Section 1987.115 Special Circumstances; Waiver of Rules This section provides that in circumstances not contemplated by these rules or for good cause the ALJ or the ARB may, upon application and notice to the parties, waive any rule as justice or the administration of FSMA requires. No comments were received on this section, and no changes were made to it.

IV. Paperwork Reduction Act This rule contains a reporting provision (filing a retaliation complaint, Section 1987.103) which was previously reviewed and approved for use by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The assigned OMB control number is 1218–0236.

V. Administrative Procedure Act The notice and comment rulemaking procedures of section 553 of the Administrative Procedure Act (APA) do not apply "to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. 553(b)(A). This is a rule of agency procedure, practice, and interpretation within the meaning of that section, since it provides procedures for the Department's handling of retaliation complaints. Therefore, publication in the Federal Register of a notice of proposed rulemaking and request for comments are not required for these regulations. Although this rule is not subject to the notice and comment procedures of the APA, the Assistant Secretary sought and considered comments to enable the agency to improve the rules by taking into account the concerns of interested persons.

Furthermore, because this rule is procedural and interpretative rather than substantive, the normal requirement of 5 U.S.C. 553(d) that a rule is effective 30 days after publication in the Federal Register is inapplicable. The Assistant Secretary also finds good cause to provide an immediate effective date for this rule. It is in the public interest that the rule be effective immediately so both parties may know what procedures are applicable to pending cases.
VI. Executive Orders 12866 and 13563; Unfunded Mandates Reform Act of 1995; Executive Order 13132

The Department has concluded that this rule is not a “significant regulatory action” within the meaning of section 3(f)(4) of Executive Order 12866, as reaffirmed by Executive Order 13563, because it is not likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866. Therefore, no regulatory impact analysis under Section 6(a)(3)(C) of Executive Order 12866 has been prepared.

For this reason, and because no notice of proposed rulemaking has been published, no statement is required under Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 et seq. Finally, this rule does not have “federalism implications.” The rule does not 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” and therefore is not subject to Executive Order 13132 (Federalism).

VII. Regulatory Flexibility Analysis

The notice and comment rulemaking procedures of Section 553 of the APA do not apply “to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.” 5 U.S.C. 553(b)(A). Rules that are exempt from APA notice and comment requirements are also exempt from the Regulatory Flexibility Act (RFA). See SBA Office of Advocacy, A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act 9 (May 2012); also found at: http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf. This is a rule of agency procedure, practice, and interpretation within the meaning of that section; therefore, the rule is exempt from both the notice and comment rulemaking procedures of the APA and the requirements under the RFA.

List of Subjects in 29 CFR Part 1987

Administrative practice and procedure, Employment, Food safety, Investigations, Reporting and recordkeeping requirements, Whistleblower.

Authority and Signature

This document was prepared under the direction and control of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health.

Signed at Washington, DC, on April 11, 2016.

David Michaels,
Assistant Secretary of Labor for Occupational Safety and Health.

Accordingly, for the reasons set out in the preamble, 29 CFR part 1987 is revised to read as follows:

PART 1987—PROCEDURES FOR HANDLING RETALIATION COMPLAINTS UNDER SECTION 402 OF THE FDA FOOD SAFETY MODERNIZATION ACT

Subpart A—Complaints, Investigations, Findings and Preliminary Orders

1987.100 Purpose and scope.
1987.102 Obligations and prohibited acts.
1987.103 Filing of retaliation complaint.

Subpart B—Ligation

1987.106 Objections to the findings and the preliminary order and requests for a hearing.
1987.110 Decision and orders of the administrative review board.

Subpart C—Miscellaneous Provisions

1987.111 Withdrawal of complaints, findings, objections, and petitions for review; settlement.
1987.112 Judicial review.
1987.113 Judicial enforcement.
1987.115 Special circumstances; waiver of rules.


Subpart A—Complaints, Investigations, Findings and Preliminary Orders

§ 1987.100 Purpose and scope.

(a) This part sets forth the procedures for, and interpretations of, section 402 of the FDA Food Safety Modernization Act (FSMA), Public Law 111–353, 124 Stat. 3885, which was signed into law on January 4, 2011. Section 402 of the FDA Food Safety Modernization Act amended the Federal Food, Drug, and Cosmetic Act (FD&C), 21 U.S.C. 301 et seq., by adding new section 1012. See 21 U.S.C. 399d. Section 1012 of the FD&C provides protection for an employee from retaliation because the employee has engaged in protected activity pertaining to a violation or alleged violation of the FD&C, or any order, rule, regulation, standard, or ban under the FD&C.

(b) This part establishes procedures under section 1012 of the FD&C for the expeditious handling of retaliation complaints filed by employees, or by persons acting on their behalf. The rules in this part, together with those codified at 29 CFR part 18, set forth the procedures under section 1012 of the FD&C for submission of complaints, investigations, issuance of findings and preliminary orders, objections to findings and orders, litigation before administrative law judges, post-hearing administrative review, and withdrawals and settlements. In addition, the rules in this part provide the Secretary’s interpretations on certain statutory issues.


As used in this part:

(a) Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health or the person or persons to whom he or she delegates authority under FSMA.

(b) Business days means days other than Saturdays, Sundays, and Federal holidays.

(c) Complainant means the employee who filed a complaint under FSMA or on whose behalf a complaint was filed.

(d) Covered entity means an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food.

(e) Employee means an individual presently or formerly working for a covered entity, an individual applying to work for a covered entity, or an individual whose employment could be affected by a covered entity.

(g) **FDA** means the Food and Drug Administration of the United States Department of Health and Human Services.

(h) **Food** means articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.


(j) **OSHA** means the Occupational Safety and Health Administration of the United States Department of Labor.

(k) **Person** includes an individual, partnership, corporation, and association.

(l) **Respondent** means the employer named in the complaint who is alleged to have violated the FSMA.

(m) **Secretary** means the Secretary of Labor or person to whom authority under the FSMA has been delegated.

(n) Any future statutory amendments that affect the definition of a term or terms listed in this section will apply in lieu of the definition stated herein.

### § 1987.102 Obligations and prohibited acts.

(a) No covered entity may discharge or otherwise retaliate against, including, but not limited to, intimidating, threatening, restraining, coercing, blacklisting or disciplining, any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee), has engaged in any of the activities specified in paragraphs (b) through (4) of this section.

(b) An employee is protected against retaliation because the employee (or any person acting pursuant to a request of the employee) has:

1. Provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of the FD&C or any order, rule, regulation, standard, or ban under the FD&C;
2. Testified or is about to testify in a proceeding concerning such violation;
3. Assisted or participated or is about to assist or participate in such a proceeding; or
4. Refused to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believes to be in violation of any provision of the FD&C, or any order, rule, regulation, standard, or ban under the FD&C.

### § 1987.103 Filing of retaliation complaint.

(a) **Who may file.** An employee who believes that he or she has been retaliated against in violation of FSMA may file, or have filed by any person on the employee’s behalf, a complaint alleging such retaliation.

(b) **Nature of filing.** No particular form of complaint is required. A complaint may be filed orally or in writing. Oral complaints will be reduced to writing by OSHA. If the complainant is unable to file the complaint in English, OSHA will accept the complaint in any language.

(c) **Place of filing.** The complaint should be filed with the OSHA office responsible for enforcement activities in the geographical area where the employee resides or was employed, but may be filed with any OSHA officer or employee. Addresses and telephone numbers for these officials are set forth in local directories and at the following Internet address: http://www.osha.gov.

(d) **Time for filing.** Within 180 days after an alleged violation of FSMA occurs, any employee who believes that he or she has been retaliated against in violation of that section may file, or have filed by any person on the employee's behalf, a complaint alleging such retaliation. The date of the postmark, facsimile transmittal, electronic communication transmittal, telephone call, hand-delivery, delivery to a third-party commercial carrier, or in-person filing at an OSHA office will be considered the date of filing. The time for filing a complaint may be tolled for reasons warranted by applicable case law. For example, OSHA may consider the time for filing a complaint to be tolled if a complaint mistakenly files a complaint with an agency other than OSHA within 180 days after an alleged adverse action.

### § 1987.104 Investigation.

(a) Upon receipt of a complaint in the investigating office, OSHA will notify the respondent of the filing of the complaint, of the allegations contained in the complaint, and of the substance of the evidence supporting the complaint. Such materials will be redacted, if necessary, consistent with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. OSHA will also notify the respondent of its rights under paragraphs (b) and (f) of this section and § 1987.110(e). OSHA will provide an unredacted copy of these same materials to the complainant (or the complainant's legal counsel if complainant is represented by counsel) and to the FDA.

(b) Within 20 days of receipt of the notice of the filing of the complaint provided under paragraph (a) of this section, the respondent and the complainant each may submit to OSHA a written statement and any affidavits or documents substantiating its position. Within the same 20 days, the respondent and the complainant each may request a meeting with OSHA to present its position.

(c) During the investigation, OSHA will request that each party provide the other parties to the whistleblower complaint with a copy of submissions to OSHA that are pertinent to the whistleblower complaint. Alternatively, if a party does not provide its submissions to OSHA to the other party, OSHA will provide them to the other party (or the party's legal counsel if the party is represented by counsel) at a time permitting the other party an opportunity to respond. Before providing such materials to the other party, OSHA will redact them, if necessary, consistent with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. OSHA will also provide each party with an opportunity to respond to the other party's submissions.

(d) Investigations will be conducted in a manner that protects the confidentiality of any person who provides information on a confidential basis, other than the complainant, in accordance with part 70 of this title. If a complaint is dismissed unless the complainant has made a prima facie showing (i.e., a non-frivolous allegation) that a protected activity was a contributing factor in the adverse action alleged in the complaint.

(2) The complaint, supplemented as appropriate by interviews of the complainant, must allege the existence of facts and evidence to make a prima facie showing as follows:

(i) The employee engaged in a protected activity;

(ii) The respondent knew or suspected that the employee engaged in the protected activity;

(iii) The employee suffered an adverse action; and

(iv) The circumstances were sufficient to raise the inference that the protected activity was a contributing factor in the adverse action.

(3) For purposes of determining whether to investigate, the respondent will be considered to have met the required burden if the complaint on its
face, supplemented as appropriate through interviews of the complainant, alleges the existence of facts and either direct or circumstantial evidence to meet the required showing, i.e., to give rise to an inference that the respondent knew or suspected that the employee engaged in protected activity and that the protected activity was a contributing factor in the adverse action. The burden may be satisfied, for example, if the complaint shows that the adverse action took place within a temporal proximity of the protected activity, or at the first opportunity available to the respondent, giving rise to the inference that it was a contributing factor in the adverse action. If the required showing has not been made, the complainant (or the complainant’s legal counsel if complainant is represented by counsel) will be so notified and the investigation will not commence.

(4) Notwithstanding a finding that a complainant has made a prima facie showing, as required by this section, further investigation of the complaint will not be conducted if the respondent demonstrates by clear and convincing evidence that it would have taken the same adverse action in the absence of the complainant’s protected activity.

(5) If the respondent fails to make a timely response or fails to satisfy the burden set forth in paragraph (e)(4) of this section, OSHA will proceed with the investigation. The investigation will proceed whenever it is necessary or appropriate to confirm or verify the information provided by the respondent.

(f) Prior to the issuance of findings and a preliminary order as provided for in §1987.105, if OSHA has reasonable cause, on the basis of information gathered under the procedures of this part, to believe that the respondent has violated FSMA and that preliminary reinstatement is warranted, OSHA will contact the respondent (or the respondent’s legal counsel if respondent is represented by counsel) to give notice of the substance of the relevant evidence supporting the complainant’s allegations as developed during the course of the investigation. This evidence includes any witness statements, which will be redacted to protect the identity of confidential informants where statements were given in confidence; if the statements cannot be redacted without revealing the identity of confidential informants, summaries of their contents will be provided. The complainant will also receive a copy of the materials that must be provided to the respondent under this paragraph. Before providing such materials, OSHA will redact them, if necessary, consistent with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. The respondent will be given the opportunity to submit a written response, to meet with the investigators, to present statements from witnesses in support of its position, and to present legal and factual arguments. The respondent must present this evidence within 10 business days of OSHA’s notification pursuant to this paragraph, or as soon thereafter as OSHA and the respondent can agree, if the interests of justice so require.


(a) After considering all the relevant information collected during the investigation, the Assistant Secretary will issue, within 60 days of the filing of the complaint, written findings as to whether or not there is reasonable cause to believe that the respondent has retaliated against the complainant in violation of FSMA.

(1) If the Assistant Secretary concludes that there is reasonable cause to believe that a violation has occurred, the Assistant Secretary will accompany the findings with a preliminary order providing relief to the complainant. The preliminary order will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and interest), terms, conditions and privileges of the complainant’s employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily. The preliminary order will also require the respondent to submit appropriate documentation to the Social Security Administration allocating any back pay award to the appropriate calendar quarters.

(2) If the Assistant Secretary concludes that a violation has not occurred, the Assistant Secretary will notify the parties of that finding.

(b) The findings and, where appropriate, the preliminary order will be sent by certified mail, return receipt requested (or other means that allow OSHA to confirm receipt), to all parties of record (and each party’s legal counsel if the party is represented by counsel). The findings and, where appropriate, the preliminary order will inform the parties of the right to object to the findings and/or order and to request a hearing, and of the right of the respondent to request an award of attorney fees not exceeding $1,000 from the administrative law judge (ALJ), regardless of whether the respondent has filed objections, if the respondent alleges that the complaint was frivolous or brought in bad faith. The findings and, where appropriate, the preliminary order also will give the address of the Chief Administrative Law Judge, U.S. Department of Labor. At the same time, the Assistant Secretary will file with the Chief Administrative Law Judge a copy of the original complaint and a copy of the findings and/or order.

(c) The findings and any preliminary order will be effective 30 days after receipt by the respondent (or the respondent’s legal counsel if the respondent is represented by counsel), or on the compliance date set forth in the preliminary order, whichever is later, unless an objection and/or a request for hearing has been timely filed as provided at §1987.106. However, the portion of any preliminary order requiring reinstatement will be effective immediately upon the respondent’s receipt of the findings and the preliminary order, regardless of any objections to the findings and/or the order.

Subpart B—Litigation

§1987.106 Objections to the findings and the preliminary order and requests for a hearing.

(a) Any party who desires review, including judicial review, of the findings and/or preliminary order, or a respondent alleging that the complaint was frivolous or brought in bad faith who seeks an award of attorney fees under FSMA, must file any objections and/or a request for a hearing on the record within 30 days of receipt of the findings and preliminary order pursuant to §1987.105. The objections, request for a hearing, and/or request for attorney fees must be in writing and state whether the objections are to the findings, the preliminary order, and/or whether there should be an award of attorney fees. The date of the postmark, facsimile transmission, or electronic communication transmitted is considered the date of filing; if the objection is filed in person, by hand delivery or other means, the objection is filed upon receipt. Objections must be filed with the Chief Administrative Law Judge, U.S. Department of Labor, and copies of the objections must be mailed at the same time to the other parties of
§ 1987.107 Hearings.

(a) Except as provided in this part, proceedings will be conducted in accordance with the rules of practice and procedure for administrative hearings before the Office of Administrative Law Judges, codified at subpart A of part 18 of this title.

(b) Upon receipt of an objection and request for hearing, the Chief Administrative Law Judge will promptly assess the case to an ALJ who will notify the parties, by certified mail, of the day, time, and place of hearing. The hearing is to commence expeditiously, except upon a showing of good cause or unless otherwise agreed to by the parties. Hearings will be conducted de novo on the record. ALJs have broad discretion to limit discovery in order to expedite the hearing.

(c) If both the complainant and the respondent object to the findings and/or order, the objections will be consolidated and a single hearing will be conducted.

(d) Formal rules of evidence will not apply, but rules or principles designed to assure production of the most probative evidence will be applied. The ALJ may exclude evidence that is immaterial, irrelevant, or unduly repetitious.


(a)(1) The complainant and the respondent will be parties in every proceeding and must be served with copies of all documents in the case. At the Assistant Secretary’s discretion, the Assistant Secretary may participate as a party or as amicus curiae at any time at any stage of the proceeding. This right to participate includes, but is not limited to, the right to petition for review of a decision of an ALJ, including a decision approving or rejecting a settlement agreement between the complainant and the respondent.

(b)(1) If both the complainant and the respondent object to the findings and/or order, the objections will be consolidated and a single hearing will be conducted. The Assistant Secretary’s discretion, the Assistant Secretary may participate as a party or as amicus curiae at any time at any stage of the proceeding. This right to participate includes, but is not limited to, the right to petition for review of a decision of an ALJ, including a decision approving or rejecting a settlement agreement between the complainant and the respondent.

(b)(2) If the ALJ determines that the respondent has not violated the law, an order will be issued denying the complaint. If, upon the request of the respondent, the ALJ determines that a complaint was frivolous or was brought in bad faith who seeks an award of attorney fees, not exceeding $1,000.

(c) The decision will be served upon all parties to the proceeding, the Assistant Secretary, and the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor. Any ALJ’s decision requiring reinstatement or lifting an order of reinstatement by the Assistant Secretary will be effective immediately upon receipt of the decision by the respondent. All other portions of the ALJ’s order will be effective 14 days after the date of the decision unless a timely petition for review has been filed with the Administrative Review Board (ARB), U.S. Department of Labor. The decision of the ALJ will become the final order of the Secretary unless a petition for review is timely filed with the ARB and the ARB accepts the petition for review.

§ 1987.109 Decision and orders of the administrative law judge.

(a) The decision of the ALJ will contain appropriate findings, conclusions, and an order pertaining to the remedies provided in paragraph (d) of this section, as appropriate. A determination that a violation has occurred may be made only if the complainant has demonstrated by a preponderance of the evidence that protected activity was a contributing factor in the adverse action alleged in the complaint.

(b) If the complainant has satisfied the burden set forth in the prior paragraph, relief may not be ordered if the respondent demonstrates by clear and convincing evidence that it would have taken the same adverse action in the absence of any protected activity.

(c)(1) If the complainant is found to have committed an unfair labor practice, the order shall require the respondent to cease and desist from engaging in such unfair labor practices and to offer reinstatement, back pay, and other remedies appropriate to the injury caused by the unfair labor practice. In addition, the order may require the respondent to take affirmative action to undo the effects of the unfair labor practice. The order shall include a statement of the reasons for the conclusion that the unfair labor practice has been committed and shall specify the remedies ordered.

(d)(1) If the ALJ concludes that the respondent has violated the law, the ALJ will issue an order that will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of the complainant’s employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred.

The decision of the Secretary is not subject to judicial review. The decision of the ALJ is deemed final. The decision of the Secretary is not subject to judicial review. The decision of the ALJ is deemed final.


(a) Any party desiring to seek review, including judicial review, of a decision of the ALJ, or a respondent alleging that the complaint was frivolous or brought in bad faith who seeks an award of attorney fees, must file a written petition for review with the ARB, which has been delegated the authority to act for the Secretary and issue final decisions under this part. The parties should identify in their petitions for review the legal conclusions or orders to which they object, or the objections may be deemed waived. A petition must be filed within 14 days of the date of the decision of the ALJ. The date of the
postmark, facsimile transmittal, or electronic communication transmittal will be considered to be the date of filing; if the petition is filed in person, by hand delivery or other means, the petition is considered filed upon receipt. The petition must be served on all parties and on the Chief Administrative Law Judge at the time it is filed with the ARB. Copies of the petition for review must be served on the Assistant Secretary and on the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor.

(b) If a timely petition for review is filed pursuant to paragraph (a) of this section, the decision of the ALJ will become the final order of the Secretary unless the ARB, within 30 days of the filing of the petition, issues an order notifying the parties that the case has been accepted for review. If a case is accepted for review, the decision of the ALJ will be inoperative unless and until the ARB issues an order adopting the decision, except that any order of reinstatement will be effective while review is conducted by the ARB, unless the ARB grants a motion by the respondent to stay that order based on exceptional circumstances. The ARB will specify the terms under which any briefs are to be filed. The ARB will review the factual determinations of the ALJ under the substantial evidence standard. If no timely petition for review is filed, or the ARB denies review, the decision of the ALJ will become the final order of the Secretary.

(c) The final decision of the ARB will be issued within 120 days of the conclusion of the hearing, which will be deemed to be 14 days after the date of the decision of the ALJ, unless a motion for reconsideration has been filed with the ALJ in the interim. In such case the conclusion of the hearing is the date the motion for reconsideration is denied or 14 days after a new decision is issued. The ARB’s decision will be served upon all parties and the Chief Administrative Law Judge by mail. The final decision will also be served on the Assistant Secretary and on the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor, even if the Assistant Secretary is not a party.

(d) If the ARB concludes that the respondent has violated the law, the ARB will issue a final order providing relief to the complainant. The final order will be comprised where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of the complainant’s employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred.

Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily. The order will also require the respondent to submit appropriate documentation to the Social Security Administration allocating any back pay award to the appropriate calendar quarters.

(e) If the ARB determines that the respondent has not violated the law, an order will be issued denying the complaint. If, upon the request of the respondent, the ARB determines that a complaint was frivolous or was brought in bad faith, the ARB may award to the respondent a reasonable attorney fee, not exceeding $1,000.

Subpart C—Miscellaneous Provisions

§1987.111 Withdrawal of complaints, findings, objections, and petitions for review; settlement.

(a) At any time prior to the filing of objections to the Assistant Secretary’s findings and/or preliminary order, a complainant may withdraw his or her complaint by notifying OSHA, orally or in writing, of his or her withdrawal. OSHA then will confirm in writing the complainant’s desire to withdraw and determine whether to approve the withdrawal. OSHA will notify the parties (and each party’s legal counsel if the party is represented by counsel) of the approval of any withdrawal. If the complaint is withdrawn because of settlement, the settlement must be submitted for approval in accordance with paragraph (d) of this section. A complainant may not withdraw his or her complaint after the filing of objections to the Assistant Secretary’s findings and/or order by filing a written withdrawal with the ALJ.

(b) The Assistant Secretary may withdraw the findings and/or preliminary order at any time before the expiration of the 30-day objection period described in §1987.106, provided that no objection has been filed yet, and substitute new findings and/or a new preliminary order. The date of the receipt of the substituted findings or order will begin a new 30-day objection period.

(c) At any time before the Assistant Secretary’s findings and/or order become final, a party may withdraw objections to the Assistant Secretary’s findings and/or order by filing a written withdrawal with the ALJ. If the case is on review with the ARB, a party may withdraw a petition for review of an ALJ’s decision at any time before that decision becomes final by filing a written withdrawal with the ARB. The ALJ or the ARB, as the case may be, will determine whether to approve the withdrawal of the objections or the petition for review. If the ALJ approves a request to withdraw objections to the Assistant Secretary’s findings and/or order, and there are no other pending objections, the Assistant Secretary’s findings and/or order will become the final order of the Secretary. If the ARB approves a request to withdraw a petition for review of an ALJ decision, and there are no other pending petitions for review of that decision, the ALJ’s decision will become the final order of the Secretary. If objections or a petition for review are withdrawn because of settlement, the settlement must be submitted for approval in accordance with paragraph (d) of this section.

(d) [1] Investigative settlements. At any time after the filing of a complaint, but before the findings and/or order are objected to or become a final order by operation of law, the case may be settled if OSHA, the complainant, and the respondent agree to a settlement. OSHA’s approval of a settlement reached by the respondent and the complainant demonstrates OSHA’s consent and achieves the consent of all three parties.

(2) Adjudicatory settlements. At any time after the filing of objections to the Assistant Secretary’s findings and/or order, the case may be settled if the participating parties agree to a settlement and the settlement is approved by the ALJ if the case is before the ALJ, or by the ARB if the ARB has accepted the case for review. A copy of the settlement will be filed with the ALJ or the ARB, as appropriate.

(e) Any settlement approved by OSHA, the ALJ, or the ARB will constitute the final order of the Secretary and may be enforced in United States district court pursuant to §1987.113.

§1987.112 Judicial review.

(a) Within 60 days after the issuance of a final order under §§1987.109 and 1987.110, any person adversely affected or aggrieved by the order may file a petition for review of the order in the United States Court of Appeals for the circuit in which the violation allegedly occurred or the circuit in which the

(a) The complainant may bring an action at law or equity for de novo review in the appropriate United States district court of the United States, which will have jurisdiction over such an action without regard to the amount in controversy, either:

(1) Within 90 days after receiving a written determination under § 1987.105(a) provided that there has been no final decision of the Secretary; or

(2) If there has been no final decision of the Secretary within 210 days of the order was issued may file a civil action seeking enforcement of the order in the appropriate United States district court.

§ 1987.115 Special circumstances; waiver of rules.

In special circumstances not contemplated by the provisions of the rules in this part, or for good cause shown, the ALJ or the ARB on review may, upon application, after three days notice to all parties, waive any rule or issue such orders that justice or the administration of FSMA requires.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2015–1108]

RIN 1625–AA08

Special Local Regulation, Daytona Beach Grand Prix of the Seas; Atlantic Ocean, Daytona Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation on the waters of the Atlantic Ocean east of Daytona Beach, Florida during the Daytona Beach Grand Prix of the Seas, a series of high-speed personal watercraft boat races. This action is necessary to provide for the safety of life on the navigable waters surrounding the event. This special local regulation will be enforced daily 8 a.m. to 5 p.m., from April 22 through April 24, 2016. This rulemaking prohibits persons and vessels from being in the regulated area unless authorized by the Captain of the Port (COTP) Jacksonville or a designated representative.

DATES: This rule is effective from April 22, 2016 through April 24, 2016 and will be enforced daily from 8 a.m. to 5 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USC–2015–1108 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 about this rulemaking, call or email Lieutenant Allan Storm, Sector Jacksonville, Waterways Management Division, U.S. Coast Guard; telephone 904–714–7616, email Allan.H.Storm@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

II. Background Information and Regulatory History

On December 7, 2015, Powerboat P1–USA, LLC notified the Coast Guard that it will conduct a series of high speed boat races in the Atlantic Ocean, offshore from Daytona Beach, FL from April 22 through 24, 2016. In response, on February 4, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulation, Daytona Beach Grand Prix of the Seas; Daytona Beach, FL (81 FR 5967). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this boat race. During the comment period that ended March 7, 2016, we received 3 comments.

Under good cause provisions in 5 U.S.C. 553(d)(3), we are making this rule effective less than 30 days after its publication in the Federal Register. The Coast Guard finds that good cause exists for making this rule effective starting April 22, 2016 because the public was notified of this event well in advance through a proposed rule to regulate waterway activities published on February 4, 2016 (81 FR 5967). Designated representatives will be on scene to assist the public with compliance during the nine hours per day that the regulation will be enforced.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The COTP Jacksonville determined that potential hazards associated with high speed boat races necessitate the establishment of a special local
regulation. The purpose of this rulemaking is to ensure the safety of life on the navigable waters of the United States by prohibiting all vessels and persons not participating in the event from entering the regulated area.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received three comments on the NPRM published February 4, 2016. Two comments received were in support of the rule. The third comment received was opposed to the rule. The comment opposed to the rule disputed the following items: (1) The Coast Guard’s position that this high speed boat race poses an extra hazard to the safety of life on the navigable waters surrounding the event, (2) the need to establish a special local regulation to mitigate the hazards associated with this event, (3) the need for Coast Guard presence to enforce the rule (due to monetary cost to taxpayers), and (4) the determination that this rule is not a “significant regulatory action.”

In regard to significant regulatory action, the commenter stated that this rule “encroaches on rights of mariners to be in a public area.”

A marine event is defined as an organized event of limited duration on the navigable waters of the United States conducted according to a prearranged schedule which presents an extra or unusual hazard to the safety of human life that cannot be protected by existing navigation. Prior to taking any regulatory action and to considering the establishment of a special local regulation, the Coast Guard utilizes a risk-informed decision making process to determine if an event meets the definition of a marine event as outlined in 33 CFR 100.05 and is likely to introduce an extra or unusual hazard to the safety of human life. The primary risk factors for determining that this is a marine event included: (1) The expected involvement of an unusually large concentration of traffic on the water that may interfere with routine navigation and (2) the event includes an inherently hazardous competition where craft are expected to travel at high speeds. Once the Coast Guard made the marine event determination, we proposed a safety risk-mitigation tool. In this case, it is the establishment of a special local regulation. Based on an analysis of the factors addressed above, the commenter’s position that this race is not a marine event justifying Coast Guard action is not supportable.

For the enforcement of this rule, the Coast Guard would utilize Federal, state, and local officers (designated representatives) for the enforcement of the regulated area. A “significant regulation” under Executive Order 12866, is one that has an impact on the economy of more than $100 million or one that adversely affects in a material way the economy or a sector of the economy; creates a serious inconsistency or interferes with another agency; materially alters the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients; or raises a novel issue of law or policy. For the reasons stated in section V.A below, the Coast Guard determines that this rule is not a significant regulatory action. It is one of a category of regulations considered “routine and frequent” by the Office of Management and Budget.

This rule establishes a special local regulation for the Daytona Beach Grand Prix of the Seas, a series of high-speed personal watercraft boat races. The regulated area would encompass the navigable waters of the Atlantic Ocean offshore from Daytona Beach, Florida and will be enforced daily 8 a.m. to 5 p.m., from April 22 through April 24, 2016. Approximately 90 high-speed personal watercraft are anticipated to participate in the races.

The regulated area would encompass an approximated offshore area that is 1,350 yards wide extending 600 yards south of the Daytona Beach pier to 1,900 yards north of the pier. No vessel or person will be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative.

The Coast Guard has determined that this temporary final rule is not a significant regulatory action for the following reasons: (1) The special local regulation would be enforced for a total of only 27 hours over the course of three days; (2) although persons and vessels would not be able to enter, transit through, anchor in, or remain within the regulated area without authorization from the COTP Jacksonville or a designated representative, they would be able to operate in the surrounding area during the enforcement period; (3) persons and vessels would still be able to enter, transit through, anchor in, or remain within the regulated area if authorized by the COTP Jacksonville or a designated representative; and (4) the Coast Guard would provide advance notification of the special local regulation to the local maritime community via Broadcast Notice to Mariners or on-scene designated representative.

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 received no comments from the Small Business Administration on this rulemaking. 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 regulated area 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 contact 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 among the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

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 Management Directive 023–01 and Commandant Instruction M16475.1D, 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 special local regulation that would prohibit persons and vessels from transiting through a 2,500 yard by 1,350 yard regulated area during a three day racing event lasting nine hours daily. It is categorically excluded from further review under paragraphs 34(b) and 35(a) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under ADDRESSES. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities
The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact 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 100
Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 33 U.S.C. 1233.

2. Add § 100.35T07–1108 to read as follows:

§ 100.35T07–1108 Special Local Regulation, Daytona Beach Grand Prix of the Seas; Atlantic Ocean, Daytona Beach, FL.

(a) Regulated area. The following regulated area is a special local regulation located offshore from Daytona Beach, FL. All waters of the Atlantic Ocean encompassed within the following points: Starting at Point 1 in position 29°14.580′ N., 081°00.820′ W.; thence northeast to Point 2 in position 29°14.783′ N., 081°00.101′ W.; thence southeast to Point 3 in position 29°13.646′ N., 080°59.549′ W.; thence southwest to Point 4 in position 29°13.434′ N., 081°00.224′ W.; thence northwest back to origin. These coordinates are based on North American Datum 1983.

(b) Definition. The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port (COTP) Jacksonville in the enforcement of the regulated area.

(c) Regulations. (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the COTP Jacksonville or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the COTP Jacksonville by telephone at 904–714–7557, or a designated representative via VHF–FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP Jacksonville or designated representative.

(3) The Coast Guard will provide notice of the regulated area through Broadcast Notice to Mariners via VHF–FM channel 16 or by on-scene designated representatives.

(d) Enforcement period. This section will be enforced daily 8 a.m. to 5 p.m. from April 22 through April 24, 2016.

Dated: April 12, 2016.

J.F. Dixon,
Captain, U.S. Coast Guard, Captain of the Port Jacksonville.

[FR Doc. 2016–08875 Filed 4–15–16; 8:45 am]
BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0295]

Drawbridge Operation Regulation; Isle of Wight (Sinepatuxent) Bay, Ocean City, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.
SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US 50 (Harry W. Kelly Memorial) Bridge across the Isle of Wight (Sinepatuxent) Bay, mile 0.5, at Ocean City, MD. The deviation is necessary to accommodate participants of the 2016 “Island 2 Island” Half Marathon.

DATES: The deviation is effective from 8 a.m. to 10:30 a.m. on Saturday, April 30, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0295] is available at http://www.regulations.gov. Type the docket number in the “SEARCH” box and click “SEARCH”. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6557, email Michael.R.Thorogood@uscg.mil.

SUPPLEMENTARY INFORMATION: The OC Tri-Running Sports, on behalf of the Maryland State Highway Administration, who owns the US 50 (Harry W. Kelly Memorial) Bridge has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.559, to facilitate the 2016 “Island 2 Island” Half Marathon.

Under this temporary deviation, the bridge will be closed to navigation from 8 a.m. to 10:30 a.m. on April 30, 2016. The closure has been requested to ensure the safety of the increased volumes of runners and spectators that will be participating in the “Island 2 Island” Half Marathon on April 30, 2016.

The bridge is a Double Bascule bridge and has a vertical clearance in the closed position of 13 feet above mean high water. Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternative route for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local Notice and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 12, 2016.

Hal R. Pitts,
Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–08896 Filed 4–15–16; 8:45 am]

BILLING CODE 9110–04–P
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 ENERGY

10 CFR Part 430


RIN 1904–AD52

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Open Meetings for the Dedicated Purpose Pool Pumps (DPPP) Working Group To Negotiate a Notice of Proposed Rulemaking (NOPR) for Energy Conservation Standards


ACTION: Notice of public meetings.

SUMMARY: The Department of Energy (DOE) announces public meetings and webinars for the DPPP Working Group. The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the Federal Register.

DATES: See SUPPLEMENTARY INFORMATION section for meeting dates.

ADDRESSES: The meetings will be held at U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585 unless otherwise stated in the SUPPLEMENTARY INFORMATION section. Individuals will also have the opportunity to participate by webinar. To register for the webinars and receive call-in information, please register at DOE’s Web site https://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/14.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On July 30, 2015, ASRAC met and unanimously passed the recommendation to form a dedicated purpose pool pumps (DPPP) working group to meet and discuss and, if possible, reach consensus on proposed Federal rules that would apply to this equipment. The ASRAC Charter allowed for 3 months of working group meetings to establish the scope, metric, definitions, and test procedure for dedicated purpose pool pumps and decide on a path forward at that time. The working group met this requirement and now more time is required to discuss potential energy conservation standards for this equipment. On January 20, 2016, ASRAC met and recommended that the DPPP Working Group continue its work to develop and recommend potential energy conservation standards for this equipment. This notice announces the next series of meetings for this working group.

DOE will host public meetings and webinars on the below dates. Meetings will be hosted at DOE’s Forrestal Building, unless otherwise stated.

- May 18, 2016; 9:00 a.m.–5:00 p.m.
- May 19, 2016; 9:00 a.m.–3:00 p.m.
- June 22, 2016; 9:00 a.m.–5:00 p.m.
- June 23, 2016; 9:00 a.m.–3:00 p.m. at DOE’s Forrestal Building, Room 4A–104

Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email asrac@ee.doe.gov. In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If you are a foreign national, and wish to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: Regina.Washington@ee.doe.gov so that the necessary procedures can be completed. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver’s license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS) recent changes have been made regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. Driver’s licenses from the following states or territory will not be accepted for building entry and one of the alternate forms of ID listed below will be required.

DHS has determined that regular driver’s licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, Louisiana, New York, American Samoa, Maine, Oklahoma, Arizona, Massachusetts, Washington, and Minnesota.

Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; an Enhanced Driver’s License or Enhanced ID-Card issued by the states of Minnesota, New York or Washington (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver’s License); A military ID or other Federal government issued Photo-ID card.

Docket: The docket is available for review at www.regulations.gov, including Federal Register notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the www.regulations.gov index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

Issued in Washington, DC, on April 8, 2016.

Kathleen B. Hogan,
Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2016–08886 Filed 4–15–16; 8:45 am]

BILLING CODE 6450–01–P
Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph Proposed Rule; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the proposed rule, published in the Federal Register of December 23, 2015 (80 FR 79776), revising its regulations on prescription and nonprescription fixed-combination and co-packaged drugs and on combinations of active ingredients under consideration for inclusion in an over-the-counter monograph. FDA is reopening the comment period to permit time for additional comments.

DATES: Submit either electronic or written comments by May 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

* Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
* For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–1260 for “Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph Proposed Rule; Reopening of the Comment Period.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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.” The Agency 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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 comments 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Diana J. Pomeranz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 6208, Silver Spring, MD 20993–0002, 240–402–4654.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 23, 2015 (80 FR 79776), FDA published a proposed rule to revise its regulations on prescription and nonprescription fixed-combination and co-packaged drugs and on combinations of active ingredients under consideration for inclusion in an over-the-counter monograph. Interested persons were originally given until March 22, 2016, to comment on the proposed rule. On March 21, 2016, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 90 days was insufficient to respond fully to FDA’s specific requests for comments and to thoroughly evaluate and address pertinent issues. Accordingly, we are reopening the comment period.

Dated: April 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08888 Filed 4–15–16; 8:45 am]

BILLING CODE 4164–01–P
DEPARTMENT OF EDUCATION
34 CFR Chapter II
[Docket ID ED–2016–OESE–0004; CFDA Number: 84.368A.]

Proposed Priorities—Enhanced Assessment Instruments

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Proposed priorities.

SUMMARY: The Assistant Secretary for Elementary and Secondary Education proposes priorities under the Enhanced Assessment Instruments Grant program, also called the Enhanced Assessment Grants (EAG) program. The Assistant Secretary may use one or more of these priorities for competitions using funds from fiscal year (FY) 2016 and later years. Depending on the availability of funds and the use of other priorities under the EAG authority, the Assistant Secretary may also choose not to use one or more of these priorities for competitions using funds from FY 2016 and later years. These proposed priorities are designed to support projects to improve States’ assessment systems.

DATES: We must receive your comments on or before May 18, 2016.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID and the term “Enhanced Assessment Grants—Comments” at the top of your comments.

FOR FURTHER INFORMATION CONTACT:
Donald Peasley, Telephone: (202) 453–7982 or by email: donald.peasley@ed.gov.

If you use a telecommunications device for the deaf (TTD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:
Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priorities, we urge you to identify clearly the specific proposed priority that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from these proposed priorities. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about these proposed priorities by accessing regulations.gov. You may also inspect the comments in room 3e124, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistant to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will
provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

Purpose of Program: The purpose of the EAG program is to enhance the quality of assessment instruments and systems used by States for measuring the academic achievement of elementary and secondary school students.

Program Authority: Section 6112 of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (NCLB), and section 1203(b)(1) of the ESEA, as amended by the Every Student Succeeds Act (Pub. L. 114–95) (ESSA).

Proposed Priorities: This notice contains three proposed priorities.

Background: Section 6112 of the ESEA, as amended by the NCLB, and section 1203(b)(1) of the ESEA, as amended by the ESSA, authorize the Department to make competitive grant awards to State educational agencies (SEAs) and consortia of SEAs to help them enhance the quality of their assessment instruments and assessment systems. Under these provisions, State grantees must meet at least one of the program’s statutory priorities, including collaborating with organizations to improve the quality, validity, reliability, and efficiency of academic assessments; measuring student academic achievement using multiple measures from multiple sources; measuring student growth on State assessments; and evaluating student academic achievement through the development of comprehensive academic assessment instruments and methods.

The grants awarded under this competitive grant award program in section 6112 will also lay the groundwork for some new opportunities in the recently reauthorized Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act. For example, the reauthorization of ESEA, will allow up to seven States or consortia of States to receive an initial demonstration authority to establish an innovative assessment and accountability system for a new approach to assessment for a trial period of up to five years. This can provide SEAs with an opportunity to demonstrate what is possible when assessment systems are redesigned with student learning at the center. The EAG program provides SEAs with support to develop innovative assessment tools and approaches which have the potential to be used by all States, including those approved under the innovative assessment and accountability demonstration authority, and be more widely adopted at scale. In addition, the EAG program provides SEAs with support in developing innovative summative assessment tools and approaches that can be used within the broader context of the multiple measures of student achievement and school accountability of the new ESSA and the President’s Testing Action Plan.

Through this notice, the Department proposes three additional priorities for the EAG program that are designed to support States in continuously improving their assessment systems to measure college- and career-readiness. We believe that an essential part of educating students involves assessing students’ progress toward meeting the high standards they need to be ready for college and the workplace. Assessments provide necessary information for States, districts, educators, families, the public, and students themselves to measure progress and improve outcomes for all learners. As such, we recognize the importance of continuously improving and innovating to ensure assessments are fair, of high quality and not duplicative, can be completed in the minimum necessary time while validly and reliably measuring a student’s knowledge and skills, and reflect the expectation that students will be prepared for success in college and career.

Proposed Priority 1—Developing Innovative Assessment Item Types and Design Approaches.

Background: The President’s Testing Action Plan highlighted the need to reduce the time spent on unnecessary, duplicative, or low-quality testing and improve assessment efficiency and quality to provide educators and parents with more timely and actionable data on students’ progress. SEAs and LEAs need to continue developing new methods for collecting evidence about what students know and are able to do as it relates to State learning standards, including by creating innovative item types and design approaches, for example, by developing modular assessments that are given throughout the school year instead of a single summative assessment given at the end of the school year.

Although traditional assessment items such as multiple-choice questions have advantages, innovative item types such as performance tasks, simulations, and interactive, multi-step, technology-rich items that support competency-based assessments or portfolio assessments which demonstrate applied skills, have the potential to provide a more comprehensive view of a student’s knowledge and mastery of standards. Examples include: Items that provide multi-step mathematics problems where students demonstrate their approaches to solving each step; items that permit graphs or other visual response types; and simulated game environments where students interact with stimuli and interaction information is collected.

As States implement more rigorous standards, it is important that assessment strategies are aligned with the higher-level cognitive skills students are expected to master. For example, performance tasks and simulations provide an opportunity for students to apply their understanding and demonstrate their abilities in real-world scenarios. Rather than simply requiring a student to select a response from a list of options, competency-based assessments can allow students to interact with materials and concepts to formulate responses. Students’ responses to, and performance on, such innovative item types provide insight into their higher-level thinking and problem-solving skills and allow educators to better understand students’ mastery of content and concepts.

We believe that good assessments should require the same kind of complex work that students do in an effective classroom or in the real world, including demonstration and application of knowledge and skills. Further, assessments should present information and questions that push students’ critical thinking skills so that students gain valuable experience while taking them. The inclusion of new, innovative item types will help to ensure that taking an assessment is a worthwhile experience for students.

1 The Consolidated Appropriations Act, 2016 (Pub. L. 114–113) appropriated funds for the EAG program under section 6112 of the ESEA, as amended by the NCLB. As such, the upcoming EAG competition will be conducted under that authority. The Department is also establishing these priorities under the authority in section 1203(b)(1) of the ESEA, as amended by the ESSA, which, if funded, would replace the EAG program under section 6112. These priorities may also be used in any competition conducted after FY 2016 under that authority.


Modular assessment approaches also can help SEAs and LEAs support students and educators in a number of significant ways by breaking down large, summative assessment forms with many items into smaller forms with fewer items (e.g., testing only one mathematics or reading competency). This will allow students to be assessed on specific competencies when they are ready and capable of demonstrating proficiency. This can allow advanced students to move ahead rapidly while providing students who need extra support the flexibility and additional time they need to learn and succeed, as well as the opportunity to demonstrate competence in the areas they have mastered.

Modules can also provide educators with more individualized, easily-integrated assessments which are used together to provide a summative analysis of each learner.

Proposed Priority: Under this priority, SEAs must:

(a) Develop, evaluate, and implement new, innovative item types for use in summative assessments in reading/language arts, mathematics, or science;

(b) Develop, evaluate, and implement new, innovative item types under paragraph (a) may include, for example, performance tasks; simulations; or interactive, multi-step, technology-rich items that can support competency-based assessments or portfolio projects;

Proposed Priority 2—Improving Assessment Scoring and Score Reporting

Background: By improving assessment scoring and score reporting, SEAs can enhance the testing experience for students and provide more timely and relevant information to parents and educators. While developing high-quality assessments that measure student knowledge and skills against States’ standards is an essential part of building strong assessment systems, ensuring that assessment results are available sooner, and provide clear and actionable information is also critically important.

With continued advancements in technology to support and enhance education in the classroom, it is also becoming possible to improve the testing experience for students by using technology to automatically score non-multiple choice assessment items. Automated scoring can decrease the time needed for scoring and releasing results, lower costs, improve score consistency, and reduce the need for training of, and coordination among, human scorers. Recent research has examined existing automated scoring systems for short and extended constructed responses and found these automated scoring systems to be similar to human scorers.

Building on the work done to date and developing better technological tools to score assessments would be advantageous to SEAs, LEAs, educators, and students. Automated scoring would allow SEAs to incorporate more non-multiple choice items, such as essays and constructed responses, in assessments while not adding significantly to the time or cost to score the tests. Assessment results could be returned more quickly to students and educators, who could in turn respond to the results data through timely implementation of additional teaching, supports, or interventions that would help students master content.

The inclusion of additional non-multiple choice items can also enhance the testing experience for students by requiring more engaging and complex demonstrations of knowledge. To improve scoring, applicants responding to this priority could propose projects to build, test, or enhance automated scoring systems for use with non-multiple choice items in reading/language arts, mathematics, and science. For example, an applicant could propose to build, test, or improve a system for reviewing brief or extended student-constructed responses.

Applicants could propose projects that will research, build, or test systems that can score assessments and provide diagnostic information to educators and parents.

Score reporting, when done well, provides valuable feedback to educators that can be used to guide instruction and supports for students. This feedback is most relevant when it is available soon after the assessment is administered and when it is actionable for students, parents, and educators. The Department also recognizes a need to improve the design and content of the reports such that they clearly communicate information to stakeholders.

Efforts to improve the usefulness of score reports could include:

Incorporating information about what students’ results mean; including multiple levels of information (e.g., overall proficiency, mastery of different standards or skills); providing examples of questions that were likely to be answered correctly or incorrectly (and why); and connecting students and their families to useful resources or aids to address identified areas for improvement. Improving communications related to score reporting could include: Presenting information in easily comprehensible formats (e.g., graphically or numerically); tailoring reporting formats to different audiences or for different modes of dissemination; making results available in a timelier manner (i.e., delivered to teachers and parents as soon as possible); and using speech recognition software to record and score students’ oral reading fluency, enabling more efficient and less prone to scoring errors.

Proposed Priority: Under this priority, SEAs must:

(a) Develop, evaluate, and implement new, innovative item types for use in summative assessments in reading/language arts, mathematics, or science;

(b) Develop new approaches to transform traditional, end-of-year summative assessment forms with many items into a series of modular assessment forms, each with fewer items;

(1) To respond to paragraph (b), applicants must develop modular assessment approaches which can be used to provide timely feedback to educators and parents as well as be combined to provide a valid, reliable, and fair summative assessment of individual learners.

(c) Applicants proposing projects under either paragraph (a) or (b) must provide a dissemination plan such that their projects can serve as models and resources that can be shared with States across the Nation.
soon as possible after the assessments are administered).

Proposal Priority: Under this priority, SEAs must:

(a) Develop innovative tools that leverage technology to score assessments;

(1) To respond to paragraph (a), applicants must propose projects to reduce the time it takes to provide test results to educators, parents, and students and to make it more cost-effective to include non-multiple choice items on assessments. These innovative tools must improve automated scoring of student assessments, in particular non-multiple choice items in reading/language arts, mathematics, and science; or

(b) Propose projects, in consultation with organizations representing parents, students, and teachers, to address needs related to score reporting and improve the utility of information about student performance included in reports of assessment results and provide better and more timely information to educators and parents;

(1) To respond to paragraph (b), applicants must include one or more of the following in their projects:

(i) Developing enhanced score reporting templates or digital mechanisms for communicating assessment results and their meaning;

(ii) Improving the assessment literacy of educators and parents to improve the interpretation of test results to support teaching and learning in the classroom; and

(iii) Developing mechanisms for secure transmission and individual use of assessment results by students and parents.

(c) Applicants proposing projects under either paragraph (a) or (b) must provide a dissemination plan such that their projects can serve as models and resources that can be shared with States across the Nation.

Proposal Priority 3—Inventory of State and Local Assessment Systems.

Background: Recently, there has been significant discussion about the amount of time students spend in formal testing, including classroom, district, and State assessments. While the Department believes that assessments are important tools for measuring progress and improving outcomes for all students, we also recognize that too much testing, or unnecessary testing, takes valuable time away from teaching and learning in the classroom.8

In response to this issue, some SEAs, local educational agencies (LEAs), and schools are currently in the process of reviewing assessments administered to students in kindergarten through grade 12 to better understand if each assessment is of high quality, maximizes instructional goals, has clear purpose and utility, and is designed to provide information on students’ progress toward achieving proficiency on State standards. To support such efforts, the Department made the development of tools to inventory State and local assessment systems an invitational priority in the FY 2015 EAG competition. Through this proposed priority, the Department would fund States that are reviewing and streamlining their statewide assessments and working with some or all of their LEAs to review and streamline local assessments, including eliminating redundant and unnecessary assessments.

This priority would support the identification of promising practices that could be followed by other SEAs, LEAs, and schools to maximize the utility of their assessments to parents, educators, and students.

Proposal Priority:

(a) Under this priority, SEAs must—

(1) Review statewide and local assessments to ensure that each test is of high quality, maximizes instructional goals, has a clear purpose and utility, and is designed to help students demonstrate mastery of State standards;

(2) Determine whether assessments are serving their intended purpose to help schools meet their goals and to eliminate redundant and unnecessary testing; and

(3) Review State and LEA activities related to test preparation to make sure those activities are focused on academic content and not on test-taking skills.

(b) To meet the requirements in paragraph (a), SEAs must ensure that tests are—

(1) Worth taking, meaning that assessments are a component of good instruction and require students to perform the same kind of complex work they do in an effective classroom and the real world;

(2) High quality, resulting in actionable, objective information about students’ knowledge and skills, including by assessing the full range of relevant State standards, eliciting complex student demonstrations or applications of knowledge, providing an accurate measure of student achievement, and producing information that can be used to measure student growth accurately over time;

(3) Time-limited, in order to balance instructional time and the need for assessments, for example, by eliminating duplicative assessments and assessments that incentivize low-quality test preparation strategies that consume valuable classroom time;

(4) Fair for all students and used to support equity in educational opportunity by ensuring that accessibility features and accommodations level the playing field so tests accurately reflect what all students, including students with disabilities and English learners, know and can do;

(5) Fully transparent to students and parents, so that States and districts can clearly explain to parents the purpose, the source of the requirement (if appropriate), and the use by teachers and schools, and provide feedback to parents and students on student performance; and

(6) Tied to improving student learning as tools in the broader work of teaching and learning.

(c) Approaches to assessment inventories under paragraph (a) must include:

(1) Review of the schedule for administration of all assessments required at the Federal, State, and local levels;

(2) Review of the purpose of, and legal authority for, administration of all assessments required at the Federal, State, and local levels; and

(3) Feedback on the assessment system from stakeholders, which could include information on how teachers, principals, other school leaders, and administrators use assessment data to inform and differentiate instruction, how much time teachers spend on assessment preparation and administration, and the assessments that administrators, teachers, principals, other school leaders, parents, and students do and do not find useful.

(d) Projects under this priority—

(1) Must be no longer than 12 months;

(2) Must include a longer-term project plan, understanding that, beginning with FY 2017, there may be dedicated Federal funds for assessment audit work as authorized under section 1202 of the ESEA, as amended by the ESSA, and understanding that States and LEAs may use other Federal funds, such as the State assessment grant funds, authorized under section 1201 of the ESEA, as amended by the ESSA, consistent with the purposes for those funds, to implement such plans; and

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8 As a part of the President’s Testing Action Plan, the Department has recently released a Dear Colleague Letter to State Chief School Officers providing examples of existing Federal funding streams, and best practices, which can be utilized at the State and local levels to improve assessment systems and reduce unnecessary testing: http://www2.ed.gov/admins/lead/account/saa/16-00025inpredcssa2292010ltr.pdf.
Types of Priorities:
When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the Federal Register. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priorities:
We will announce the final priorities in a notice in the Federal Register. We will determine the final priorities after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use these priorities, we invite applications through a notice in the Federal Register.

Paperwork Reduction Act of 1995
As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps ensure that: the public understands the Department’s collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

The proposed priorities contain information collection requirements that are approved by OMB under the Departmental application control number 1894-0006; this proposed regulation does not affect the currently approved data collection.

Executive Orders 12866 and 13563
Regulatory Impact Analysis
Under Executive Order 12866, the Secretary must determine whether this proposed regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an “economically significant” rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We have reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing these proposed priorities only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department’s programs and activities.

The proposed priorities included in this notice would benefit students, parents, educators, administrators, and other stakeholders by improving the quality of State assessment instruments and systems. The proposed priority for an inventory of State and local assessment systems would encourage States to ensure that assessments are of high quality, maximize instructional goals, and have clear purpose and utility. Further, it would encourage States to eliminate unnecessary or redundant tests. The proposed priority for improving assessment scoring and score reporting would allow for States to score non-multiple choice assessment items more quickly and at a lower cost.
and ensure that assessments provide timely, actionable feedback to students, parents, and educators. The proposed priority for developing innovative assessment item types and design approaches, including the development of modular assessments, would yield new, more authentic methods for collecting evidence about what students know and are able to do and provide educators with more individualized, easily integrated assessments that can support competency-based learning and other forms of personalized instruction.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under FOR FURTHER INFORMATION CONTACT.

Electronic Access to This Document: The official version of this document is available free at the site. The Federal Register and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the Federal Register, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the Federal Register by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: April 12, 2016.

Ann Whalen,
Senior Advisor to the Secretary Delegated the Duties of Assistant Secretary for Elementary and Secondary Education.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131
RIN 2040–AF60

Aquatic Life Criteria for Copper and Cadmium in Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to establish federal Clean Water Act (CWA) aquatic life criteria for freshwaters under the state of Oregon’s jurisdiction, to protect aquatic life from the effects of exposure to harmful levels of copper and cadmium. In 2013, EPA determined that the freshwater acute cadmium criterion and freshwater acute and chronic copper criteria that Oregon adopted in 2004 did not meet CWA requirements to protect aquatic life in the state. Therefore, EPA proposes to establish federal freshwater criteria for cadmium and copper that take into account the best available science, EPA policies, guidance and legal requirements, to protect aquatic life uses in Oregon.

DATES: Comments must be received on or before June 2, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2016–0012, at http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. 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, 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-padoockets.

EPA is offering two virtual public hearings so that interested parties may also provide oral comments on this proposed rule. The first hearing will be on Monday, May 16, 2016 from 4:00 pm to 6:00 pm Pacific Time. The second hearing will be on Tuesday, May 17, 2016 from 9:00 am to 11:00 am Pacific Time. For more details on the public hearings and a link to register, please visit http://www.epa.gov/wqs-tech/water-quality-standards-regulations-oregon.

FOR FURTHER INFORMATION CONTACT: Erica Fleisig, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 566–1057; email address: fleisig.ERICA@epa.gov.

SUPPLEMENTARY INFORMATION: This proposed rule is organized as follows:

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B. EPA’s Disapproval of Oregon’s Freshwater Copper and Cadmium Criteria
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III. Freshwater Cadmium Aquatic Life Criteria
A. EPA’s National Recommended Cadmium Criteria
B. Proposed Acute Cadmium Criterion for Oregon’s Freshwaters
C. Implementation of Proposed Freshwater Acute Cadmium Criterion in Oregon

IV. Freshwater Copper Aquatic Life Criteria
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B. Proposed Acute and Chronic Copper Criteria for Oregon’s Freshwaters
C. Implementation of Proposed Freshwater Acute and Chronic Copper Criteria in Oregon

D. Ongoing State Efforts To Develop Copper Criteria for Oregon’s Freshwaters
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C. Variances
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B. Method for Estimating Costs
C. Results

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I. General Information

Does this action apply to me?

Copper and cadmium naturally occur at low levels in surface waters but, at higher concentrations, can be toxic to aquatic life. Anthropogenic activities such as coal combustion, mining, electroplating, iron and steel production, and use of pigments, fertilizers and pesticides, can increase levels of cadmium in the environment. Sources of elevated copper in the environment include mining, fabrication of paper, metal products and electronics, and discharges from wastewater treatment plants.

Entities such as industries, stormwater management districts, or publicly owned treatment works (POTWs) that discharge pollutants to freshwaters of the United States under the state of Oregon’s jurisdiction could be indirectly affected by this rulemaking, because federal WQS promulgated by EPA would be applicable to CWA regulatory programs, such as National Pollutant Discharge Elimination System (NPDES) permitting. Citizens concerned with water quality in Oregon could also be interested in this rulemaking. Categories and entities that could potentially be affected include the following:

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples of potentially affected entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>Industries discharging pollutants to freshwaters of the United States in Oregon.</td>
</tr>
<tr>
<td>Municipaliities</td>
<td>Publicly owned treatment works or other facilities discharging pollutants to freshwaters of the United States in Oregon.</td>
</tr>
<tr>
<td>Stormwater Management Districts</td>
<td>Entities responsible for managing stormwater runoff in the state of Oregon.</td>
</tr>
</tbody>
</table>

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be indirectly affected by this action. Any parties or entities who depend upon or contribute to the water quality of Oregon’s waters could be affected by this proposed rule. To determine whether your facility or activities could be affected by this action, you should carefully examine this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the FOR FURTHER INFORMATION CONTACT section.

II. Background

A. Statutory and Regulatory Authority

CWA section 101(a)(2) establishes a national goal wherever attainable of “water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water . . . .” These are commonly referred to as the “fishable/swimmable” goals of the CWA.

CWA section 303(c) (33 U.S.C. 1313(c)) directs states to adopt WQS for their waters subject to the CWA. CWA section 303(c)(2)(A) and EPA’s implementing regulations at 40 CFR part 131 require, among other things, that a state’s WQS specify designated uses of the waters, and water quality criteria that protect those uses. EPA’s regulations at 40 CFR 131.11(a)(1) provide that “[s]uch criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use.” In addition, 40 CFR 131.10(b) provides that “[i]n designating uses of a water body and the appropriate criteria for those uses, the [s]tate shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.”

States are required to review applicable WQS at least once every three years and, if appropriate, revise or adopt new standards (CWA section 303(c)(1)). Any new or revised WQS must be submitted to EPA for review and approval or disapproval (CWA section 303(c)(2)(A) and (c)(3)). If EPA determines that a WQS that a state submits to EPA for review does not meet the requirements of the CWA, EPA must notify the state of the changes necessary to meet CWA requirements (CWA section 303(c)(3)). CWA section 303(c)(3) and (c)(4) further specify that if a state does not make those changes within 90 days of notification, EPA must promptly prepare and publish a revised or new WQS for the state. Under CWA section 303(c)(4)(B), the Administrator is authorized to determine, even in the absence of a state submission, that a new or revised standard is needed to meet CWA requirements.

Under CWA section 304(a), EPA periodically publishes criteria recommendations for states to consider when adopting water quality criteria for particular pollutants to meet the CWA section 101(a)(2) goals. In establishing numeric criteria, states should adopt water quality criteria based on EPA’s CWA section 304(a) criteria, section 304(a) criteria modified to reflect site-specific conditions, or other scientifically defensible methods (40 CFR 131.11(b)(1)). Ultimately, whatever methods are used, criteria must protect the designated use and be based on sound scientific rationale (40 CFR 131.11(a)(1)).

B. EPA’s Disapproval of Oregon’s Freshwater Copper and Cadmium Criteria

On July 8, 2004, Oregon submitted 89 revised aquatic life criteria for 25 toxic pollutants to EPA for review under CWA 303(c). Many of Oregon’s revised criteria were the same as EPA’s nationally recommended 304(a) aquatic life criteria at the time. A subsequent consent decree between EPA and Northwest Environmental Advocates established deadlines for EPA to complete its CWA 303(c) review of Oregon’s aquatic life criteria. Prior to taking a final action on the aquatic life criteria, EPA requested formal consultation with the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) on its proposed approval of the criteria, consistent with section 7 of the Endangered Species Act (ESA). EPA initiated this consultation on January 14, 2008, by submitting a biological evaluation to the NMFS and USFWS, which contained an analysis of the potential effects of EPA’s proposed approval of Oregon’s criteria on
threatened and endangered species in Oregon.\(^1\)

On July 31, 2012, the USFWS provided its biological opinion to EPA. The biological opinion found that EPA’s proposed approval of Oregon’s aquatic life criteria would not jeopardize the continued existence of endangered species for which USFWS was responsible. However, on August 14, 2012, the NMFS concluded in its biological opinion that seven of Oregon’s revised freshwater criteria would jeopardize the continued existence of endangered species in Oregon for which the NMFS was responsible. These seven criteria were the freshwater criteria Oregon adopted to protect aquatic life from adverse acute and chronic effects from ammonia, copper, and aluminum,\(^2\) as well as the criterion to prevent adverse acute effects from cadmium. The NMFS biological opinion contained Reasonable and Prudent Alternatives (RPAs) for each of the four pollutants that would avoid the likelihood of jeopardy to the species. For ammonia, cadmium, and copper using EPA’s 2007 BLM-based aquatic life criteria and for acute and chronic aluminum, the RPA specified a process for deriving revised freshwater criteria. For the chronic ammonia criterion, the RPA specified that Oregon’s previously applicable chronic ammonia criterion, which was based on EPA’s 1985 304(a) recommendation, should remain in place. The NMFS RPA for acute and chronic copper criteria was to establish “a new acute criterion of 2.3 \(\mu g/L\) for freshwater copper using EPA’s 2007 [Biological Load Limit (BLM)]-based aquatic life criteria” and “a new chronic criterion of 1.45 \(\mu g/L\) for freshwater copper using EPA’s 2007 BLM-based aquatic life criteria.” On January 19, 2016 the NMFS sent EPA a letter clarifying that “…use of EPA’s 2007 copper BLM to derive copper criteria that are specific to individual locations or ecoregions is appropriate under the RPA, provided that the state of Oregon has the appropriate data to input into the BLM and appropriate procedures to use the BLM.”

On January 31, 2013, EPA disapproved several of Oregon’s revised aquatic life criteria under CWA 303(c), including the acute cadmium freshwater criterion, and the acute and chronic freshwater ammonia, copper, and aluminum criteria that the NMFS concluded would jeopardize endangered species in Oregon.\(^3\) Oregon made changes to its freshwater ammonia criterion in response to EPA’s 2013 disapproval and submitted revised freshwater ammonia criteria to EPA on January 23, 2015. EPA evaluated the revised freshwater ammonia criteria’s consistency with the RPA for ammonia contained in the 2012 NMFS biological opinion, concluded that the revised criteria would protect endangered species in Oregon, and approved the revised criteria on August 4, 2015. Although Oregon has been working closely with EPA to derive protective freshwater copper criteria that the state would adopt in a future rulemaking, the state has not yet addressed EPA’s 2013 disapproval of its freshwater criteria for cadmium, copper, and aluminum. EPA is proposing the freshwater acute cadmium, and acute and chronic copper criteria in this rule in accordance with CWA section 303(c)(3) and (c)(4) RPA. EPA intends to propose freshwater acute and chronic criteria for aluminum in Oregon in a separate rulemaking at a later date following completion of updates to EPA’s CWA section 304(a) recommended criteria for aluminum.

C. General Recommended Approach for Deriving Aquatic Life Criteria

Under the Agency’s CWA section 304(a) authority, EPA develops methodologies and specific criteria to protect aquatic life and human health. These methodologies and criteria are subject to public as well as scientific expert review before EPA releases them as formal agency recommendations for states to consider when developing and adopting water quality criteria. To derive criteria for the protection of aquatic life, EPA follows its Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses (referred to as the “1985 Guidelines”).\(^4\) These guidelines describe an objective way to estimate the highest concentration of a substance in water that will not present a significant risk to the aquatic organisms in the water.

Numeric criteria derived using EPA’s 1985 Guidelines are expressed as short-term (acute) and long-term (chronic) values. The combination of a criteria maximum concentration (CMC), a one-hour average value, and a criteria continuous concentration (CCC), a four-day average value, protects aquatic life from acute and chronic toxicity, respectively.\(^5\) Neither value is to be exceeded more than once in three years. EPA selected the CMC’s one-hour averaging period because high concentrations of certain pollutants can cause death in one to three hours, and selected the CCC’s four-day averaging period to prevent increased adverse effects on sensitive life stages. EPA based its once every three years exceedance frequency recommendation on the ability of aquatic ecosystems to recover from the exceedances (when the average concentration over the duration of the averaging period is above the CCC or the CMC).\(^6\)

Since fresh and salt waters have different chemical compositions and different species assemblages, it is necessary to derive separate acute and chronic criteria for fresh and salt waters. Additionally, criteria may be based on certain water characteristics (e.g., pH, temperature, hardness, dissolved organic carbon (DOC), etc.), since water chemistry can influence a pollutant’s

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\(^1\) EPA initiated consultation on Oregon’s aluminum criteria based on its mistaken belief that Oregon’s criteria were entirely equivalent to EPA’s 1988 304(a) recommended criteria. However, Oregon’s criteria specified that they applied “to waters with \(pH\) values less than 6.6 and hardness values less than 12 mg/L (as CaCO\(_3\))” whereas EPA’s 1988 304(a) recommended criteria “apply at \(pH\) values of 6.5–9.0.” EPA ultimately disapproved Oregon’s criteria because the state had not supplied a scientific rationale for the difference between Oregon’s statement of the conditions under which the criteria would be valid and EPA’s specified \(pH\) range for the criteria. Since EPA was disapproving the aluminum criteria, it sent a letter to the NMFS and USFWS identifying this change. The USFWS had already completed and transmitted its non–jeopardy letter by that point, so it was too late for EPA to withdraw the consultation request for aluminum. However, in the letter to the NMFS, EPA withdrew its request for consultation on Oregon’s acute and chronic aluminum criteria.

\(^2\) The NMFS acknowledged EPA’s request to withdraw the aluminum criteria from consultation; however, they did not have time to modify the biological opinion to exclude acute and chronic aluminum from the document.

\(^3\) The NMFS determined that the criterion Oregon adopted to protect aquatic life from adverse chronic effects from cadmium would not jeopardize the continued existence of endangered species; EPA approved Oregon’s chronic cadmium criterion in January 2013.


\(^5\) In EPA’s 2001 304(a) recommendation for cadmium and the 2007 304(a) recommendation for copper, EPA specified that the acute cadmium and chronic copper criteria (CMCs) had 24-hour (rather than one-hour) durations. Subsequently, in the 2016 304(a) update for cadmium, EPA revised the cadmium CMC duration to one-hour to reflect the acute criteria duration recommended in the 1985 Guidelines. EPA proposes that the duration for both copper and cadmium CMCs in this rule be one-hour, to be consistent with the updated 304(a) recommendation for cadmium and with EPA’s 1985 Guidelines. As articulated on page 35 of USEPA’s 1991 Technical Support Document for Water Quality-based Toxics Control, March, 1991 (EPA/822/R-91/001), a one-hour averaging period is expected to be fully protective for the fastest-acting toxicants, and even more protective for slower-acting toxicants.

bioavailability and toxicity. For metals in particular, EPA recommends expressing the criteria as functions of chemical constituents of the water, since those constituents can form complexes with metals and render the metals biologically unavailable, or compete with metals for binding sites on aquatic organisms. Additionally, in 1995, EPA recommended that criteria for metals be expressed as dissolved (rather than total) metal concentrations, since the concentration of dissolved metal better approximates the toxic fraction.

The 1985 Guidelines specify that it is necessary to have toxicity test data from a minimum of eight families of aquatic organisms to derive criteria. These families are intended to be representative of a wide spectrum of aquatic life, and act as surrogates for untested species. Therefore, the specific test organisms do not need to be present in the water(s) where the criteria will apply. However, states may develop site-specific criteria using species residing at the site if they maintain similar broad taxonomic representation.

EPA derives acute criteria from 48- to 96-hour tests of lethality or immobilization. EPA derives chronic criteria from longer term (often longer than 28-day) tests that measure survival, growth, or reproduction. If sufficient chronic toxicity data are not available, chronic criteria are set by determining a ratio of acutely toxic to chronically toxic concentrations. Where appropriate, EPA recommends that criteria be lowered to protect commercially or recreationally important species.

For more detailed information on how EPA derives protective aquatic life criteria, see the 1985 Guidelines.

III. Freshwater Cadmium Aquatic Life Criteria

A. EPA’s National Recommended Cadmium Criteria

Water hardness (determined by the presence of calcium and magnesium ions, and expressed as calcium carbonate, CaCO₃) affects the toxicity of cadmium, as calcium and magnesium ions compete with cadmium for binding sites on aquatic organisms’ gills. Organisms show more sensitivity to cadmium in lower hardness (soft) water than in hard water. EPA therefore expresses the national 304(a) recommended acute and chronic cadmium criteria as functions of water hardness.

EPA previously published final 304(a) recommended aquatic life criteria for cadmium in 2001. In recent years, EPA embarked on an update to the science underlying the 2001 national cadmium criteria recommendations. This work included a literature search of toxicological databases, evaluation of those data, recalibration of the criteria based on those data updates, and revision of supporting documentation. In 2013, EPA completed an external peer review of the draft updated cadmium criteria and revised them accordingly. EPA then published the draft criteria for public comment in the Federal Register, and solicited comments for 60 days (December 1, 2015, 80 FR 75097). EPA revised the criteria to respond to the public comments, and expects the final updated 304(a) recommended cadmium criteria to be published in the Federal Register in April 2016.

B. Proposed Acute Cadmium Criterion for Oregon’s Freshwaters

To protect aquatic life in Oregon’s freshwaters from acute toxic effects from cadmium, EPA proposes the one-hour average CMC not exceed \( e^{(0.9789 \times \ln(\text{hardness}) - 3.866) \times \text{CF} (\mu g/L, \text{dissolved})} \) more than once every three years. “CF” refers to the conversion factor and is used to convert the total recoverable concentration to a dissolved concentration, consistent with EPA’s policy on criteria for metals. The equation for the acute cadmium CF is \( \text{CF} = 1.136672 \times (0.641838) \). This is the same freshwater acute cadmium criterion (and associated CF) as in EPA’s final 2016 national updated 304(a) recommended cadmium criteria. The (\ln hardness) term in both the CMC equation and the CF equation is the natural logarithm of the ambient water hardness in mg/L (CaCO₃).

Where site-specific hardness data are unavailable, EPA proposes to use a default hardness concentration of 25 mg/L (as CaCO₃), which equates to a one-hour average dissolved cadmium concentration of 0.49 \( \mu g/L \). As with other metals criteria in Oregon that are expressed as a function of hardness, the acute cadmium criterion equation requires ambient hardness data that represent the entire site to which the criterion will apply to calculate an acute cadmium criterion for a site. However, EPA recognizes that, in certain situations, there will not be sufficiently representative ambient hardness data to adequately characterize the site; thus, EPA is proposing a default hardness concentration to provide clarity to NPDES permit writers and water body assessors on what acute cadmium criterion applies at the site. EPA evaluated the protectiveness of using a default hardness of 25 mg/L by calculating the 10th percentile of existing hardness concentrations in Oregon’s waters, using U.S. Geological Survey (USGS) data on calcium and magnesium ion levels in waters within each of the nine Level III ecoregions in Oregon. EPA selected the 10th percentile as a statistic that is both protective and can be reliably determined from small sample sizes. The USGS dataset that EPA evaluated indicates that the lowest 10th percentile ecoregional hardness in Oregon is 28 mg/L, suggesting that a default hardness concentration of 25 mg/L would be protective of the majority of Oregon’s waters. However, certain water bodies in Oregon, such as relatively un-impacted headwaters, could have hardness concentrations below 25 mg/L, and Oregon should prioritize collecting ambient hardness data in those waters to ensure the resulting acute cadmium criteria are protective of aquatic life.

EPA’s proposal to use a default hardness of 25 mg/L, in the absence of sufficiently representative ambient hardness data should not be confused with use of a low-end hardness floor criteria. See Oregon Department of Environmental Quality. 2014. Methodology for Oregon’s 2012 Water Quality Report and List of Water Quality Limited Waters (Pursuant to Clean Water Act Sections 303(d) and 305(b) and OAR 340-041– 0046), Pages 76–77.

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7 Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States’ Compliance—Revision of Metals Criteria, May 4, 1995, 60 FR 22229.
8 See USEPA, 1985.
11 Oregon currently uses a default hardness concentration of 25 mg/L if no hardness data are available to calculate hardness-dependent metals.
even when ambient data are available measuring hardness below 25 mg/L. Consistent with EPA guidance, a site’s actual ambient water hardness should be used to calculate the criterion when sufficiently representative hardness data are available, even if the hardness is below 25 mg/L.\textsuperscript{13}

In describing potential remedies to address EPA’s January 2013 disapproval, EPA noted that “new scientific data on the toxicity of cadmium are now available and would need to be reviewed regarding their quality and relevance prior to being considered in developing an updated recommendation for a specific numeric criterion protective of Oregon aquatic life.”\textsuperscript{14} EPA’s 2016 section 304(a) recommended cadmium criteria update represents a thorough review and incorporation of the latest scientific data on cadmium toxicity to aquatic life. The updated 304(a) recommended freshwater acute cadmium criterion, which EPA is proposing to apply in Oregon, now incorporates a more robust dataset on cadmium’s acutely toxic effects, and was lowered to protect commercially and recreationally important salmonids, consistent with EPA’s 1985 Guidelines. Additionally, EPA’s proposal of a default hardness value as part of the criterion for Oregon will ensure that protective cadmium criteria can be easily derived for all freshwaters in the state. Therefore, EPA proposes that the 2016 section 304(a) recommended acute cadmium criterion, in combination with a protective hardness default that will apply in the absence of sufficiently representative ambient hardness data, will protect aquatic life in Oregon.

C. Implementation of Proposed Freshwater Acute Cadmium Criterion in Oregon

When calculating a hardness-based criterion value, Oregon should consider the following when defining a site to which the acute cadmium criterion applies: (1) Metals are generally persistent, so calculating the criterion using hardness values from a small site at or near the discharge point could result in a criterion that is not protective of areas that are outside the defined site, and (2) as the size of a site increases, the spatial and temporal variability is likely to increase; thus, more water samples may be required to adequately characterize the entire site.\textsuperscript{15}

Additionally, pursuant to 40 CFR 131.10(b), Oregon must consider downstream WQS when calculating a protective criterion concentration in upstream waters.

When setting Water Quality-Based Effluent Limitations (WQBELs), Oregon should determine the water body’s ambient hardness level under critical conditions (i.e., low hardness) when cadmium toxicity is expected to be higher, such that the resulting cadmium criterion is protective of the entire site at critical and less than critical conditions. EPA’s NPDES Permit Writers’ Manual describes the importance of determining effluent and receiving water critical conditions, because if a discharge is controlled so that it does not cause water quality criteria to be exceeded in the receiving water under critical conditions, then water quality criteria should be attained under all other conditions.\textsuperscript{16} Because organisms are more sensitive to cadmium when corresponding hardness concentrations are low, Oregon should ensure that sufficiently representative ambient hardness data are collected to have confidence that critical conditions in the water body are being adequately captured.

Substantial changes in a site’s ambient hardness will likely affect the resulting acute cadmium criterion at that site. Therefore, EPA recommends that Oregon periodically revisit each water body’s acute cadmium criterion and re-run the equation when changes in water hardness are evident or suspected at a site, and also as additional monitoring data become available.

IV. Freshwater Copper Aquatic Life Criteria

A. EPA’s National Recommended Copper Criteria

In 2007, EPA issued revised section 304(a) national recommended freshwater aquatic life criteria for copper that represent the best available science and understanding of the interaction between water chemistry and copper toxicity.\textsuperscript{17} These criteria recommendations incorporate use of a Biotic Ligand Model (BLM), which is a metal bioavailability model that uses receiving water body characteristics to develop water quality criteria on a site-specific basis. The BLM requires ambient data on ten water body-specific characteristics to calculate a freshwater copper criterion (temperature, pH, dissolved organic carbon (DOC), calcium, magnesium, sodium, potassium, sulfate, chloride, and alkalinity).

Along with the criteria recommendations, EPA released supplementary materials related to using the BLM on a site-specific basis to derive criteria. Training materials that EPA released in 2007 discussed considerations such as collecting sufficiently representative data to account for a site’s spatial and temporal variability, properly defining the site to which the BLM-derived criterion applies, reconciling multiple model runs, and estimating input parameters when site-specific data are lacking.\textsuperscript{18} To address situations where site-specific data are not available for some of the BLM’s ten input variables, EPA published for public comment the Draft Technical Support Document: Recommended Estimates for Missing Water Quality Parameters for Application in EPA’s Biotic Ligand Model (EPA 820–R–16–016) on February 16, 2016 (81 FR 7784).

B. Proposed Acute and Chronic Copper Criteria for Oregon’s Freshwaters

To protect aquatic life in Oregon’s freshwaters, EPA proposes the CMC and CCC based on the 2007 304(a) recommended copper BLM. EPA proposes to express the CMC as a one-hour average dissolved copper concentration (in µg/L) and the CCC as a four-day average dissolved copper concentration (in µg/L), and that the CMC and CCC are not to be exceeded more than once every three years. As with hardness data used to determine the acute cadmium criterion discussed earlier, EPA recommends that Oregon collect ambient data to determine protective copper criteria by site. In the absence of sufficiently representative ambient data to run the BLM, EPA proposes default input values.


\textsuperscript{14} USEPA. 2013. EPA Clean Water Act 303(c) Determinations On Oregon’s New and Revised Aquatic Life Toxic Criteria Submitted on July 8, 2004, and as Amended by Oregon’s April 23, 2007 and July 21, 2011 Submissions. Page 46.


for DOC, calcium, magnesium, sodium, potassium, sulfate, chloride, and alkalinity that are based on the 10th percentile of existing concentrations of these variables in waters within each of Oregon’s Level III ecoregions. If information exists to characterize a water body’s stream order (a measure of the relative size of a stream), EPA proposes to instead use the 10th percentile concentrations by stream order within each of Oregon’s Level III ecoregions. These defaults (by ecoregion and by stream order within each ecoregion) are set forth in Tables 1 and 2 below and are described further in EPA’s Draft Technical Support Document: Recommended Estimates for Missing Water Quality Parameters for Application in EPA’s Biotic Ligand Model which can be found in the record for this rulemaking. Because EPA is proposing default input parameters, protective copper criteria can be easily derived for assessment and permitting purposes (even in the absence of ambient data). EPA solicits comments on the Agency’s proposal to use the 10th percentile of existing concentrations to derive default input parameters. EPA also solicits comments on using default input parameters based on a different percentile, such as the 5th or 25th (or another percentile within that range). Calculations of default input parameters at the 5th and 25th percentiles can also be found in the record for this rulemaking (see Fifth and Twenty-Fifth Percentile Estimates for Copper BLM Input Parameters by Oregon Level III Ecoregion).

Finally, EPA proposes that in order to calculate final acute and chronic copper criteria, Oregon use a value not to exceed the 10th percentile of individual BLM outputs for the site. While the 10th percentile should be protective in a majority of cases, certain circumstances may warrant use of a more stringent BLM output. When 10 or fewer data points are available for a given site, EPA proposes that Oregon use the lowest individual acute and chronic BLM outputs as the final acute and chronic criteria. EPA solicits comment on this approach, as well as alternative percentiles or approaches to reconciling individual copper BLM outputs into final acute and chronic copper criteria values.

EPA’s proposed acute and chronic copper criteria for Oregon’s freshwaters are as follows:

Acute (CMC) and chronic (CCC) freshwater copper criteria shall be developed using EPA’s 2007 Aquatic Life Ambient Freshwater Quality Criteria—Copper (EPA–822–R–07–001), which incorporates use of the copper biotic ligand model (BLM).

Where sufficiently representative ambient data for DOC, calcium, magnesium, sodium, potassium, sulfate, chloride, or alkalinity are not available, the state shall use the 10th percentile estimated values from Table 1 based on the applicable ecoregion (or Table 2, based on the applicable ecoregion and stream order).

The final copper criteria shall be calculated as no greater than the 10th percentile of the distribution of individual BLM outputs at a site. If 10 or fewer BLM outputs are available for a given site, the lowest individual acute and chronic BLM output values shall be used as the final acute and chronic copper criteria for that site.

### Table 1—BLM Default Inputs for Each Level III Ecoregion in Oregon

<table>
<thead>
<tr>
<th>Level III Ecoregion</th>
<th>Calcium (mg/L)</th>
<th>Magnesium (mg/L)</th>
<th>Sodium (mg/L)</th>
<th>Potassium (mg/L)</th>
<th>Chloride (mg/L)</th>
<th>Sulfate (mg/L)</th>
<th>DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Coast Range</td>
<td>8.4</td>
<td>3.2</td>
<td>4.1</td>
<td>0.64</td>
<td>33</td>
<td>3.2</td>
<td>4.8</td>
</tr>
<tr>
<td>9 Eastern Cascades</td>
<td>8.2</td>
<td>2.9</td>
<td>4.4</td>
<td>0.90</td>
<td>30</td>
<td>4.7</td>
<td>3.8</td>
</tr>
<tr>
<td>4 Cascades</td>
<td>6.6</td>
<td>2.9</td>
<td>3.5</td>
<td>0.74</td>
<td>35</td>
<td>2.2</td>
<td>3.2</td>
</tr>
<tr>
<td>12 Snake River Plain</td>
<td>33</td>
<td>10</td>
<td>13</td>
<td>2.3</td>
<td>109</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td>78 Klamath Mountains</td>
<td>8.7</td>
<td>4.6</td>
<td>4.0</td>
<td>0.66</td>
<td>44</td>
<td>2.1</td>
<td>3.5</td>
</tr>
</tbody>
</table>

### Table 2—BLM Default Inputs for Each Stream Order Within Each Level III Ecoregion in Oregon

<table>
<thead>
<tr>
<th>Level III Ecoregion</th>
<th>Stream order</th>
<th>Calcium (mg/L)</th>
<th>Magnesium (mg/L)</th>
<th>Sodium (mg/L)</th>
<th>Potassium (mg/L)</th>
<th>Chloride (mg/L)</th>
<th>Sulfate (mg/L)</th>
<th>DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Coast Range</td>
<td>SO 1–3</td>
<td>6.0</td>
<td>0.8</td>
<td>1.3</td>
<td>0.1</td>
<td>44</td>
<td>0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>12 Snake River Plain</td>
<td>SO 1–3</td>
<td>24.0</td>
<td>9.4</td>
<td>10.2</td>
<td>1.4</td>
<td>127</td>
<td>4.6</td>
<td>11</td>
</tr>
<tr>
<td>78 Klamath Mountains</td>
<td>SO 1–3</td>
<td>7.9</td>
<td>3.2</td>
<td>4.0</td>
<td>0.6</td>
<td>36</td>
<td>2.1</td>
<td>2.4</td>
</tr>
</tbody>
</table>

19EPA is not proposing default input values for the other two BLM inputs, pH and temperature, because pH and temperature are highly variable and routinely monitored. EPA anticipates that sufficiently representative site-specific data will be available for these parameters. Even though EPA is proposing default values for DOC, EPA recommends that Oregon collect site-specific measurements of DOC if possible, because copper toxicity and BLM predictions are highly sensitive to DOC concentrations.

20See USEPA, 2016. EPA’s proposed default inputs are from Tables 4, 8, 9, 10 and 20.
EPA’s 2007 copper BLM represents the latest scientific knowledge on copper speciation and bioavailability. In describing potential remedies to address EPA’s January 2013 disapproval, EPA noted that Oregon could use the 2007 copper BLM. The model provides predictable and repeatable outcomes, and EPA is proposing protective default inputs to use in the absence of site-specific data. EPA proposes that the combination of the 2007 copper BLM and default inputs will protect aquatic life in Oregon.

C. Implementation of Proposed Freshwater Acute and Chronic Copper Criteria in Oregon

EPA’s proposed copper criteria for Oregon will be the first BLM-based criteria in Oregon and, therefore, the state does not have associated implementation methods. EPA strongly recommends that Oregon develop such methods, and give similar consideration to site selection, characterization of critical conditions, and data representativeness, as discussed for cadmium earlier in this proposed rule. Aquatic organisms are more sensitive to copper when corresponding DOC and pH levels in the water are low, so Oregon should ensure that sufficiently representative data are collected for the BLM’s input parameters to have confidence that critical conditions are adequately characterized.

When Oregon derives copper criteria using the BLM, to promote transparency and ensure predictable and repeatable outcomes, EPA recommends that the state make each criterion and the geographic extent of the site to which the criterion applies publicly available on the state’s Web site along with information such as:

1. The number of sampling events used to derive the criterion;
2. Whether the criterion relied on site-specific data, estimated data, or a combination of both; and
3. The date when the criterion was developed.

Finally, as discussed earlier with respect to ambient hardness levels, substantial changes in a site’s water chemistry will likely affect any resulting copper criterion at that site. In addition, with regular monitoring and a robust, site-specific dataset, criteria can be developed that more accurately reflect site conditions and copper bioavailability than criteria set using default values or limited data sets. Therefore, EPA recommends that Oregon periodically revisit its copper criteria and re-run the BLM when changes in water chemistry are evident or suspected at a site, and also as additional monitoring data become available.

D. Ongoing State Efforts To Develop Copper Criteria for Oregon’s Freshwaters

EPA’s proposed methodology for deriving protective acute and chronic copper criteria described in the preceding paragraphs is not necessarily the only scientifically defensible and protective approach, and consistent with 40 CFR 131.11(b)(1)(iii), Oregon has the option to establish criteria based on other scientifically defensible methods. In 2015, the Oregon Department of Environmental Quality (DEQ) conducted an analysis of the copper BLM in preparation for adopting revised copper criteria to address EPA’s 2013 disapproval. DEQ has spent significant time and resources collecting BLM input parameters at 138 locations across the state, as well as evaluating various methods to develop defaults that can be used in the absence of sufficiently representative ambient data. To date, DEQ has generally modeled its approach after the methodology presented in EPA’s Draft Technical Support Document: Recommended Estimates for Missing Water Quality Parameters for Application in EPA’s Biotic Ligand Model (EPA 822–R–15–106), but is considering different data sources and alternative geographic groupings of water bodies. EPA is working closely with DEQ, and will continue to provide input on the state’s copper criteria development efforts.

E. Incorporation by Reference

EPA is proposing that the final EPA rule regulatory text will incorporate one EPA document by reference. In accordance with the requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference EPA’s 2007 Aquatic Life Ambient Freshwater Quality Criteria—Copper (EPA–822–R–07–001), discussed in section IV.A. of this preamble. EPA has made, and will continue to make, this document generally available electronically through www.regulations.gov and/or in hard copy at the appropriate EPA office (see the ADDRESSES section of this preamble for more information).

V. Critical Low-Flows and Mixing Zones

To ensure that the proposed criteria are applied appropriately to protect Oregon’s aquatic life uses, EPA is proposing critical low-flow values for Oregon to use in calculating the available dilution for the purposes of determining the need for and establishing WQBELs in NPDES permits. Dilution is one of the primary mechanisms by which the concentrations of contaminants in effluent discharges are reduced following their introduction into a receiving water. Low flows can exacerbate the effects of effluent discharges because, during a low-flow event, there is less water available for dilution, resulting in higher instream pollutant concentrations. If criteria are implemented using inappropriate critical low-flow values (i.e., values that are too high), the resulting ambient concentrations could exceed criteria when low flows occur.21

EPA’s March 1991 Technical Support Document for Water Quality-based Toxics Control recommends two methods for calculating acceptable critical low-flow values: The traditional hydrologically based method developed by the USGS and a biologically based method developed by EPA.22 The hydrologically based critical low-flow value is determined statistically using probability and extreme values, while the biologically based critical low-flow is determined empirically using the

Table 2—BLM Default Inputs for Each Stream Order Within Each Level III Ecoregion in Oregon—Continued

<table>
<thead>
<tr>
<th>Level III Ecoregion</th>
<th>Stream order</th>
<th>Calcium (mg/L)</th>
<th>Magnesium (mg/L)</th>
<th>Sodium (mg/L)</th>
<th>Potassium (mg/L)</th>
<th>Alkalinity (mg/L)</th>
<th>Chloride (mg/L)</th>
<th>Sulfate (mg/L)</th>
<th>DOC (mg/L)</th>
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<tbody>
<tr>
<td>80 Northern Basin and Range</td>
<td>SO 7–9</td>
<td>6.3</td>
<td>1.1</td>
<td>4.3</td>
<td>2.2</td>
<td>24</td>
<td>0.2</td>
<td>2.5</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>SO 1–3</td>
<td>15</td>
<td>5.7</td>
<td>4.1</td>
<td>0.8</td>
<td>54</td>
<td>2.0</td>
<td>9.3</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>8.9</td>
<td>2.4</td>
<td>7.7</td>
<td>2.1</td>
<td></td>
<td>2.1</td>
<td>5.1</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>15</td>
<td>5.7</td>
<td>4.1</td>
<td>0.8</td>
<td>54</td>
<td>2.0</td>
<td>9.3</td>
<td>1.0</td>
</tr>
</tbody>
</table>


specific duration and frequency associated with the criterion. For the acute cadmium and acute and chronic copper criteria, EPA proposes the following critical low-flow values: Acute Aquatic Life (CMC): 1Q10 or 1B3 Chronic Aquatic Life (CCC): 7Q10 or 4B3

Using the hydrologically based method, the 1Q10 represents the lowest one-day average flow event expected to occur once every ten years, on average, and the 7Q10 represents the lowest seven-consecutive-day average flow event expected to occur once every ten years, on average. Using the biologically based method, 1B3 represents the lowest one-day average flow event expected to occur once every three years, on average, and 4B3 represents the lowest four-consecutive-day average flow event expected to occur once every three years, on average.23

The criteria in this proposed rule, once finalized, would apply at the point of discharge unless Oregon authorizes a mixing zone. Where Oregon authorizes a mixing zone, the criteria would apply at the locations allowed by the mixing zone (i.e., the CCC would apply at the defined boundary of the chronic mixing zone and the CMC would apply at the defined boundary of the acute mixing zone).24

VI. Endangered Species Act

As noted earlier in this proposed rule, the NMFS’s 2012 biological opinion concluded that the acute cadmium and acute and chronic copper criteria that Oregon adopted in 2004 would jeopardize the continued existence of endangered species in Oregon. The opinion also contained RPAs for cadmium and copper that would avoid the likelihood of jeopardy to endangered species in Oregon. EPA will continue to work closely with the NMFS to ensure that the acute cadmium criterion that EPA ultimately finalizes is protective of federally listed species in Oregon. For copper, the NMFS further clarified in January 2016 that adoption of EPA’s 2007 copper BLM, which EPA is proposing in this rule, would be consistent with the 2012 RPA.

VII. Under what conditions will Federal standards be not promulgated or withdrawn?

Under the CWA, Congress gave states primary responsibility for developing and adopting WQS for their waters (CWA section 303(a)–(c)). Although EPA is proposing cadmium and copper aquatic life criteria for Oregon’s freshwaters to remedy EPA’s 2013 disapproval, Oregon continues to have the option to adopt and submit to EPA acute cadmium and acute and chronic copper criteria for the state’s freshwaters consistent with CWA section 303(c) and EPA’s implementing regulations at 40 CFR part 131. EPA encourages Oregon to expeditiously adopt protective aquatic life criteria. Consistent with CWA section 303(c)(4), if Oregon adopts and submits cadmium and/or copper aquatic life criteria, and EPA approves such criteria before finalizing this proposed rule, EPA would not proceed with the promulgation for those waters and/or pollutants for which EPA approves Oregon’s criteria.

If EPA finalizes this proposed rule, and Oregon subsequently adopts and submits cadmium and/or copper aquatic life criteria, EPA proposes that once EPA approves Oregon’s WQS, the EPA-approved criteria in Oregon’s WQS would become the applicable criteria for CWA purposes and EPA’s promulgated criteria would no longer be applicable criteria. EPA would undertake a rulemaking to withdraw the federal criteria for cadmium and/or copper, but that process would not delay Oregon’s approved criteria from becoming the sole applicable criteria for CWA purposes.

VIII. Alternative Regulatory Approaches and Implementation Mechanisms

Oregon will have considerable discretion to implement these aquatic life criteria, once finalized, through various water quality control programs. Among other things, EPA’s regulations: (1) Specify how states and authorized tribes establish, modify or remove designated uses, (2) specify the requirements for establishing criteria to protect designated uses, including criteria modified to reflect site-specific conditions, (3) authorize states and authorized tribes to adopt WQS variances to provide time to achieve the applicable WQS, and (4) allow states and authorized tribes to include compliance schedules in NPDES permits. Each of these approaches are discussed in more detail below.

A. Designating Uses

EPA’s proposed cadmium and copper criteria apply to freshwaters in Oregon where the protection of fish and aquatic life is a designated use (see Oregon Administrative Rules at 340–041–8033, Table 30). The federal regulations at 40 CFR 131.10 provide information on establishing, modifying, and removing designated uses. If Oregon removes designated uses such that no fish or aquatic life uses apply to any particular water body affected by this rule and adopts the highest attainable use,25 and EPA finds that removal to be consistent with CWA section 303(c) and the implementing regulations at 40 CFR part 131, then the federal cadmium and copper aquatic life criteria would no longer apply to that water body. Instead, any criteria associated with the newly designated highest attainable use would apply to that water body.

B. Site-Specific Criteria

The regulations at 40 CFR 131.11 specify requirements for modifying water quality criteria to reflect site-specific conditions. In the context of this rulemaking, a site-specific criterion (SSC) is an alternative value to the federal freshwater cadmium or copper aquatic life criteria that would be applied on a watershed, area-wide, or water body-specific basis that meets the regulatory test of protecting the designated use, being scientifically defensible, and ensuring the protection and maintenance of downstream WQS. A SSC may be more or less stringent than the otherwise applicable federal criteria. A SSC may be appropriate when further scientific data and analyses can bring added precision to express the concentration of cadmium and/or copper that protects the aquatic life-related designated use in a particular water body.

C. Variances

40 CFR part 131 defines WQS variances at § 131.3(o) as time-limited designated uses and supporting criteria for a specific pollutant(s) or water quality parameter(s) that reflect the highest attainable conditions during the term of the WQS variance. WQS variances adopted in accordance with 40 CFR part 131 allow states and authorized tribes to address water quality challenges in a transparent and predictable way. Variances help states and authorized tribes focus on making incremental progress in improving water quality, rather than pursuing a downgrade of the underlying water quality goals through a designated use change, when the current designated use is difficult to attain. Oregon has
sufficient authority to use variances when implementing the criteria, as long as such variances are adopted consistent with 40 CFR 131.14. Oregon may use its currently EPA-approved variance procedures with respect to a temporary modification of its uses as it pertains to any federal criteria (see OAR 340–041–0059) when adopting such variances.

D. Compliance Schedules
EPA’s regulations at 40 CFR 122.47 and 40 CFR 131.15 allow states and authorized tribes to include permit compliance schedules in their NPDES permits if dischargers need additional time to meet their WQBELs based on the applicable WQS. EPA’s updated regulations at 40 CFR part 131 also include provisions authorizing the use of permit compliance schedules to ensure that a decision to allow permit compliance schedules includes public engagement and transparency (80 FR 51022, August 21, 2015). Oregon already has an EPA-approved regulation authorizing the use of permit compliance schedules (see OAR 340–041–0061), consistent with 40 CFR 131.15. That state regulation is not affected by this rule, and Oregon is authorized to grant compliance schedules, as appropriate, based on the federal criteria.

IX. Economic Analysis
EPA’s proposed cadmium and copper criteria may serve as a basis for development of NPDES permit limits. Oregon has NPDES permitting authority, and retains considerable discretion in implementing standards. EPA evaluated the potential costs to NPDES dischargers associated with state implementation of EPA’s proposed criteria. This analysis is documented in Economic Analysis for the Proposed Rule: Aquatic Life Criteria for Copper and Cadmium in Oregon, which can be found in the record for this rulemaking.

Any NPDES-permitted facility that discharges cadmium or copper in Oregon could potentially incur compliance costs. The types of affected facilities could include industrial facilities and POTWs discharging treated wastewater to surface waters (i.e., point sources). EPA expects that dischargers would use similar process and treatment controls to come into compliance with the proposed cadmium and copper criteria as they would to comply with Oregon’s existing aquatic life criteria for cadmium and copper (i.e., “baseline criteria”). EPA estimates the incremental impacts of the proposed rule against a baseline of full implementation of currently approved criteria.

For this analysis, EPA did not estimate the potential for costs to stormwater or nonpoint sources such as agricultural runoff. EPA recognizes that Oregon may require controls for nonpoint sources. However, it is difficult to model and evaluate the potential cost impacts of this rule to those sources because they are intermittent, variable, and occur under hydrologic or climatic conditions associated with precipitation events. Also, baseline total maximum daily loads (TMDLs) for waters with baseline impairment for cadmium or copper have not yet been developed. Therefore, determining which waters would not achieve standards based on the proposed aquatic life criteria after complying with existing (baseline) regulations and policies may not be possible.

A. Identifying Affected Entities
For economic analysis purposes, EPA developed hypothetical applications of the proposed cadmium and copper criteria using conservative estimates for hardness and the BLM inputs, respectively. The criteria that EPA derived for the cost analysis would likely be different from and possibly lower (more stringent) than the actual criteria applications that Oregon would derive using ambient data from each water body. As described earlier in this proposed rule, EPA recommends that Oregon collect sufficiently representative ambient data to derive the most accurate and protective cadmium and copper aquatic life criteria.

Using the criteria derived for the cost analysis, EPA identified 10 point source facilities that could potentially be affected by the rule—all are major dischargers. Major facilities are typically those that discharge more than 1 million gallons per day (mgd). Of these potentially affected facilities, 7 are POTWs and 3 are industrial dischargers. EPA did not include facilities covered by general permits in its analysis because data for such facilities are limited, and loads are usually much lower. EPA did not have cadmium or copper effluent data to evaluate minor facilities for this preliminary analysis.

B. Method for Estimating Costs
EPA estimated costs for the 10 potentially affected facilities. EPA evaluated existing baseline permit conditions, reasonable potential to exceed estimates of the aquatic life criteria based on the proposed rule, and potential to exceed projected effluent limitations based on available effluent monitoring data. In instances of exceedances of projected effluent limitations under the proposed criteria, EPA determined the likely compliance scenarios and costs. Only compliance actions and costs that would be needed above the baseline level of controls are attributable to the proposed rule.

EPA assumed that dischargers would pursue the least cost means of compliance with WQBELs. Incremental compliance actions attributable to the proposed rule may include pollution prevention, end-of-pipe treatment, and alternative compliance mechanisms (e.g., variances). EPA annualized capital costs over an assumed technology lifespan of 20 years, adding recurring Operation & Maintenance costs, and discounted using 3% and 7% discount rates to obtain total annual costs per facility.

C. Results
Based on the results for 10 facilities, EPA estimated a total incremental annual cost attributable to the proposed criteria of approximately $0.1 million to $18.2 million at a 3% discount rate.26 The low end of the range reflects the assumption that achieving very low copper limits is infeasible (e.g., available treatment technologies cannot consistently achieve the limits) and dischargers will need to apply for variances. The high end of the range reflects the assumption that dischargers can achieve the projected effluent limits through end-of-pipe treatment. All of the incremental costs are attributable to municipal and industrial dischargers for treatment of copper. There was no reasonable potential to exceed the proposed acute cadmium criterion.

If the revised criteria result in an incremental increase in impaired waters, resulting in the need for TMDL development, there could also be some costs to nonpoint sources of metals. Using available ambient monitoring data, EPA compared cadmium and copper concentrations to the baseline and proposed criteria, identifying waterbodies that may be incrementally impaired (i.e., impaired under the proposed criteria but not under the baseline). Baseline impairment ranged from 8 to 46 stations, depending on whether EPA used impaired water body information from 2010 or 2012. Using available monitoring data, EPA identified copper impairments at 82 monitoring stations based on the proposed criteria. Therefore, water quality data indicate potential for incremental impairment at 36 to 74 stations. This increase suggests that

26 The estimated costs using a 7% discount rate range from $0.1 million to $22.6 million.
nonpoint sources may bear some compliance costs, although data are not available to estimate the magnitude of these costs. If the net increase in
stations (36 to 74) is an indication of the potential increase in the number of
TMDLs, then the costs for TMDL development could range from
approximately $1.3 million (36 TMDLs × $37,000) to $3.0 million (74 TMDLs ×
$40,000) 27. The control of nonpoint
sources such as in the context of a
TMDL could result in less stringent
requirements, and thus lower costs, for
point sources.

X. Statutory and Executive Order
Reviews

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

This action is not a significant regulatory action and was therefore not
submitted to the Office of Management and
Budget (OMB) for review. The
proposed rule does not establish any
requirements directly applicable to
regulated entities or other sources of
toxic pollutants. However, these WQS
may serve as a basis for development of
NPDES permit limits. Oregon has
NPDES permitting authority, and retains
considerable discretion in implementing
standards. In the spirit of Executive
Order 12866, EPA evaluated the
potential costs to NPDES dischargers
associated with state implementation of
EPA’s proposed criteria. This analysis,
Economic Analysis for the Proposed
Rule: Aquatic Life Criteria for Copper
and Cadmium in Oregon, is summarized in
section IX of the preamble and is
available in the docket.

B. Paperwork Reduction Act

This action does not impose an
information collection burden under the
PRA. While actions to implement these
WQS could entail additional paperwork
burden, this action does not directly
contain any information collection,
reporting, or record-keeping
requirements.

C. Regulatory Flexibility Act

I certify that this action will not have a
significant economic impact on a
substantial number of small entities
under the RFA. This action will not
impose any requirements on small
entities. Small entities, such as small
businesses or small governmental
jurisdictions, are not directly regulated
by this rule.

D. Unfunded Mandates Reform Act

This action does not contain any
unfunded mandate as described in
UMRA, 2 U.S.C. 1531–1538, and does
not significantly or uniquely affect small
governments. As these water quality
criteria are not self-implementing, the
action imposes no enforceable duty on
any state, local or tribal governments or
the private sector.

E. Executive Order 13132 (Federalism)

This action does not have federalism
implications. It will not have substantial
direct effects on the states, on the
relationship between the national
government and the states, or on the
distribution of power and
responsibilities among the various
levels of government. This rule does not
alter Oregon’s considerable discretion in
implementing these WQS, nor would it
preclude Oregon from adopting WQS
that meet the requirements of the CWA,
either before or after promulgation of
the final rule, which would eliminate
the need for federal standards upon EPA
approval. Thus, Executive Order 13132
does not apply to this action.

In the spirit of Executive Order 13132 and
consistent with EPA policy to
promote communications between EPA
and state and local governments, EPA
specifically solicits comments on this
proposed action from state and local
officials.

F. Executive Order 13175 (Consultation
and Coordination With Indian Tribal
Governments)

This action does not have tribal
implications as specified in Executive
Order 13175. This proposed rule does
not impose substantial direct
compliance costs on federally
recognized tribal governments, nor does
it substantially affect the relationship
between the federal government and
tribes, or the distribution of power and
responsibilities between the federal
government and tribes. Thus, Executive
Order 13175 does not apply to this
action.

Many tribes in the Pacific Northwest
hold reserved rights to take fish for
subsistence, ceremonial, religious, and
commercial purposes. EPA developed
the criteria in this proposed rule to
protect aquatic life in Oregon from the
effects of exposure to harmful levels of
cadmium and copper. Protecting the
health of fish in Oregon will, therefore,
support tribal reserved fishing rights,
including treaty-reserved rights, where
such rights apply in waters under state
jurisdiction.

Consistent with the EPA Policy on
Consultation and Coordination with
Indian Tribes, EPA consulted with tribal
officials during the development of this
action. On November 23, 2015, EPA sent
a letter to tribal leaders in Oregon
offering to consult on the proposed
cadmium and copper criteria in this
rule. On December 15, 2015, EPA held
a conference call with tribal water
quality technical contacts to explain
EPA’s proposed action and timeline.
Formal consultation on the proposed
action was not requested by any of the
tribes. EPA will continue to
communicate with the tribes prior to its
final action.

G. Executive Order 13045 (Protection
of Children From Environmental Health
and Safety Risks)

EPA interprets Executive Order 13045
as applying only to those regulatory
actions that concern environmental
health or safety risks that EPA has
reason to believe may
disproportionately affect children, per
the definition of “covered regulatory
action” in section 2–202 of the
Executive Order. This action is not
subject to Executive Order 13045
because it does not concern an
environmental health risk or safety risk.

H. Executive Order 13211 (Actions That
Significantly Affect Energy Supply,
Distribution, or Use)

This action is not subject to Executive
Order 13211, because it is not a
significant regulatory action under
Executive Order 12866.

I. National Technology Transfer and
Advancement Act of 1995

This proposed rulemaking does not
involve technical standards.

J. Executive Order 12898 (Federal
Actions To Address Environmental
Justice in Minority Populations and
Low-Income Populations)

The human health or environmental
risk addressed by this action will not
have potential disproportionately high and
adverse human health or
environmental effects on minority, low-
income or indigenous populations. The
criteria in this proposed rule will
support the health and abundance of
aquatic life in Oregon, and will
therefore benefit all communities that
rely on Oregon’s ecosystems.

List of Subjects in 40 CFR Part 131

Environmental protection, Indians—
lands, Incorporation by reference,
Intergovernmental relations, Reporting
and recordkeeping requirements, Water
pollution control.
Dated: March 31, 2016.

Gina McCarthy, Administrator:

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

Subpart D—Federally Promulgated Water Quality Standards

■ 2. Add § 131.46 to read as follows:

§ 131.46 Aquatic Life Criteria for Copper and Cadmium in Oregon.

(a) Scope. This section promulgates aquatic life criteria for cadmium and copper in freshwaters in Oregon.

(b) Criteria for cadmium and copper in Oregon. The aquatic life criteria in Table 1 apply to all freshwaters in Oregon where fish and aquatic life are designated uses.

---

TABLE 1—PROPOSED CADMIUM AND COPPER AQUATIC LIFE CRITERIA FOR OREGON FRESHWATERS

<table>
<thead>
<tr>
<th>Metal</th>
<th>CAS No.</th>
<th>Criterion Maximum Concentration (CMC) 3 (µg/L)</th>
<th>Criterion Continuous Concentration (CCC) 4 (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadmium 1 2</td>
<td>7440439</td>
<td>[3.866 × ((ln hardness) − 3.866)] × CF</td>
<td>[CF = 1.136672 − ([(ln hardness) × (0.041838)]]</td>
</tr>
<tr>
<td>Copper 1</td>
<td>7440508</td>
<td>Acute (CMC) and chronic (CCC) freshwater copper criteria shall be developed using EPA’s 2007 Aquatic Life Ambient Freshwater Quality Criteria—Copper (EPA—822–R–07–001), which incorporates use of the copper biotic ligand model (BLM). Where sufficiently representative ambient data for DOC, calcium, magnesium, sodium, potassium, sulfate, chloride, or alkalinity are not available, the state shall use the 10th percentile estimated values from Table 2 of paragraph (c) of this section based on the applicable ecoregion (or Table 3 of paragraph (c) of this section, based on the applicable ecoregion and stream order). The final copper criteria shall be calculated as no greater than the 10th percentile of the distribution of individual BLM outputs at a site. If 10 or fewer BLM outputs are available for a given site, the lowest individual acute and chronic BLM output values shall be used as the final acute and chronic copper criteria for that site.</td>
<td></td>
</tr>
</tbody>
</table>

1 The criteria for cadmium and copper are expressed as dissolved metal concentrations.
2 CF is the conversion factor used to convert between the total recoverable and dissolved forms of cadmium. The term (ln hardness) in the CMC and the CF equation is the natural logarithm of the ambient hardness in mg/L (CaCO3). A default hardness concentration of 25 mg/L shall be used to calculate cadmium criteria in the absence of sufficiently representative ambient hardness data. A hardness concentration of 25 mg/L equates to a one-hour average dissolved cadmium concentration of 0.49 µg/L.
3 The CMC is the highest allowable one-hour average instream concentration of cadmium or copper. The CCC is not to be exceeded more than once every three years. The CCC is rounded to two significant figures.
4 The CCC is the highest allowable four-hour average instream concentration of copper. The CCC is not to be exceeded more than once every three years. The CCC is rounded to two significant figures.

(c) Estimated Values to Derive Copper Criteria. The default inputs to calculate copper criteria using the BLM in the absence of sufficiently representative ambient data are shown in Tables 2 and 3.

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TABLE 2—BLM DEFAULT INPUTS FOR EACH LEVEL III ECOREGION IN OREGON

<table>
<thead>
<tr>
<th>Level III Ecoregion</th>
<th>Calcium (mg/L)</th>
<th>Magnesium (mg/L)</th>
<th>Sodium (mg/L)</th>
<th>Potassium (mg/L)</th>
<th>Alkalinity (mg/L)</th>
<th>Chloride (mg/L)</th>
<th>Sulfate (mg/L)</th>
<th>DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Coast Range</td>
<td>8.4</td>
<td>3.2</td>
<td>4.1</td>
<td>0.64</td>
<td>33</td>
<td>3.2</td>
<td>4.8</td>
<td>0.7</td>
</tr>
<tr>
<td>3 Willamette Valley</td>
<td>8.2</td>
<td>2.9</td>
<td>4.4</td>
<td>0.90</td>
<td>30</td>
<td>4.7</td>
<td>3.8</td>
<td>0.4</td>
</tr>
<tr>
<td>4 Cascades</td>
<td>6.6</td>
<td>2.9</td>
<td>3.5</td>
<td>0.74</td>
<td>35</td>
<td>2.2</td>
<td>3.2</td>
<td>0.3</td>
</tr>
<tr>
<td>9 Eastern Cascades</td>
<td>8.2</td>
<td>3.8</td>
<td>6.0</td>
<td>1.0</td>
<td>44</td>
<td>3.2</td>
<td>5.0</td>
<td>0.5</td>
</tr>
<tr>
<td>10 Columbia Plateau</td>
<td>15</td>
<td>5.2</td>
<td>9.3</td>
<td>1.8</td>
<td>40</td>
<td>3.3</td>
<td>10</td>
<td>1.0</td>
</tr>
<tr>
<td>11 Blue Mountains</td>
<td>11</td>
<td>3.9</td>
<td>7.7</td>
<td>1.4</td>
<td>49</td>
<td>3.3</td>
<td>7.1</td>
<td>0.8</td>
</tr>
<tr>
<td>12 Snake River Plain</td>
<td>33</td>
<td>10</td>
<td>13</td>
<td>2.3</td>
<td>109</td>
<td>10</td>
<td>22</td>
<td>1.2</td>
</tr>
<tr>
<td>78 Klamath Mountains</td>
<td>8.7</td>
<td>4.6</td>
<td>4.0</td>
<td>0.66</td>
<td>44</td>
<td>2.1</td>
<td>3.5</td>
<td>0.6</td>
</tr>
<tr>
<td>80 Northern Basin and Range</td>
<td>26</td>
<td>8.2</td>
<td>20</td>
<td>2.7</td>
<td>89</td>
<td>15</td>
<td>24</td>
<td>1.0</td>
</tr>
</tbody>
</table>

---

TABLE 3—BLM DEFAULT INPUTS FOR EACH STREAM ORDER WITHIN EACH LEVEL III ECOREGION IN OREGON

<table>
<thead>
<tr>
<th>Level III Ecoregion</th>
<th>Stream order</th>
<th>Calcium (mg/L)</th>
<th>Magnesium (mg/L)</th>
<th>Sodium (mg/L)</th>
<th>Potassium (mg/L)</th>
<th>Alkalinity (mg/L)</th>
<th>Chloride (mg/L)</th>
<th>Sulfate (mg/L)</th>
<th>DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Coast Range</td>
<td>SO 1–3</td>
<td>6.0</td>
<td>0.8</td>
<td>1.3</td>
<td>0.1</td>
<td>44</td>
<td>0.6</td>
<td>1.1</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>3.6</td>
<td>1.0</td>
<td>2.0</td>
<td>0.2</td>
<td>15</td>
<td>1.6</td>
<td>2.2</td>
<td>0.7</td>
</tr>
<tr>
<td>3 Willamette Valley</td>
<td>SO 7–9</td>
<td>12</td>
<td>3.4</td>
<td>4.3</td>
<td>0.8</td>
<td>56</td>
<td>2.3</td>
<td>6.3</td>
<td>0.7</td>
</tr>
<tr>
<td>4 Cascades</td>
<td>SO 1–3</td>
<td>9.9</td>
<td>3.8</td>
<td>5.6</td>
<td>1.5</td>
<td>29</td>
<td>4.6</td>
<td>2.8</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>7.1</td>
<td>2.5</td>
<td>4.3</td>
<td>0.8</td>
<td>29</td>
<td>4.6</td>
<td>2.8</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>5.0</td>
<td>1.6</td>
<td>3.4</td>
<td>0.6</td>
<td>20</td>
<td>2.7</td>
<td>2.3</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>1.0</td>
<td>0.2</td>
<td>1.8</td>
<td>0.2</td>
<td>0.0</td>
<td>0.5</td>
<td>0.2</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>3.5</td>
<td>1.0</td>
<td>2.8</td>
<td>0.4</td>
<td>16</td>
<td>0.8</td>
<td>0.8</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>13</td>
<td>3.6</td>
<td>3.7</td>
<td>0.9</td>
<td>52</td>
<td>1.7</td>
<td>6.9</td>
<td>0.3</td>
</tr>
</tbody>
</table>
### TABLE 3—BLM DEFAULT INPUTS FOR EACH STREAM ORDER WITHIN EACH LEVEL III ECOREGION IN OREGON—Continued

<table>
<thead>
<tr>
<th>Level III Ecoregion</th>
<th>Stream order</th>
<th>Calcium (mg/L)</th>
<th>Magnesium (mg/L)</th>
<th>Sodium (mg/L)</th>
<th>Potassium (mg/L)</th>
<th>Alkalinity (mg/L)</th>
<th>Chloride (mg/L)</th>
<th>Sulfate (mg/L)</th>
<th>DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 Eastern Cascades Slopes and Foothills</td>
<td>SO 1–3</td>
<td>4.4</td>
<td>0.9</td>
<td>2.3</td>
<td>0.4</td>
<td>35</td>
<td>0.2</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>5.5</td>
<td>0.8</td>
<td>2.4</td>
<td>0.5</td>
<td>22</td>
<td>0.9</td>
<td>2.2</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>24.0</td>
<td>9.4</td>
<td>10.2</td>
<td>1.4</td>
<td>127</td>
<td>4.6</td>
<td>11</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>8.6</td>
<td>3.2</td>
<td>4.0</td>
<td>0.9</td>
<td>33</td>
<td>1.4</td>
<td>3.1</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>5.7</td>
<td>1.5</td>
<td>2.0</td>
<td>0.7</td>
<td>16</td>
<td>0.8</td>
<td>4.2</td>
<td>1.0</td>
</tr>
<tr>
<td>10 Columbia Plateau</td>
<td>SO 1–3</td>
<td>8.6</td>
<td>3.2</td>
<td></td>
<td></td>
<td></td>
<td>169</td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>3.7</td>
<td>0.8</td>
<td>1.6</td>
<td>0.7</td>
<td>16</td>
<td>0.3</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>8.5</td>
<td>1.5</td>
<td>3.3</td>
<td>0.7</td>
<td>32</td>
<td>0.8</td>
<td>5.0</td>
<td>0.8</td>
</tr>
<tr>
<td>11 Blue Mountains</td>
<td>SO 1–3</td>
<td>13</td>
<td>2.0</td>
<td>6.1</td>
<td>0.8</td>
<td>35</td>
<td>1.4</td>
<td>3.7</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>13</td>
<td>2.5</td>
<td>4.9</td>
<td>1.2</td>
<td>40</td>
<td>2.2</td>
<td>3.8</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>37</td>
<td>10</td>
<td>13</td>
<td>2.5</td>
<td>122</td>
<td>11</td>
<td>30</td>
<td>1.2</td>
</tr>
<tr>
<td>12 Snake River Plain</td>
<td>SO 1–3</td>
<td>13</td>
<td>2.0</td>
<td>6.1</td>
<td>0.8</td>
<td>35</td>
<td>1.4</td>
<td>3.7</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>13</td>
<td>2.5</td>
<td>4.9</td>
<td>1.2</td>
<td>40</td>
<td>2.2</td>
<td>3.8</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>37</td>
<td>10</td>
<td>13</td>
<td>2.5</td>
<td>122</td>
<td>11</td>
<td>30</td>
<td>1.2</td>
</tr>
<tr>
<td>78 Klamath Mountains</td>
<td>SO 1–3</td>
<td>6.3</td>
<td>1.1</td>
<td>4.3</td>
<td>2.2</td>
<td>24</td>
<td>0.2</td>
<td>2.5</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>SO 4–6</td>
<td>15</td>
<td>5.7</td>
<td>4.1</td>
<td>0.8</td>
<td>54</td>
<td>2.0</td>
<td>9.3</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>SO 7–9</td>
<td>8.9</td>
<td>2.4</td>
<td>7.7</td>
<td>2.1</td>
<td></td>
<td>2.1</td>
<td>5.1</td>
<td>1.0</td>
</tr>
</tbody>
</table>

(d) **Applicability.** (1) The criteria in paragraph (b) of this section are the applicable acute cadmium and acute and chronic copper aquatic life criteria in all freshwaters in Oregon where fish and aquatic life are a designated use. After the effective date of this rule, in cases where EPA determines that state cadmium or copper aquatic life criteria meet the requirements of Clean Water Act section 303(c) and 40 CFR part 131, Oregon’s cadmium or copper criteria will apply rather than the criteria in paragraph (b) of this section.

(2) The criteria established in this section are subject to Oregon’s general rules of applicability in the same way and to the same extent as are other federally promulgated and state-adopted numeric criteria when applied to freshwaters in Oregon where fish and aquatic life are a designated use.

(i) For all waters with mixing zone regulations or implementation procedures, the criteria apply at the appropriate locations within or at the boundary of the mixing zones; otherwise the criteria apply throughout the water body including at the end of any discharge pipe, conveyance or other discharge point.

(ii) The state shall not use a low flow value that is less stringent than the values listed below for waters suitable for the establishment of low flow return frequencies (i.e., streams and rivers) when calculating the available dilution for the purposes of determining the need for and establishing Water Quality-Based Effluent Limitations in National Pollutant Discharge Elimination System permits:

<table>
<thead>
<tr>
<th>Acute criteria (CMC)</th>
<th>1Q10 or 1B3.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic criteria (CCC)</td>
<td>7Q10 or 4B3.</td>
</tr>
</tbody>
</table>

Where:

1. **1Q10** is the lowest one-day average flow event expected to occur once every ten years, on average (determined hydrologically).
2. **1B3** is the lowest one-day average flow event expected to occur once every three years, on average (determined biologically).
3. **7Q10** is the lowest seven-consecutive-day average flow event expected to occur once every ten years, on average (determined hydrologically).
4. **4B3** is the lowest four-consecutive-day average flow event expected to occur once every three years, on average (determined biologically).
DEPARTMENT OF AGRICULTURE
Forest Service
Forest Resource Coordinating Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Forest Resource Coordinating Committee (Committee) will meet in Washington, DC. The Committee is authorized under section 8005 of the Food, Conservation, and Energy Act of 2008 (the Act) (Pub. L. 110–246). Additional information concerning the Committee, including the meeting agenda, supporting documents and minutes, can be found by visiting the Committee’s Web site at http://www.fs.fed.us/spf/coop/frcc/.

DATES: The meeting will be held on the following dates:
1. May 25, 2016, from 8:00 a.m. to 5:00 p.m. Eastern Daylight Time (EDT); and
2. May 26, 2016, from 8:00 a.m. to 5:00 p.m. EDT.

The meeting is 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 at the USDA Forest Service, Sidney R. Yates Building, Pinchot Conference Room, 201 14th Street SW., Washington, DC. Members of the public should RSVP to facilitate entry into the Yates Building.

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 placed on the Committee’s Web site listed above.

FOR FURTHER INFORMATION CONTACT: Andrea Bedell-Loucks, Designated Federal Officer, by phone at 202–205–1190; or Lori McKean, Committee Coordinator, by phone at 570–296–9672.

Individuals who use telecommunication devices for the deaf (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. Learn how to frame recommendations;
2. Hear about Office of Sustainability & Climate Changes’ State & Private Forestry Climate Change Performance Scorecard; and
3. Refine outreach strategies to key partners.

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 submit a request in writing by May 13, 2016, 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 May 1, 2016. Written comments and time requests for oral comments must be sent to Andrea Bedell-Loucks, 1400 Independence Avenue SW., Mailstop 1123, Washington, DC 20250; or by email to abloucks@fs.fed.us. A summary of the meeting will be posted on the Committee’s Web site listed above within 21 days after the meeting.

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 accommodations. For access to the facility or proceedings, please contact the person listed under the FOR FURTHER INFORMATION CONTACT.

Dated: April 11, 2016.

James E. Hubbard,
Deputy Chief, State and Private Forestry.
[FR Doc. 2016–08805 Filed 4–15–16; 8:45 am]
BILLING CODE 3411–15–P

Federal Register
Vol. 81, No. 74
Monday, April 18, 2016

DEPARTMENT OF AGRICULTURE
Rural Utilities Service
Announcement of Grant Application Deadlines and Funding Levels

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Funds Availability (NOFA).

SUMMARY: The Rural Utilities Service (RUS), an agency of the United States Department of Agriculture (USDA), herein referred to as RUS or the Agency, announces its Community Connect Grant Program application window for Fiscal Year (FY) 2016. This notice is being issued in order to allow potential applicants time to submit proposals and give the Agency time to process applications within the current fiscal year.

In addition to announcing the application window, RUS announces the minimum and maximum amounts for Community Connect grants applicable for the fiscal year. The Community Connect Grant Program regulation can be found at 7 CFR part 1739 (Subpart A).

DATES: Submit completed paper or electronic applications for grants according to the following deadlines:

• Paper submissions: Paper submissions must be postmarked and mailed, shipped, or sent overnight no later than June 17, 2016 to be eligible for FY 2016 grant funding. Late or incomplete applications will not be eligible for FY 2016 grant funding.

• Electronic submissions: Electronic submissions must be received no later than June 17, 2016 to be eligible for FY 2016 grant funding. Late or incomplete applications will not be eligible for FY 2016 grant funding.

If the submission deadline falls on Saturday, Sunday, or a Federal holiday, the application is due the next business day.

ADDRESSES: Copies of the FY 2016 Application Guide and materials for the Community Connect Grant Program may be obtained through:


Completed applications may be submitted the following ways:
and practical applications of the new broadband service, based on the criteria contained in the Rural Utilities Service (RUS).

Overview

Federal Agency: Rural Utilities Service (RUS).
Funding Opportunity Title: Community Connect Grant Program.
Announcement Type: Initial announcement.
Catalog of Domestic Assistance (CFDA) Number: 10.863.
Dates: Submit completed paper or electronic applications for grants according to the deadlines indicated in Section D(5).

A. Program Description

The purpose of the Community Connect Grant Program is to provide financial assistance in the form of grants to eligible applicants that will provide broadband service to currently unserved, lower-income, and extremely rural areas. This broadband service is intended to foster economic growth and deliver enhanced educational, health care, and public safety services on a community-oriented connectivity basis. RUS will give priority to rural areas that have the greatest need for broadband services, based on the criteria contained herein.

Grant authority will be used for the deployment of broadband service to extremely rural, lower-income communities on a community-oriented connectivity basis. By cultivating the deployment of new broadband services, the community-oriented connectivity concept will stimulate innovative uses and practical applications of the new broadband facilities in order to improve economic development and provide enhanced educational and health care opportunities in rural areas. Such an approach will also give rural communities the opportunity to benefit from the advanced technologies necessary to achieve these goals. The regulation for the Community Connect Program can be found at 7 CFR part 1739 (Subpart A).

As in years past, the FY 2016 Community Connect Grant Application Guide has been updated based on program experience. All applicants should carefully review and prepare their applications according to instructions in the FY 2016 Application Guide and sample materials. Expenses incurred in developing applications will be at the applicant’s own risk.

B. Federal Award Information

$11,740,000 is available for grants. Under 7 CFR 1739.2, the Administrator established a minimum grant amount of $100,000 and a maximum grant amount of $3,000,000 for FY 2016.

The standard grant agreement, which specifies the term of each award, is available at http://www.rd.usda.gov/files/UTP_CommConnectGrantAgreement.pdf. The Agency will make awards, and successful applicants will be required to execute documents appropriate to the project before the Agency will advance funding.

While prior Community Connect grants cannot be renewed, existing Community Connect awardees may submit applications for new projects, which the Agency will evaluate as new applications. All grant applications must be submitted during the application window.

C. Eligibility Information

1. Eligible Applicants (See 7 CFR 1739.10)

   a. Only entities legally organized as one of the following are eligible for Community Connect Grant Program financial assistance:
      i. An incorporated organization;
      ii. An Indian tribe or tribal organization, as defined in 25 U.S.C. 450b;
      iii. A state or local unit of government; or
      iv. A cooperative, private corporation, or limited liability company organized on a for-profit or not-for-profit basis.

   b. Applicants must have the legal capacity and authority to enter into contracts, to comply with applicable federal statutes and regulations, and to own and operate the broadband facilities as proposed in their application.

   c. Applicants must have an active registration with current information in the System for Award Management (SAM) (previously the Central Contractor Register (CCR)) at https://www.sam.gov and have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number. Further information regarding SAM registration and DUNS number acquisition can be found in Sections D(3) and D(4) of this Notice.

2. Ineligible Applicants

   a. Individuals and partnerships are not eligible for financial assistance.

   b. Corporations that have been convicted of a Federal felony within the past 24 months are not eligible. Any corporation that has been assessed to have any unpaid federal tax liability, for which all judicial and administrative remedies have been exhausted or have lapsed and is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible for financial assistance.

   c. In accordance with the Consolidated Appropriations Act, 2016, Sections 743–4, an entity that requires employees or contractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information is not eligible for financial assistance.

3. Cost Sharing or Matching


   a. Grant applicants must demonstrate matching contributions in cash of at least fifteen percent (15%) of the total amount of financial assistance requested. Matching contributions must be used for eligible purposes of Community Connect grant assistance, as discussed in 7 CFR 1739.12, 7 CFR 1739.13, and Section D(6) of this Notice for more information.

   b. Applications that do not provide sufficient documentation of the required fifteen percent match will be declared ineligible.
4. Other

Eligible projects must propose to fulfill the following requirements (see 7 CFR 1739.11 for more information): a. Minimum Broadband Service Requirements. Until otherwise revised in the Federal Register, for applications in FY 2016, to qualify as Broadband Service, the minimum rate-of-data transmission is four megabits per second downstream plus one megarbit per second upstream for both fixed and mobile broadband service.

b. Minimum Broadband Grant Speed. The minimum bandwidth that an applicant must propose to deliver to every customer in the proposed funded service area is ten megabits downstream and one megarbit upstream for both fixed and mobile service to the customer.

c. Rural Area. A Rural Area refers to any area, as confirmed by the most recent decennial Census of the United States, which is not located within:

| 1. A city, town, or incorporated area that has a population of greater than 20,000 inhabitants; or |
| 2. An urbanized area contiguous and adjacent to a city or town that has a population of greater than 50,000 inhabitants. For purpouses of the definition of Rural Area, an urbanized area means a densely populated territory as defined in the most recent decennial Census. |
| 3. A contiguous geographic area within an eligible Rural Area or eligible Rural Areas, in which Broadband Service does not currently exist, and where the applicant proposes to offer service at the Broadband Grant Speed to all residential and business customers. A PFSA must not overlap with the Service Areas of current RUS borrowers and grantees. |

d. Proposed Funded Service Area (PFSA). Applicants must propose a contiguous geographic area within an eligible Rural Area or eligible Rural Areas, in which Broadband Service does not currently exist, and where the applicant proposes to offer service at the Broadband Grant Speed to all residential and business customers. A PFSA must not overlap with the Service Areas of current RUS borrowers and grantees.

e. Critical Community Facilities. Applicants must propose to offer service, free of charge to users, at the Broadband Grant Speed to all Critical Community Facilities located within the Proposed Funded Service Area for at least two (2) years.

f. Community Center. Applicants must propose to provide a Community Center with at least two (2) Computer Access Points and wireless access at the Broadband Grant Speed free of charge to users for at least two (2) years.

D. Application and Submission Information

The FY 2016 Application Guide provides specific detailed instructions for each item in a complete application. The Agency emphasizes the importance of including every required item and strongly encourages applicants to follow the instructions carefully, using the examples and illustrations in the FY 2016 Application Guide. Applications submitted by the application deadline, but have critical missing items will be returned as ineligible. The Agency will not solicit or consider scoring or eligibility information that is submitted after the application deadline. However, depending on the specific scoring criteria, applications that do not include all items necessary for scoring may still be eligible applications, but may not receive full or any credit if the information cannot be verified. See the FY 2016 Application Guide for a full discussion of each required item. For requirements of completed grant applications, refer to 7 CFR 1739.15.

1. Address To Request Application Package

The FY 2016 Application Guide, copies of necessary forms and samples,
<table>
<thead>
<tr>
<th>Application Item</th>
<th>Regulation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>L. Compliance with Other Statutes and Regulations</td>
<td>7 CFR part 15 (Subpart A)</td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970.</td>
<td>7 CFR part 3017</td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Debarment, Suspension, and Other Responsibility Matters.</td>
<td>7 CFR part 3018</td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Lobbying for Contracts, Grants, Loans, and Cooperative Agreements.</td>
<td>7 CFR 1970</td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Drug-Free Workplace</td>
<td></td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Architectural Barriers</td>
<td></td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
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<tr>
<td>Flood Hazard Area Precautions</td>
<td></td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Non-Duplication of Services</td>
<td></td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Federally Collection Policies for Commercial Debt</td>
<td></td>
<td>Form provided in FY 2016 Application Tool Kit.</td>
</tr>
<tr>
<td>Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.</td>
<td></td>
<td>Form provided in FY 2016 Application Tool Kit (corporate applicants—only).</td>
</tr>
</tbody>
</table>

e. Number of copies of submitted applications.
   i. Applications submitted on paper.
      Submit the original application and two (2) copies to RUS.
   ii. Applications submitted electronically. Submit the electronic application once. Carefully read the FY 2016 Application Guide for guidance on submitting an electronic application. Applicants should identify and number each page in the same manner as the paper application.

3. Dun and Bradstreet Universal Numbering System (DUNS) Number
   The applicant for a grant must supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number as part of the application. The Standard Form 424 (SF-424) contains a field for the DUNS number. The applicant can obtain the DUNS number free of charge by calling Dun and Bradstreet. Go to http://fedgov.dnb.com/webform for more information on DUNS number acquisition or confirmation.

4. System for Award Management (SAM)
   Prior to submitting a paper or an electronic application, the applicant must register in the System for Award Management (SAM) at https://www.sam.gov/portal/public/SAM/. Throughout the RUS application review and the active Federal grant funding period, SAM registration must be active with current data at all times. To maintain active SAM registration, the applicant must review and update the information in the SAM database annually from the date of initial registration or from the date of the last update. The applicant must ensure that the information in the database is current, accurate, and complete.

5. Submission Dates and Times
   a. Paper applications must be postmarked and mailed, shipped, or sent overnight no later than June 17, 2016 to be eligible for FY 2016 grant funding. Late applications, applications which do not include proof of mailing or shipping, and incomplete applications are not eligible for FY 2016 grant funding. If the submission deadline falls on Saturday, Sunday, or a Federal holiday, the application is due the next business day. In the event of an incomplete application, the Agency will notify the applicant in writing, return the application, and terminate all further action.
      i. Address paper applications to the Administrator, Office of Loan Programs, U.S. Department of Agriculture, 1400 Independence Ave. SW., Room 2808, STOP 1597, Washington, DC 20250–1597. Applications should be marked, “Attention: Deputy Assistant Administrator, Office of Loan Origination and Approval.”
      ii. Paper applications must show proof of mailing or shipping by the deadline consisting of one of the following:
         A. A legibly dated U.S. Postal Service (USPS) postmark;
         B. A legible mail receipt with the date of mailing stamped by the USPS; or
         C. A dated shipping label, invoice, or receipt from a commercial carrier.
   iii. Due to screening procedures at the U.S. Department of Agriculture, packages arriving via regular mail through the USPS are irradiated, which can damage the contents and delay delivery to the Community Connect Program. RUS encourages applicants to consider the impact of this procedure in selecting their application delivery method.
   iv. RUS encourages applicants who wish to apply through Grants.gov to submit their applications in advance of the deadline.
   v. If system errors or technical difficulties occur, use the customer support resources available at the Grants.gov Web site.

6. Funding Restrictions
   a. Eligible grant purposes.
      Grant funds may be used to finance:
      i. The construction, acquisition, or leasing of facilities, including spectrum, land or buildings to deploy service at the Broadband Grant Speed to all participating Critical Community Facilities and all required facilities needed to offer such service to all residential and business customers...
located within the Proposed Funded Service Area; ii. The improvement, expansion, construction, or acquisition of a Community Center that furnishes free internet access at the Broadband Grant Speed and provision of Computer Access Points. Grant funds provided for such costs shall not exceed the lesser of ten percent (10%) of the grant amount requested or $150,000; and iii. The cost of bandwidth to provide service free of charge at the Broadband Grant Speed to Critical Community Facilities for the first two (2) years of operation.

b. Ineligible grant purposes. Grant funds may not be used to finance:
   i. The duplication of any existing Broadband Service provided by another entity;
   ii. Operating expenses other than the cost of bandwidth for two (2) years to provide service at the Broadband Grant Speed to Critical Community Facilities; or
   iii. Any other operating expenses not specifically permitted in 7 CFR 1739.12.

c. Other. For more information, see 7 CFR 1739.3 for definitions, 7 CFR 1739.12 for eligible grant purposes, and 7 CFR 1739.13 for ineligible grant purposes.

E. Application Review Information

1. Criteria

   a. Needs Category. An analysis of the challenges of the following criteria, laid out on a community-wide basis, and how the project proposes to address these issues (up to 50 points):
      i. Economic characteristics;
      ii. Educational challenges;
      iii. Health care needs; and
      iv. Public safety issues.

   b. Stakeholder Involvement Category. The extent of the Project’s planning, development, and support from local residents, institutions, and Critical Community Facilities (up to 40 points);

   c. Experience Category. The level of experience and past success of broadband systems operation for the management team (up to 10 points);

   d. Special Consideration Areas Category. In accordance with 7 CFR 1739.1(a), applicants may receive special consideration if they submit documentation demonstrating that they will provide broadband service within the following areas (15 points):
      i. Tribal jurisdiction or trust areas,
      ii. Promise Zone (for further information, see the Promise Zone Web site at http://www.hud.gov/promisezones/), or

   e. In making a final selection among and between applications with comparable rankings and geographic distribution, the Administrator may take into consideration the characteristics of the Proposed Funded Service Area (PFSA), as identified in 7 CFR 1739.17(d).

2. Review and Selection Process

   a. Successful applications.

   b. Applications conforming with this
   c. Other. For more information, see 7 CFR 1739.3 for definitions, 7 CFR 1739.12 for eligible grant purposes, and 7 CFR 1739.13 for ineligible grant purposes.

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2. Review and Selection Process

   a. Successful applications.

   b. Applications conforming with this
Recipients of Community Connect Grant Program financial assistance must provide annual performance activity reports to RUS until the project is complete and the funds are expended. A final performance report is also required; the final report may serve as the last annual report. The final report must include an evaluation of the success of the project in meeting the Community Connect Grant Program objectives. See 7 CFR 1739.19 and 2 CFR 200.328 for additional information on these reporting requirements.

3. Reporting
   a. Performance reporting. All recipients of Community Connect Grant Program financial assistance must provide annual performance activity reports to RUS until the project is complete and the funds are expended. A final performance report is also required; the final report may serve as the last annual report. The final report must include an evaluation of the success of the project in meeting the Community Connect Grant Program objectives. See 7 CFR 1739.19 and 2 CFR 200.328 for additional information on these reporting requirements.
   b. Financial reporting. All recipients of Community Connect Grant Program financial assistance must provide an annual audit, beginning with the first year in which a portion of the financial assistance is expended. Audits are governed by United States Department of Agriculture audit regulations. See 7 CFR 1739.20 and 2 CFR part 200 (Subpart F) for a description of the financial reporting requirements.
   c. Recipient and Sub-recipient Reporting. The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR part 170. The reporting requirements under the Transparency Act pursuant to 2 CFR 170 are as follows:
      1. First Tier Sub-Awards of $25,000 or more (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to https://www.fsrs.gov no later than the end of the month following the month the obligation was made. Please note that currently underway is a consolidation of eight federal procurement systems, including the Federal Sub-award Reporting System (FSRS), into one system, the System for Award Management (SAM). As a result, the FSRS will soon be consolidated into and accessed through https://www.sam.gov/portal/public/SAM/. The Total Compensation of the Recipient’s Executives (the five most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to https://www.sam.gov/portal/public/SAM/ by the end of the month following the month in which the award was made.
      2. The Total Compensation of the Sub-recipient’s Executives (the five most highly compensated executives) must be reported by the Sub-recipient (if the Sub-recipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the sub-award was made.
      3. Record Keeping and Accounting. The contract will contain provisions related to record keeping and accounting requirements.

G. Federal Awarding Agency Contacts
   1. Web site: http://www.rd.usda.gov/programs-services/community-connect-grants. This site maintains up-to-date resources and contact information for the Community Connect Grant Program.
   4. Email: community.connect@wdc.usda.gov.
   5. Main Point of Contact: Shawn Arner, Deputy Assistant Administrator, Office of Loan Origination and Approval, Rural Utilities Service, U.S. Department of Agriculture.

H. Other Information
   1. USDA Non-Discrimination Statement
      USDA prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual’s income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by USDA. (Not all prohibited bases will apply to all programs and/or employment activities.)

   2. How to File a Complaint
      a. Equal Employment Opportunity Complaint. Individuals who wish to file an employment complaint must contact their Agency’s EEO Counselor within 45 days of the date of the alleged discriminatory act, event, or in the case of a personnel action. Additional information can be found online at http://www.ascr.usda.gov/complaint_filing_file.html.
      b. Program Discrimination Complaint. Individuals who wish to file a Program Discrimination Complaint must complete the USDA Program Discrimination Complaint Form (PDF), found online at http://www.ascr.usda.gov/complaint_filing_cust.html or at any USDA office, or call (866) 632–9992 to request the form. A letter may also be written containing all of the information requested in the form. Send the completed complaint form or letter by mail to the U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442, or email at program.intake@usda.gov.

3. Persons With Disabilities
   Individuals who are deaf, hard of hearing, or have speech disabilities and wish to file either an EEO or program complaint may contact USDA through the Federal Relay Service at (800) 877–8339 (English) or (800) 845–6136 (Spanish).

   Persons with disabilities who wish to file a program complaint, please see information above on how to contact USDA by mail or email. Individuals who require alternative means of communication for program information (e.g., Braille, large print, audiotape, etc.) may contact USDA’s TARGET Center at 202–720–2600 (voice and TDD).

   Dated: March 21, 2016.

Joshua Cohen
Deputy Administrator, Rural Utilities Service.
[PR Doc. 2016–08931 Filed 4–15–16; 8:45 am]

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the California State Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of public meeting.

DATES: Wednesday, June 1, 2016, 12:00 p.m.–1:00 p.m. (Pacific Time).

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the California State Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Pacific Time) Wednesday, June 1, 2016, for the purpose of considering the Committee’s report on voting integrity in California. This meeting is available to the public through the following toll-free call-in number: 888–427–9419; when
COMMISSION ON CIVIL RIGHTS
Public Meeting of the Hawai‘i State Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of Public Meeting.

DATES: Monday, May 23, 2016, 2:00–3:00 p.m. (UTC–10).

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Hawai‘i State Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Hawaiian Time) Monday, May 23, 2016, for the purpose of considering new topics for the Hawai‘i State Advisory Committee’s new project for FY 2016.

This meeting is available to the public through the following toll-free call-in number: 888–428–9473; when prompted, please provide conference ID number: 1594001.

Persons wishing to email their comments may do so by sending them to Angela French-Bell, Regional Director, Western Regional Office, at abell@usccr.gov.

Persons wishing to email their comments may do so by sending them to Angela French-Bell, Regional Director, Western Regional Office, at abell@usccr.gov.

FOR FURTHER INFORMATION CONTACT: Angela French-Bell, DFO, at (213) 894–3437 or abell@usccr.gov.

Dated April 12, 2016.
David Mussatt,
Chief, Regional Programs Coordination Unit.

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS
Notice of Public Meeting of the Alaska State Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of public meeting.


Time: 12:00 p.m.—1:00 p.m. (Alaska Time).

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Alaska Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Alaska Time) Wednesday, April 27, 2016, and Monday, May 16, 2016 for the purpose of considering and voting upon new topics for the Alaska Advisory Committee’s new project for FY 2016.

FOR FURTHER INFORMATION CONTACT: Angela French-Bell, DFO, at (213) 894–3437 or abell@usccr.gov.
These meetings are available to the public through the following toll-free call-in numbers: April 27, 2016: 888–417–8465; when prompted, please provide conference ID number: 7924734. May 16, 2016: 888–556–4997; when prompted, please provide conference ID number: 4783937. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number.

Persons with hearing impairments may follow the proceedings by dialing the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting. Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments within thirty (30) days of the meeting. The comments must be received in the Western Regional Office of the Commission by Friday, May 27, 2016, and Thursday, June 16, 2016, respectively. The address is Western Regional Office, U.S. Commission on Civil Rights, 300 N. Los Angeles Street, Suite 1010, Los Angeles, CA 90012.

Persons wishing to email their comments may do so by sending them to Angela French-Bell, Regional Director, Western Regional Office, at abell@usccr.gov.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at the Commission’s Web site, http://www.usccr.gov, or by clicking on the “Meeting Details” and “Documents” links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission’s Web site, www.usccr.gov, or to contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at https://database.faca.gov/committee/meetings.aspx?cid=264 and clicking on the “Meeting Details” and “Documents” links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission’s Web site, www.usccr.gov, or to contact the Rocky Mountain Regional Office at (303) 866–1040.

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the New Mexico Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the New Mexico Advisory Committee to the Commission will convene at 10:00 a.m. (MDT) on Thursday, May 5, 2016, via teleconference. The purpose of the meeting is to review progress of planning for briefing meeting on the approved project Elder Abuse. The committee will also discuss if there is a need to establish subcommittees.

Members of the public may listen to the discussion by dialing the following conference call toll-free number: 1–888–452–4023; Conference ID: 4078555. Please be advised that before being placed into the conference call, the operator will ask callers to provide their names, their organizational affiliations (if any), and an email address (if available) prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free phone number.

Persons with hearing impairments may also follow the discussion by calling the Federal Relay Service (FRS) at 1–800–977–8339 and provide the FRS operator with the conference call toll-free number: 1–888–452–4023; Conference ID: 4078555. Members of the public are invited to submit written comments; the comments must be received in the regional office by Monday, April 25, 2016. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80224, faxed to (303) 866–1050, or emailed to Evelyn Bohor at ebohor@usccr.gov. Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Agenda For May 16, 2016:

I. Introductory Remarks
II. Vote on Proposal
III. Public Comment
IV. Adjournment

FOR FURTHER INFORMATION CONTACT:
Angela French-Bell, DFO, at (213) 894–3437 or abell@usccr.gov.

Dated: April 12, 2016.

David Mussatt,
Chief, Regional Programs Coordination Unit.

BILLING CODE 6335–01–P
DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–85–2015]

Foreign-Trade Zone (FTZ) 20—Newport News, Virginia; Authorization of Proposed Production Activity, Canon Virginia, Inc., Subzone 20D, (Toner Cartridges and Bottles); Newport News, Virginia


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 (80 FR 220, January 5, 2016). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board’s regulations, including Section 400.14.

Dated: April 12, 2016.

Andrew McGilvray,
Executive Secretary.

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Denying Export Privileges

In the Matter of: Paweena Pechner, a/k/a Paweena Montasood, 399 Maplewood Avenue, Portsmouth, NH 03801

Respondent. CheapShop4You LLC, 399 Maplewood Avenue, Portsmouth, NH 03801

Related Person:

A. Denial of Export Privileges of Paweena Pechner

On July 17, 2014, in the U.S. District Court for the District of New Hampshire, Paweena Pechner, a/k/a Paweena Montasood (“Pechner”), was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (“AECA”). Specifically, Pechner knowingly and willfully caused to be exported from the United States to Thailand firearms which were designated as defense articles on the United States Munitions List, without having obtained from the United States Department of State a license or written approval for the export of these defense articles. Pechner was sentenced to probation for two years, assessed a penalty of $600, and fined $3,000.

Section 766.25 of the Export Administration Regulations (“EAR” or “Regulations”)1 provides, in pertinent part, that “[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the EAA, the EAR, of any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)); or section 38 of the Arms Export Control Act (22 U.S.C. 2778).” 15 CFR 766.25(a); see also Section 11(h) of the EAA, 50 U.S.C. 4610(h). The denial of export privileges under this provision may be for a period of up to ten (10) years from the date of the conviction. 15 CFR 766.25(d); see also 50 U.S.C. 4610(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security’s Office of Exporter Services may revoke any Bureau of Industry and Security (“BIS”) licenses previously issued in which the person had an interest at the time of her conviction.

BIS received notice of Pechner’s conviction for violating the AECA, and has provided notice and an opportunity for Pechner to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS received a submission from Pechner. Based upon my review and consideration of that submission, and consultations with BIS’s Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Pechner’s export privileges under the Regulations for a period of ten (10) years from the date of Pechner’s conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Pechner had an interest at the time of her conviction.

B. Denial of Export Privileges of Related Person CheapShop4You LLC

Pursuant to Sections 766.25(h) and 766.23 of the Regulations, the Director of BIS’s Office of Exporter Services, in consultation with the Director of BIS’s Office of Export Enforcement, may, in order to prevent evasion of a denial order, make a denial order applicable not only to the respondent, but also to other persons related to the respondent by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business.

As provided in Section 766.23 of the Regulations, BIS gave notice to CheapShop4You LLC (“CheapShop4You”) that its export privileges under the Regulations could be denied for up to ten (10) years due to its relationship with Pechner and that BIS believed that naming CheapShop4You as a person related to Pechner would be necessary to prevent evasion of a denial order imposed against Pechner. In providing such notice, BIS gave CheapShop4You an opportunity to oppose its addition to the Pechner Denial Order as a related party.

Having received and reviewed a submission from Pechner, I have decided, following consideration of that

B. Carrying on negotiations

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of a Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by a Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby a Denied Person acquires or attempts to acquire such ownership, possession, or control; or

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from a Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from a Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by a Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by a Denied Person, if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, in addition to the Related Person named above, after notice and opportunity for comment as provided in section 766.23 of the Regulations, any individual, firm, corporation, or other association or organization or other person related to a Denied Person by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order if necessary to prevent evasion of this Order.

Fourth, in accordance with Part 756 and Section 766.25 of the Regulations, Pechner may file an appeal of the issuance of this Order against her with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, in accordance with Part 756 and Section 766.23(c) of the Regulations, CheapShop4You may file an appeal of its naming as a related person in this Order with the Under Secretary of Commerce for Industry and Security. This appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Sixth, a copy of this Order shall be provided to Pechner and CheapShop4You. This Order shall be published in the Federal Register.

Seventh, this Order is effectively immediately and shall remain in effect until July 17, 2024.

Issued this 11th day of April, 2016.

Karen H. Nies-Vogel,
Director, Office of Exporter Services.

BUREAU OF INDUSTRY AND SECURITY

DEPARTMENT OF COMMERCE

Order Denying Export Privileges


On May 7, 2015, in the U.S. District Court for the Eastern District of Pennsylvania, Alexandre Astakhov (“Astakhov”), was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (“AECA”). Specifically, Astakhov knowingly and willfully attempted to export from the United States to Russia, and aided and abetted the attempted export of, defense articles, that is two L–3 CNVD–T thermal clip-on night vision devices, which were designated as a defense article on the United States Munitions List, without having first obtained from the Department of State a license for such export or written authorization for such export. Astakhov was sentenced to 39 months of imprisonment, three years of supervised release, 150 hours of community service, a criminal fine of $2,500 and a $200 assessment.

Section 766.25 of the Export Administration Regulations (“EAR” or “Regulations”)1 provides, in pertinent part:

part, that “[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the Export Administration Act (“EAA”), the EAR, or any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. 2778).” 15 CFR 766.25(a); see also Section 11(h) of the EAA, 50 U.S.C. 4610(h). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d); see also 50 U.S.C. 4610(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security’s Office of Exporter Services may revoke any Bureau of Industry and Security (“BIS”) licenses previously issued in which the person had an interest in at the time of her conviction.

BIS has received notice of Astakhov’s conviction for violating the AECA, and has provided notice and an opportunity for Astakhov to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has received a submission from Astakhov.

Based upon my review and consultations with BIS’s Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Astakhov’s export privileges under the Regulations for a period of 10 years from the date of Astakhov’s conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Astakhov had an interest at the time of her conviction.

Accordingly, it is hereby ORDERED:

First, from the date of this Order until May 7, 2025, Alexandre Astakhov, with a last known address of Register Number: 68614–066, USP Lewisburg, U.S. Penitentiary, Federal Prison Camp, P.O. Box 2000, Lewisburg, PA 17837, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (the “Denied Person”), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as “item”) exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;
B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or
C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;
B. Take any action that facilitates the acquisition of or attempted acquisition by the Denied Person of the ownership, possession, control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;
C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;
D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or
E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Astakhov by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Astakhov may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to the Astakhov. This Order shall be published in the Federal Register.

Sixth, this Order is effective immediately and shall remain in effect until May 7, 2025.

Issued this 11 day of April 2016.

Karen H. Nies-Vogel, Director, Office of Exporter Services.

[FR Doc. 2016–08919 Filed 4–15–16; 8:45 am]
BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

Calcium Hypochlorite From the People’s Republic of China: Rescission of Countervailing Duty Administrative Review; 2014–2015

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

SUMMARY: The Department of Commerce (“the Department”) is rescinding the administrative review of the countervailing duty order on calcium hypochlorite from the People’s Republic of China (“PRC”) for May 27, 2014 through December 31, 2015.

DATES: Effective: April 18, 2016.

FOR FURTHER INFORMATION CONTACT: Katie Marksberry, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–7906.

SUPPLEMENTARY INFORMATION:
administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: April 11, 2016.

Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–08907 Filed 4–15–16; 8:45 am]
BILLING CODE 3510–05–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–844]

Narrow Woven Ribbons With Woven Selvedge From Taiwan; Final Results of Antidumping Duty Administrative Review; 2013–2014

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

SUMMARY: On October 7, 2015, the Department of Commerce (the Department) published the Preliminary Results of the fourth administrative review of the antidumping duty (AD) order on narrow woven ribbons with woven selvedge (NWR) from Taiwan. The review covers two producers/exporters of the subject merchandise, Roung Shu Industry Corporation (Roung Shu) and A-Madeus Textile Ltd. (A-Madeus). The period of review (POR) is September 1, 2013, through August 31, 2014. We gave interested parties an opportunity to comment on the Preliminary Results and, based upon our analysis of the comments, we continue to find that sales of subject merchandise to the United States have been made at prices below normal value (NV). The final dumping margins for the reviewed companies are listed below in the

DATE: Effective Date: April 18, 2016.

FOR FURTHER INFORMATION CONTACT: David Crespo or Alice Maldonado, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3693 and (202) 482–4682, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 2015, the Department published the Preliminary Results in the Federal Register. In November 2015, we received a case brief from A-Madeus and a rebuttal brief from the petitioners. On February 3, 2016, the Department postponed the final results by 60 days. The Department conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise subject to this order covers narrow woven ribbons with woven selvedge. The merchandise subject to this order is classifiable under the harmonized tariff schedule of the United States (HTSUS) statistical categories 5806.32.1020; 5806.32.1030; 5806.32.1050 and 5806.32.1060. Subject merchandise also may enter under subheadings 5806.31.00; 5806.32.20; 5806.39.20; 5806.39.30; 5808.90.00; 5810.91.00; 5810.99.00; 5903.90.10; 5903.90.25; 5907.00.60; and 5907.00.80 and under statistical categories 5806.32.1080; 5810.92.9080; 5806.32.1050 and 5806.32.1060.

The petitioners in this case are Berwick Offray LLC and its wholly-owned subsidiary, Lion Ribbon Company, Inc. See the February 3, 2016, memorandum to Gary Taverner, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations through Melissa G. Skinner, Director, Office II from David Crespo, Senior International Trade Compliance Analyst, entitled “Narrow Woven Ribbons With Woven Selvedge from Taiwan: Extension of Deadline for Final Results of Antidumping Duty Administrative Review.”

On January 27, 2016, the Department exercised its discretion to toll all administrative deadlines due to the recent closure of the Federal Government. All deadlines in this segment of the proceeding have been extended by four business days. Therefore, the revised deadline for the final results of this review is now April 11, 2016. See Memorandum to the Record from Ron Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, entitled, “Tolling of Administrative Deadlines as a Result of the Government Closure during Snowstorm “Jonas”” (January 27, 2016).

Changes Since the Preliminary Results

Based on a review of the record and our analysis of the comments received, we made no changes to the margin calculations for Roung Shu or to the rate assigned to A-Madeus in these final results. For further discussion, see the Issues and Decision Memorandum.

Period of Review

The POR is September 1, 2013, through August 31, 2014.

Final Results of the Review

We are assigning the following weighted-average dumping margins to the firms listed below:

<table>
<thead>
<tr>
<th>Producer/exporter</th>
<th>Dumping margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-Madeus Textile Ltd</td>
<td>30.64</td>
</tr>
<tr>
<td>Roung Shu Industry Corporation</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), the Department has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise and deposits of estimated duties, where applicable, in accordance with the final results of this review. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review.

Pursuant to the Final Modification for Reviews,7 because Roung Shu’s weighted-average dumping margin is zero, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties,9 pursuant to 19 CFR 351.106(o)(2).

For A-Madeus, we will base the assessment rate assigned to the corresponding entries on the margin listed above, using the same methodology stated in the Preliminary Results.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for Roung Shu and A-Madeus will be equal to the dumping margins established in the final results of this administrative review (except, if the rate is zero or de minimis, a zero cash deposit rate will be required for that company); (2) for merchandise exported by manufacturers or exporters not covered in this administrative 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; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 4.37 percent, the all-others rate determined in the LTFV investigation.9 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 the Secretary’s presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of 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.

This notice is published in accordance with section 751(a)(1) and 777(i)(1) of the Act.

Dated: April 11, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Issues and Decision Memorandum

1. Summary
2. Background
3. Margin Calculations
4. Scope of the Order
5. Discussion of the Issues
   a. The Assigned Rate to A-Madeus
   b. Recommendation

[FR Doc. 2016–08904 Filed 4–15–16; 8:45 am]

BILLING CODE 3510–DS–P

7 See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification, 77 FR 8101 [February 14, 2012] (Final Modification for Reviews).

8 Id., 77 FR at 8102.

9 See Order, 75 FR 56985.
DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
RIN 0648–XE565
Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice; availability of permit application and request for comment.

SUMMARY: Notice is hereby given that NMFS has received an update to an application for a direct take permit, in the form of a Hatchery and Genetic Management Plan (HGMP), from the Chelan County Public Utility District (PUD) pursuant to the Endangered Species Act (ESA). The HGMP specifies the operation of a portion of a hatchery program rearing salmon in the Methow Basin within the State of Washington. This document serves to notify the public of the availability of the update to the existing permit application for comment prior to a decision by NMFS whether to issue the permit for the proposed hatchery program. NMFS also notifies the public of the intention to issue a separate ESA permit to the Confederated Tribes and Bands of the Yakama Nation for operation of a component of the program described in the application update.

DATES: Comments must be received at the appropriate address or email mailbox (see ADDRESSES) no later than 5 p.m. Pacific time on May 18, 2016.

ADDRESSES: Written comments on the application should be addressed to the NMFS Sustainable Fisheries Division, 1201 NE. Lloyd Boulevard, Suite 1100, Portland, OR 97232, or faxed to 503–872–2737. Comments may be submitted by email. The mailbox address for providing email comments is: ChelanPlan.wcr@noaa.gov. Include in the subject line of the email comment the following identifier: Comments on Chelan’s 2016 Methow Hatchery Plan. The HGMP is available on the Internet at www.westcoast.fisheries.noaa.gov.

FOR FURTHER INFORMATION CONTACT: Charlene Hurst, at phone number: (503) 230–5409, or via email: charlene.n.hurst@noaa.gov.

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Steelhead (O. mykiss): Threatened, naturally produced and artificially propagated Upper Columbia River.

Chinook salmon (Oncorhynchus tshawytscha): Endangered, naturally produced and artificially propagated Upper Columbia River.

Background

Section 9 of the ESA and Federal regulations prohibit the “taking” of a species listed as endangered or threatened. The term “taking” is defined under the ESA to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS may issue permits to take listed species for any act otherwise prohibited by section 9 for scientific purposes or to enhance the propagation or survival of the affected species under section 10(a)(1)(A) of the ESA. NMFS regulations governing permits for threatened and endangered species are promulgated at 50 CFR 222.307.

The Methow spring Chinook hatchery program is an ongoing hatchery program designed to meet conservation and mitigation responsibilities related to impacts from development in the Methow and Columbia River basins. On November 13, 2012, NMFS received an ESA section 10(a)(1)(A) permit application from the Douglas and Grant County PUDs and the Washington Department of Fish and Wildlife (WDFW) for the Methow spring Chinook hatchery program. The permit application was in the form of an HGMP and was made available for public comment on December 10, 2013 (78 FR 74116).

On March 29, 2016, the Chelan County PUD submitted an HGMP updating a portion of the original permit application. The HGMP includes a gene flow management plan, a reduction in the number of juveniles released, and a description of an additional remote acclimation/release site. A separate section 10(a)(1)(A) permit would be issued to the Confederated Tribes and Bands of the Yakama Nation for operation of this additional remote acclimation/release site, as described in the Chelan County PUD HGMP.

Authority

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the permit application, associated documents, and comments submitted thereon to determine whether the application meets the requirements of section 10(a)(1)(A) of the ESA. If it is determined that the requirements are met, permits will be issued to WDFW, the PUDs, and the Confederated Tribes and Bands of the Yakama Nation. NMFS will publish a record of its final action in the Federal Register.

Dated: April 13, 2016.

Angela Somma,
Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

BILING CODE 3510–22–P

DEPARTMENT OF DEFENSE
Department of the Army, Corps of Engineers

National Wetland Plant List

AGENCY: Army Corps of Engineers, DoD.

ACTION: Final notice.

SUMMARY: The U.S. Army Corps of Engineers (Corps), as part of an interagency effort with the U.S. Environmental Protection Agency (EPA), the U.S. Fish and Wildlife Service (FWS) and the U.S. Department of Agriculture Natural Resources Conservation Service (NRCS), is announcing the availability of the final 2016 National Wetland Plant List (NWPL). The NWPL is used to determine whether the hydrophytic vegetation parameter is met when conducting wetland determinations under the Clean Water Act and the Wetland Conservation Provisions of the Food Security Act. Other applications of the list include wetland restoration, establishment, and enhancement projects. The list will become effective on May 1, 2016 and will be used in any wetland delineation performed after this date. Delineations received prior to this date may still use the 2014 NWPL, or you may choose to use the 2016 list. Always reference the list used on any wetland delineation/determination forms.

DATES: The 2016 NWPL will become effective on May 1, 2016.


SUPPLEMENTARY INFORMATION:

Background

The NWPL has undergone several revisions since its inception in 1988. The Corps led interagency efforts to update the list in 2012, 2013, and 2014. The 2012 list contained 7,828 species,
the 2013 update contained 7,937 species, and the 2014 update contained 8,061 species. Additions, or deletions, to these lists represent new records, range extensions, nomenclatural and taxonomic changes, and newly proposed species. The latest review process began in 2015 and included the review by Regional Panels (RPs), the National Panel (NP), and the public, whom provided input on changes to the wetland indicator status of 1,689 species. Four groups of species were examined during this update. The first group consisted of wetland ratings for 25 species (including six new additions) that the public requested on the NWPL Web site (November 10, 2014 to January 31, 2015) and during the Federal Register Comment Period (September 14, 2015 to November 13, 2015). The second group consisted of 166 species with highly variable ratings spanning more than three ratings categories nationally (e.g., rated FACW in the Arid West and UPL in the Caribbean). The third group consisted of five nationally problematic species. Initially, the public requested a rating change for these five species in one region. However, their ratings were re-examined in all regions where they occur, based on a NP request (a total of 21 ratings). Seven species occurred in more than one of these three groups. The fourth group consisted of input received on the wetland ratings of 1,500 species that occur in the South Pacific Islands (SPI) subregion. In group one, based on public requests for rating changes, 88% of the wetland ratings for 25 species were changed on the 2016 NWPL. In group two, species with highly variable ratings, the ratings of all of the species were changed to some degree. In group three, the nationally problematic species, 76% of the 21 ratings were changed for five species. In group four, the SPI species, 12.6% of the ratings were changed.

The NWPL was first published by the FWS in 1988 and first updated in 2012 to include 7,828 species. The 2014 update contained 8,061 species (Lichvar et al. 2014). Four were rated UPL in all regions where they occur, so there were a total of 8,057 species that occur in wetlands. This update contains 8,092 species, a net change of 35 more species (39 species added in the SPI, six new species in the Continental U.S. (CONUS), and removal of ten UPL species). These 8,092 species have 27,984 unique ratings since each can occur in more than one of the ten regions. The 2016 list includes changes in plant indicator status (OBL, FACW, FAC, FACU, and UPL designations) from the 2014 list for 186 species found in the CONUS. Since these 186 species can occur in multiple Corps delineation regions, each having a unique rating, there were a total of 306 rating changes. The indicator status (rating) represents the likelihood that a particular plant occurs in a wetland or upland. The specific breakout of the 306 rating changes was: 49 percent (150 ratings) were assigned wetter indicator ratings and 51 percent (156 ratings) species were assigned drier indicator ratings. Ratings for 41 species were wetter in one region and drier in another region and ratings of three species did not change. In the SPI, there were 185 ratings changes, for a grand total of 495 rating changes in the entire list. A summary of rating changes by region and the response to the technical comments is available at: http://wetland_plants.usace.army.mil/. Policy-level and review process comments are summarized below.

Discussion of Public Comments

Overview

In response to the September 14, 2015, Federal Register notice, a total of 18 comments were received and reviewed on 50 species from eight Corps wetland delineation regions and one subregion. One additional comment was submitted by mistake. The Corps received seven written comments in response to the September 14, 2015, Federal Register notice. One agency responded that they had no comments on the proposed ratings and appreciated the opportunity to review the draft NWPL. Three raised technical issues and three commented only on species, offering no objections or comments on the update, and a total of 36 species were commented on in these six letters. Comments on 14 species from 11 individuals were electronically submitted on the NWPL Web site. The final 2016 NWPL was compiled based on the RP and NP reviews and consideration of the 18 comments received.

General Comments

Most comments pertained to the rating of specific species in several regions, some supported ratings changes and some did not. The rationale for all ratings changes is provided in the response to technical comments document. One commenter was concerned with the inclusion of invasive/non-native species on the NWPL and how ratings are assigned to these species. Nativity to a particular region of the country is irrelevant for the purpose of assigning wetland indicator ratings. Instead, wetland ratings are based on how often a plant species is found to occur in wetlands vs. uplands (Lichvar et al., 2012, Lichvar and Minkin 2008). For both native and non-native species, wetland indicator ratings are assigned based on the NWPL Review Standard. The Review Standard involves a review of literature citations, herbaria records, and field observations. RPs and NP assign final ratings based on this evidence and professional experience.

Another commenter expressed concerns that the process for requesting changes to ratings is a burden on the public with regard to time or cost. The time and cost of requesting a rating change is minimal and reasonable; an individual or group simply needs to explain the rationale behind their proposed rating change in order to begin an open dialog on the current wetland rating. The change requests are processed by the RPs and NP, through which the NWPL Review Standard is applied to the species in question. One commenter requested the inclusion of non-governmental, private-sector and academic experts on the NWPL panels, stating that government-only membership prevents the public from benefiting from expertise of botanists and other experts who are not federal employees. We do not feel that private sector or academic representatives should serve on the interagency regional or national panels as voting members. We encourage outside entities to provide input into the ratings process by providing scientific information, field data, literature reviews, and the like during the Federal Register notice process and by providing comments on the NWPL Web site. The information obtained can be useful to provide “expertise, knowledge, and clarity” to the NWPL process in this manner and helps inform final NWPL ratings.

A final concern was the lack of habitat descriptions from the literature for many NWPL species. One commenter suggested removing from the NWPL all species that lack literature. Another criticized the lack of literature from a particular Corps region. The Corps has developed a future plan for collecting habitat citations for all the species that lack them. Ratings of these species will be re-examined in light of any new data according to this timeline: Habitat citations for species that occur in the largest number of U.S. counties will be compiled in 2016, for review during the 2017 NWPL update. Supporting literature for species that occur in fewer counties will be compiled in 2018, for the 2019 NWPL update. Consistent with the current and past updates to the
NWPL, we will post the following information to the NWPL Web site: The species’ current regional rating, RP rating, NP rating, a summary of the types of data (e.g., literature and herbaria records) used to assign ratings, and the recently acquired literature.

Supporting documentation will be obtained from trustworthy sources, and the use of state, regional, and national floras or peer-reviewed journal articles is preferred. Online references and herbaria records will expedite data gathering provided the source is reliable. The number of citations/records considered adequate will vary with each species’ range. Species with broad ranges that occur in several Corps regions will require more documentation than a species that is endemic to one or two counties. Likewise, few regionally specific references are available for species whose range recently expanded into a new Corps region. For instance, habitat references for species with recent range expansions into the South Pacific Islands, and the Caribbean may be difficult to obtain. Under these circumstances, citations from adjacent states or regions will be considered. During updates these citations from adjacent regions may be used to help guide decisions in regions that lack habitat citations due to recent range expansions. We believe that a minimum of ten citations or herbarium records for each species that currently lacks references is adequate for most species. Fewer records for rare or endemic species will be acceptable. The Corps welcomes public participation in this ongoing effort to improve wetland indicator ratings. Recent habitat citations for wetland plant species that lack literature may be contributed via email (nwpl@usace.army.mil).

The Corps believes we have adequately reviewed the comments and allowed for public and agency input for the proposal. More extensive response to comments can be viewed at http://wetland.plants.usace.army.mil/. Future updates to the NWPL will occur biennially according to the following procedures. A change in indicator status may be requested at any time at http://wetland.plants.usace.army.mil/ by clicking on the “Submit a NWPL Change Request” link and submitting the appropriate data. Data includes ecological data, literature reviews, frequency and abundance data, testing descriptions, and geographic data for the taxon in wetlands and uplands in the Corps wetland region or subregion for which the change is proposed. The regions and subregions are based on Land Resource Regions (LRRs) and Major Land Resource Areas (MLRAs) (http://soils.usda.gov/survey/geography/mhra/) and are shown for each wetland supplement region on the NWPL Web site. If the commenter feels that a wetland supplement region needs a subregion that has not yet been developed, the commenter should identify the MLRAs involved and provide a list of species from within that region that need their own wetland ratings. In addition to these public requests, biennial updates will also include changes in nomenclature and taxonomy, range extensions, and newly proposed species. Proposed rating changes will be compiled in January of odd years (i.e., 2017, 2019) and sent to the RPs for input in February. The NP will assign wetland ratings to non-consensus species and will review all regional lists in April. The proposed changes will be compiled over the summer and published in the Federal Register for public comment in September. In October, public comments will be summarized and the National Panel will review and respond to comments. The final changes will be published in the Federal Register in December of odd years.

The Corps, in cooperation with the USEPA, USFWS and NRCS, is publishing final wetland indicator statuses for the 2016 NWPL. The final NWPL is available at http://wetland.plants.usace.army.mil/ and state, regional, and national lists can be downloaded from this site. This completes the review of the NWPL. All comments received have been evaluated and final indicator statuses have been set.

Administrative Requirements

Plain Language

In compliance with the principles in the President’s Memorandum of June 1, 1998, (63 FR 31855) regarding plain language, this preamble is written using plain language. The use of “we” in this notice refers to the Corps. We have also used the short sentence and common everyday terms except for necessary technical terms.

Paperwork Reduction Act

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 Office of Management and Budget (OMB) control number. For the Corps Regulatory Program under Section 10 of the Rivers and Harbors Act of 1899, Section 3 of the Clean Water Act, and Section 103 of the Marine Protection, Research and Sanctuaries Act of 1972, the current OMB approval number for information collection requirements is maintained by the Corps of Engineers (OMB approval number 0710–0003, which expires on August 31, 2015 (extension request currently in review). This update will not have an effect on the paperwork burden because a wetland delineation is not required for a complete application for most permit types. The delineation of special aquatic sites for a complete preconstruction notification only applies to nationwide permits (NWP) and any additional hours will be included in the burden estimate for the 2017 NWP rulemaking.

The action will not substantially change paperwork burdens on the regulated public because the use of 2016 NWPL will merely be substituted for the 2014 list currently used in the application process in jurisdictional determinations. Further, the NWPL can be viewed on-line or merged into existing documents (e.g., pick lists for delineations/determination forms) and subsequent updates will be made electronically.

Executive Orders 12866 and 13563

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821), we must determine whether the regulatory action is “significant” and therefore subject to review by OMB and the requirements of the Executive Orders. The Executive Orders define “significant regulatory action” as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Orders 12866 and 13563, we determined that this action is not a “significant regulatory action” and therefore, it is not subject to review under requirements of the Executive Orders.

Executive Order 13132

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires the Corps to develop an
accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” The action does not have federalism implications. We do not believe that the action has substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. The action does not impose any additional substantive obligations on State or local governments. Therefore, Executive Order 13132 does not apply to this action.

Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 et seq.

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of the proposed issuance and modification of NWPs on small entities, a small entity is defined as: (1) A small business based on Small Business Administration size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of the action on small entities, we certify that the updates to the NWPL will not have a significant impact on a substantial number of small entities since it does not change the Corps’ current wetland delineation/identification procedures, or the circumstances under which a wetland delineation is required to make a decision on a Department of the Army permit application. The NWPL is only used to determine if a site has wetland plant community and is not the sole factor for determining whether a site is a wetland under the Clean Water Act. To be considered a wetland under the Clean Water Act, the site must also have wetland hydrology and hydric soils.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, the agencies generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “federal mandates” that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating a rule for which a written statement is needed, Section 205 of the UMRA generally requires the agencies to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows an agency to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the agency publishes with the final rule an explanation why that alternative was not adopted. Before an agency establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed, under Section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

We have determined that the NWPL issued today does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The use of the NWPL is consistent with current agency practice, does not impose new substantive requirements and therefore does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Therefore, the NWPL issued today is not subject to the requirements of Sections 202 and 205 of the UMRA. For the same reasons, we have determined that the NWPL update contains no regulatory requirements that might significantly or uniquely affect small governments. Therefore, the issuance of the NWPL is not subject to the requirements of Section 203 of UMRA.

Environmental Documentation

A decision document has been prepared for this action after all comments received were evaluated. The decision document is available through Headquarters, U.S. Army Corps of Engineers, Operations and Regulatory Community of Practice, 441 G Street NW., Washington, DC 20314–1000.

Authority

We utilize the NWPL in conducting wetland determinations under the authority of Section 404 of the Clean Water Act (33 U.S.C. 1344) and Section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 401 et seq.).

Dated: April 5, 2016.

Edward E. Belk, Jr., P.E.,
Chief, Operations and Regulatory Division, Directorate of Civil Works.

[FR Doc. 2016–08917 Filed 4–15–16; 8:45 am]
BILING CODE 3720–58–P

DEPARTMENT OF EDUCATION

Announcement of an Open Public Meeting

AGENCY: National Advisory Council on Indian Education, Department of Education.

ACTION: Announcement of an Open Public Meeting.

SUMMARY: This notice sets forth the schedule of an upcoming public meeting conducted by the National Advisory Council on Indian Education (NACIE). Notice of the meeting is required by section 10(a)(2) of the Federal Advisory Committee Act and intended to notify the public of its opportunity to attend. In order to facilitate the Secretary’s attendance, this notice is being published less than 15 days prior to the scheduled meeting date.

DATES: The NACIE meeting will be held on April 25–26, 2016; April 25, 2016—8:30 a.m.—4:00 p.m. Eastern Daylight Saving Time, April 26, 2015—9:00 a.m.—1:00 p.m. Eastern Daylight Saving Time. The meeting location is 400 Maryland Ave., Room 3C100, SW., Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Tina Hunter, Designated Federal Official, Office of Elementary and Secondary
SUPPLEMENTARY INFORMATION: NACIE's Statutory Authority and Function: The National Advisory Council on Indian Education is authorized by § 6141 of the Elementary and Secondary Education Act, as amended by Every Student Succeeds Act (ESSA). The Council is established within the Department of Education to advise the Secretary of Education on the funding and administration (including the development of regulations, and administrative policies and practices) of any program over which the Secretary has jurisdiction and includes Indian children or adults as participants or programs that may benefit Indian children or adults, including any program established under Title VI, part A of the Elementary and Secondary Education Act as amended by ESSA. The Council submits to the Congress, not later than June 30 of each year, a report on the activities of the Council that includes recommendations the Council considers appropriate for the improvement of Federal education programs that include Indian children or adults as participants or that may benefit Indian children or adults, and recommendations concerning the funding of any such program.

The National Advisory Council on Indian Education (NACIE), a component of the Office of Indian Education, United States Department of Education, 400 Maryland Avenue SW., Washington, DC 20020, Monday-Friday, 8:30 a.m. to 5:00 p.m. Eastern Daylight Saving Time or by emailing TribalConsultation@ed.gov or by calling Terrie Nelson on (202) 401–0424 to schedule an appointment.

Reasonable Accommodations: The hearing site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format), notify Vickie Banagan on 205–2189 or at vickie.banagan@ed.gov no later than April 20, 2016. Although we will attempt to meet a request received after request due date, we may not be able to make the requested auxiliary aid or service because of insufficient time to make arrangements.

Electronic Access to this Document: The official version of this document is the document published in the Federal Register. Free Internet access to the official edition of the Federal Register and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document as well as all other documents of this Department published in the Federal Register, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the Federal Register by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: The National Advisory Council on Indian Education is authorized by Section 6141 of the Elementary and Secondary Education Act, as amended by ESSA.

Ann Whalen,
Senior Advisor to the Secretary Delegated the Duties of Assistant Secretary for Elementary and Secondary Education.
[FR Doc. 2016–08929 Filed 4–15–16; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION
[Docket No.: ED–2016–ICCD–0042]

Agency Information Collection Activities; Submission to the Office of Management and Budget; for Review and Approval; Comment Request; Application Package for Strengthening Historically Black Graduate Institutions (HBGI)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 et seq.), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before May 18, 2016.

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–2016–ICCD–0042. Comments submitted in response to this notice should be submitted electronically through the Federal Rulemaking Portal at http://www.regulations.gov by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. 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 Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Winston Skerrett, 202–453–7605.

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 record.

Title of Collection: Application Package for Strengthening Historically Black Graduate Institutions (HBGI).

OMB Control Number: 1840–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Respondents/Affected Public: 24.

Total Estimated Number of Annual Burden Hours: 576.

Abstract: The Strengthening Historically Black Graduate Institutions (HBGI) Program provides grants to assist institutions in establishing and strengthening their physical plants, development offices, endowment funds, academic resources and student services so that they may continue to participate in fulfilling the goal of equality of educational opportunity in graduate education.

Dated: April 13, 2016.

Kate Mullan,

Acting Director, Information Collection

Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–08849 Filed 4–15–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 16–22–CGL]

SeaOne Gulfport, LLC; Application for Long-Term, Multi-Contract Authorization To Export Natural Gas Contained in Compressed Gas Liquid to Non-Free Trade Agreement Countries

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of an application (Application), filed on September 18, 2015, by SeaOne Gulfport, LLC (SeaOne), requesting long-term, multi-contract authorization to export up to a total of 1.0 billion cubic feet per day (Bcf/d) of natural gas contained in Compressed Gas Liquid (CGL) by vessel 1 to any country located in or adjoining the Caribbean Basin and the Gulf of Mexico with which the United States does not have a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). 2 SeaOne requests the authorization for a 30-year term to commence on the date of first commercial export. The Application was filed under section 3 of the Natural Gas Act (NGA), 15 U.S.C. Section 717b, and Part 590 of the Department of Energy’s (“DOE”) regulations, 10 CFR part 590 (2011).

SeaOne seeks to export the CGL from its proposed Gulfport CGL production facility, currently being developed within the existing Port of Gulfport, Mississippi. Additional details can be found in SeaOne’s Application, posted on the DOE/FE Web site at http://energy.gov/sites/prod/files/2016/04/f30/16-22-cgl.pdf and in SeaOne’s response to questions, posted on the DOE/FE Web site at http://energy.gov/sites/prod/files/2016/04/f30/Supplement.pdf. Protests, motions to intervene, notices of intervention, and written comments in response to the Application are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, June 17, 2016.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.


Hand Delivery or Private Delivery Services: (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

DOE/FE Evaluation

The Application will be reviewed pursuant to section 3(a) of the NGA, 15 U.S.C. 717b(a), and DOE will consider any issues required by law or policy. To the extent determined to be relevant, these issues will include the domestic need for the natural gas proposed to be exported, the adequacy of domestic natural gas supply, U.S. energy security, and the cumulative impact of the requested authorization and any other natural gas export application(s) previously approved on domestic natural gas supply and demand fundamentals. DOE may also consider other factors bearing on the public interest, including the impact of the proposed exports on the U.S. economy (including GDP, consumers, and industry), job creation, the U.S. balance of trade, and international considerations; and whether the authorization is consistent with DOE’s policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. As part of this analysis, DOE will consider the following two studies examining the cumulative impacts of exporting domestically produced LNG insofar as they may be applicable to this proceeding:

Effect of Increased Levels of Liquefied Natural Gas Exports on U.S. Energy Markets, conducted by the U.S. Energy Information Administration.
upon DOE’s request (2014 EIA LNG Export Study); and

• The Macroeconomic Impact of Increasing U.S. LNG Exports, conducted jointly by the Center for Energy Studies at Rice University’s Baker Institute for Public Policy and Oxford Economics, on behalf of DOE (2015 LNG Export Study).4

Additionally, DOE will consider the following environmental document:

• Addendum to Environmental Review Documents Concerning Exports of Natural gas As From the United States, 79 FR 48132 (Aug. 15, 2014); 5

Parties that may oppose this Application should address the above-listed issues and documents in their comments and/or protests, as well as other issues deemed relevant to the Application.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 et seq., requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Due to the complexity of the issues raised by the Applicant, interested parties will be provided 60 days from the date of publication of this Notice in which to submit their comments, protests, motions to intervene, or notices of intervention.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention, as applicable. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to fergas@hq.doe.gov, with FE Docket No. 16–22–CGL in the title line; (2) mailing an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in ADDRESSES; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in ADDRESSES. All filings must include a reference to FE Docket No. 16–22–CGL. PLEASE NOTE: If submitting a filing via email, please include all related documents and attachments (e.g., exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

A decisional record on the Application will be developed through responses to this notice by parties, including the parties’ written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Application is available for inspection and copying in the Office of Regulation and International Engagement docket room, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: http://www.fe.doe.gov/programs/gasregulation/index.html.

Issued in Washington, DC, on April 12, 2016.
John A. Anderson, Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.

[FR Doc. 2016–08884 Filed 4–15–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Public Availability of FY 2015 Service Contract Inventories and Supplemental Data

April 6, 2016.

AGENCY: Federal Energy Regulatory Commission, DOE.


SUMMARY: In accordance with Section 111 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), the Federal Energy Regulatory Commission (FERC) is publishing this notice to advise the public on the availability of the FY 2015 Service Contract Inventory, a report that analyzes the Commission’s FY 2015 Service Contract Inventory and an inventory supplement that identifies the amount invoiced and direct labor hours for covered service contract actions.

The service contract inventory provides information on service contract actions over $25,000 that FERC completed in FY 2015. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010, by the Office of Management and Budget’s Office of Federal Procurement Policy (OFPP).


FERC has posted its FY 2015 inventory and summary at the following link: http://www.ferc.gov/about/offices/oei/oei-fo/oei-acquisition.asp.

FOR FURTHER INFORMATION CONTACT: Katharine Lindner, Acquisition Services Division, Office of the Executive Director, Federal Energy Regulatory Commission.
DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2512–075; Project No. 14439–001]

Hawks Nest Hydro, LLC; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. Type of Application: New Major License.

b. Project Nos.: 2512–075 and 14439–001.

c. Date filed: December 29, 2015.

d. Applicant: Hawks Nest Hydro, LLC (Hawks Nest Hydro).

e. Name of Project: Hawks Nest and Glen Ferris Hydroelectric Projects.

f. Location: The existing Hawks Nest and Glen Ferris projects are located on the New and Kanawha rivers, respectively. Both projects are located in Fayette County, West Virginia. The projects do not occupy any federal lands.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)–825(r).

h. Applicant Contact: Steven Murphy, Manager, Licensing, Brookfield Renewable Energy Group, 33 West 1st Street South, Fulton, New York 13069; Telephone (315) 598–6130.

i. FERC Contact: Monir Chowdhury, (202) 502–6736, or monir.chowdhury@ferc.gov.

j. Deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions: 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions using the Commission’s eFiling system at http://www.ferc.gov/docs-filing/eFiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at http://www.ferc.gov/docs-filing/eComment.asp. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include the applicable project name(s) and docket number(s) (e.g., Hawks Nest P–2512–075).

The Commission’s Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The existing project works consist of: (1) a 590-foot-long spillway section that generally curves upstream; (ii) a 128-foot-long five-bay stoplog sluice; (iii) a 1,232-foot-long right spillway that runs diagonally in a downstream direction; (iv) a trash sluice section; (v) a 54-foot-long by 38-foot-wide east powerhouse with a 62-foot-wide intake structure; and (vi) a 64.5-foot-long by 63-foot-wide west powerhouse with an 82.3-foot-wide intake structure, with both powerhouses integral to the dam; (2) a 190-acre reservoir with a gross storage capacity of approximately 1,500 acre-feet at the dam crest elevation of 651.0 feet NGVD29; (3) two turbine-generator units in the east powerhouse, each with a rated capacity of approximately 1.9 MW; (4) six turbine-generator units in the west powerhouse, each with a rated capacity of approximately 0.4 MW; (5) a 4-mile-long, 13.8-kV transmission line; and (6) appurtenant facilities.

The existing Glen Ferris Hydroelectric Project consists of: (1) a low concrete dam with a maximum height of 12 feet above the river bed and a crest elevation of 651.0 feet NGVD29, consisting of (from left to right—looking downstream) (i) a 590-foot-long spillway section that generally curves upstream; (ii) a 128-foot-long five-bay stoplog sluice; (iii) a 2,132-foot-long right spillway that runs diagonally in a downstream direction; (iv) a trash sluice section; (v) a 54-foot-long by 38-foot-wide east powerhouse with a 62-foot-wide intake structure; and (vi) a 64.5-foot-long by 63-foot-wide west powerhouse with an 82.3-foot-wide intake structure, with both powerhouses integral to the dam; (2) a 190-acre reservoir with a gross storage capacity of approximately 1,500 acre-feet at the dam crest elevation of 651.0 feet NGVD29; (3) two turbine-generator units in the east powerhouse, each with a rated capacity of approximately 1.9 MW; (4) six turbine-generator units in the west powerhouse, each with a rated capacity of approximately 0.4 MW; (5) a 4-mile-long, 13.8-kV transmission line; and (6) appurtenant facilities.

The Glen Ferris Hydroelectric Project is currently operated in a run-of-river mode with no usable storage capacity. Hawks Nest Hydro proposes to continue run-of-river operation and increase the existing minimum flow for the bypassed reach. The project generates an annual average of 544,253 megawatt-hours.

The existing Hawks Nest Hydroelectric Project requires that the project release a continuous minimum flow of 100 cubic feet per second into the bypassed reach between the dam and the powerhouse (Article 402). Hawks Nest Hydro proposes to continue run-of-river operation and increase the existing minimum flow for the bypassed reach. The project generates an average annual of 544,253 megawatt-hours.

The existing Glen Ferris Hydroelectric Project consists of: (1) a low concrete dam with a maximum height of 12 feet above the river bed and a crest elevation of 651.0 feet NGVD29, consisting of (from left to right—looking downstream) (i) a 590-foot-long spillway section that generally curves upstream; (ii) a 128-foot-long five-bay stoplog sluice; (iii) a 2,132-foot-long right spillway that runs diagonally in a downstream direction; (iv) a trash sluice section; (v) a 54-foot-long by 38-foot-wide east powerhouse with a 62-foot-wide intake structure; and (vi) a 64.5-foot-long by 63-foot-wide west powerhouse with an 82.3-foot-wide intake structure, with both powerhouses integral to the dam; (2) a 190-acre reservoir with a gross storage capacity of approximately 1,500 acre-feet at the dam crest elevation of 651.0 feet NGVD29; (3) two turbine-generator units in the east powerhouse, each with a rated capacity of approximately 1.9 MW; (4) six turbine-generator units in the west powerhouse, each with a rated capacity of approximately 0.4 MW; (5) a 4-mile-long, 13.8-kV transmission line; and (6) appurtenant facilities.

The Glen Ferris Hydroelectric Project is currently operated in a run-of-river mode with no usable storage capacity. Hawks Nest Hydro proposes to continue run-of-river operation. The project generates an average annual of 41,482 megawatt-hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission’s Web site at http://www.ferc.gov or the “eLibrary” link. Enter the docket number excluding the last three digits in
the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

Register online at http://www.ferc.gov/docs-filing/esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission’s Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title “PROTEST,” “MOTION TO INTERVENE,” “COMMENTS,” “REPLY COMMENTS,” “RECOMMENDATIONS,” “PRELIMINARY TERMS AND CONDITIONS,” or “PRELIMINARY FISHWAY PRESCRIPTIONS”; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. Procedural Schedule:
The application will be processed according to the following revised Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Target date</th>
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<tbody>
<tr>
<td>Commission Issues Draft EA</td>
<td>June 2016</td>
</tr>
<tr>
<td>Comments on Draft EA</td>
<td>December 2016</td>
</tr>
<tr>
<td>Modified Terms and Conditions</td>
<td>January 2017</td>
</tr>
<tr>
<td>Commission Issues Final EA</td>
<td>March 2017</td>
</tr>
<tr>
<td>All filings must</td>
<td>June 2017</td>
</tr>
</tbody>
</table>

The proposed project would consist of the following: (1) An existing 12-foot-high dam; (2) an 1,000-acre-size impoundment with a storage capacity of 2,100-acre-foot and drainage area of 6,753 square miles; (3) a new 700-foot-long, 180-foot-wide intake; (4) a new 300-foot-long, 180-foot-wide tailrace; (5) four new 2-megawatt (MW) turbines; (6) a new 65-foot-long, 197-foot-wide powerhouse; (7) a new 60-foot-long, 50-foot-wide substation; (8) a new 528-foot-long, 60-kilovolt transmission line; and (9) appurtenant facilities. The estimated annual generation of the Bosher Project would be 68,500 megawatt-hours.

Applicant Contact: Mr. Ander Gonzalez, Energy Resources USA Inc., 350 Lincoln Road, 2nd Floor, Miami Beach, FL 33139; phone: (954) 248–5425.

FERC Contact: Woohee Choi; phone: (202) 502–6336.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission’s eFiling system at http://www.ferc.gov/docs-filing/efiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at http://www.ferc.gov/docs-filing/eComment.asp. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14758–000.

More information about this project, including a copy of the application, can be viewed or printed on the “eLibrary”
DEPARTMENT OF ENERGY
Federal Energy Regulatory Commission
[Project No. 2246–065]
Yuba County Water Agency; Notice Soliciting Comments on Final Technical Memoranda

On March 31, 2016, Yuba County Water Agency, licensee for the Yuba River Project, filed Technical Memoranda 7–11 and 7–11a, Fish Behavior and Hydraulics near Narrows 2 Powerhouse and Radio Telemetry of Spring- and Fall-Run Chinook Migratory Behavior Downstream of Narrows 2 Powerhouse. The memoranda were required by studies approved by the Commission on September 30, 2011 (modified on December 28, 2011; April 12, 2012; and March 29, 2013) (Study 11) and August 22, 2013 (Study 11a).

The Commission is soliciting comments on these memoranda. Any comments should be filed within 30 days of the date of this notice. The Commission strongly encourages electronic filing. Please file all documents using the Commission’s eFiling system at http://www.ferc.gov/docs-filing/eFiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at http://www.ferc.gov/docs-filing/eComment.asp. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

A copy of the EA may also be accessed using this link: http://elibrary.ferc.gov/idmws/common/OpenNat.asp?fileID=14107074.

DEPARTMENT OF ENERGY
Federal Energy Regulatory Commission
[Project No. 5891–009]
Deschutes Valley Water District; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission’s (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the Deschutes Valley Water District’s (licensee) application to amend the license in order to construct and operate fish passage facilities at the Opal Springs Hydroelectric Project No. 5891. The project is located on the Crooked River in Jefferson County, Oregon. The project occupies federal lands administered by the U.S. Bureau of Land Management.

The application, filed with the Commission on October 8, 2015, contains an Environmental Analysis in its Exhibit E. After independent review of the licensee’s Exhibit E, Commission staff has decided to adopt the licensee’s Environmental Analysis and issue it as the staff’s Environmental Assessment (EA). The EA analyzes the potential environmental impacts of construction and operation of fish passage facilities plus the proposed mitigation measures and concludes that granting the proposed amendment would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is on file with the Commission and is available for public inspection. The EA may be viewed on the Commission’s Web site at http://www.ferc.gov using the “eLibrary” link. Enter the docket number (P–5891) in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or call toll-free at 1–866–208–3676 or (202) 502–8659 (for TTY).

A copy of the EA may also be accessed using this link: http://elibrary.ferc.gov/idmws/common/OpenNat.asp?fileID=14010704.

DEPARTMENT OF ENERGY
Federal Energy Regulatory Commission
[Project No. 1940–029]
Wisconsin Public Service Corporation; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. Type of Application: New Major License.

b. Project No.: P–1940–029.

c. Date filed: March 28, 2016.

d. Applicant: Wisconsin Public Service Corporation.

e. Name of Project: Tomahawk Hydroelectric Project.

f. Location: The existing project is located on the Wisconsin River in
Lincoln County, Wisconsin. The project does not affect federal lands.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791(a)–825(r).

h. Applicant Contact: Todd P. Jastremski, Asset Manager Hydro Operations, WE Energies, 800 Industrial Park Drive, Iron Mountain, MI 49801; or at (906) 779–4099.

i. FERC Contact: Lee Emery at (202) 502–8379 or by email at lee.emery@ferc.gov.

j. This application is not ready for environmental analysis at this time.

k. The existing Tomahawk Hydroelectric Project consists of: (1) A 27-foot-high, 3,400-foot-long reinforced concrete and embankment dam that includes a 2,450-foot-long left embankment section, a 300-foot-long right embankment section, 9-foot-long sluice gate section, 267-foot-long radial gate section, 160-foot-long slab and buttress section, and a 60-foot-long abutment section with a crest elevation of 1,441.0 feet National Geodetic Vertical Datum (NGVD); (2) a 2,773-acre reservoir (Lake Mohawksin) at a full-pool elevation of 1,435.5 feet NGVD; (3) a 67-foot-long by 41-foot-wide powerhouse intake trash racks with a 2.7-inch clear bar spacing; (4) two 2.4-kilovolt (kV) generator leads and an associated 3.75-megavolt-ampere, 2.4/24.9-kV three phase transformer; (6) an interconnected substation located adjacent to the powerhouse; and (7) appurtenant facilities.

The project is operated in a limited peaking mode, with maximum allowed daily reservoir fluctuations of approximately 0.8 feet (1,435.5 feet NGVD to 1,434.7 feet NGVD). During normal peaking operations, the reservoir is drawn down from the maximum pond elevation during the day and refilled at night providing one peaking cycle per day. The amount of fluctuation is determined primarily by the volume of water which can normally be restored to the Tomahawk reservoir during off-peak hours. During low flow periods, the project is required to maintain a minimum flow of 162 cubic feet per second (cfs) or inflow, whichever is less. The operation of the Tomahawk Project is coordinated with the downstream WPS Projects (Grandfather Falls and Alexander Projects) and with the Grandmother Falls Project to make the most effective use of the available water resource.

The normal tailwater elevation of the project is 1,419.5 feet NGVD. The impoundment provides about 14.5 feet of gross head for power generation purposes. The hydraulic capacity of the project is 2,634 cfs and water flowing through the turbines is discharged via the draft tubes into the tailrace immediately below the dam. Electricity generated from the project is transmitted from the powerhouse via two 2.5-kV generator leads and a 3.75 MVA 2.4/24.9-kV three-phase transformer to the adjacent substation and into Wisconsin Public Service Corporation’s distribution system. Wisconsin Public Service Corporation is proposing to continue current operations at the Project for the term of the new license.

l. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission’s Web site at 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. For assistance, contact FERCONlineSupport@ferc.gov, (866) 208–3676 (toll free) or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in item h above.

m. You may also register online at http://www.ferc.gov/docs-filing/esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects.

n. Procedural schedule:

The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Target date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice of Acceptance/Notice of Ready for Environmental Analysis</td>
<td>June 2016.</td>
</tr>
<tr>
<td>Filing of recommendations, preliminary terms and conditions, and fishway prescriptions</td>
<td>August 2016.</td>
</tr>
<tr>
<td>Comments due on EA</td>
<td>January 2017.</td>
</tr>
<tr>
<td>Modified terms and conditions</td>
<td>March 2017.</td>
</tr>
</tbody>
</table>

o. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: April 6, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–08861 Filed 4–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF15–33–000]

Northern Natural Gas Company; Notice of Intent To Prepare an Environmental Assessment for the Planned Northern Lights 2017 Expansion Project, Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Northern Lights 2017 Expansion Project involving construction and operation of facilities by Northern Natural Gas Company (Northern) in Dakota County, Minnesota. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so
that the Commission receives them in Washington, DC on or before May 11, 2016.

If you sent comments on this project to the Commission before the opening of this docket on September 28, 2015, you will need to file those comments in Docket No. PF15–33–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission’s current environmental mailing list for this project. State and local government representatives should notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval would convey with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled “An Interstate Natural Gas Facility On My Land? What Do I Need To Know?” is available for viewing on the FERC Web site (www.ferc.gov). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission’s proceedings.

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission will provide equal consideration to all comments received, whether filed in written form or provided verbally. The Commission encourages electronic filing of comments and has expert staff available to assist you at [202] 502–8258 or efiling@ferc.gov. Please carefully follow these instructions so that your comments are properly recorded.

1. You can file your comments electronically using the eComment feature on the Commission’s Web site (www.ferc.gov) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “eRegister.” If you are filing a comment on a particular project, please select “Comment on a Filing” as the filing type; or
2. You can file your comments electronically by using the eFiling feature on the Commission’s Web site (www.ferc.gov) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “eRegister.” If you are filing a comment on a particular project, please select “Comment on a Filing” as the filing type; or
3. You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (PF15–33–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Planned Project

Northern plans to construct and operate approximately 4.8 miles of branch line loop 1 extensions in Sherburne and Isanti counties, Minnesota, and to install an additional 15,900-horsepower compressor unit to an existing compressor station site in Rice County, Minnesota. The Northern Lights 2017 Expansion Project would allow Northern to transport an incremental load of 76 million cubic feet on Northern’s existing system. According to Northern, its project would meet the firm transportation service elected during an October 2015 open season by Xcel Energy Inc., CenterPoint Energy, Al-Corn Clean Fuel, and Midwest Natural Gas, Inc.

The Northern Lights 2017 Expansion Project would consist of the following facilities:

- 2.0 miles extending the existing 8-inch-diameter Princeton branch line loop and a new associated valve;
- 2.8 miles extending the existing 12-inch-diameter St. Cloud branch line loop and a new associated valve;
- a 15,900-horsepower Solar Mars turbine compressor unit at the Faribault Compressor Station; and
- cathodic protection test stations.

The general location of the project facilities is shown in appendix 1.2

Land Requirements for Construction

Construction of the planned facilities would disturb about 112.4 acres of land for the aboveground facilities and the pipeline. In addition to its existing

1 A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.
2 The appendices referenced in this notice will not appear in the Federal Register. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called “eLibrary” or from the Commission’s Public Reference Room, 888 First Street NE., Washington, DC 20426, or call [202] 502–8371. For instructions on connecting to eLibrary, refer to page 7 of this notice.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the planned project under these general headings: Geology and soils; land use; water resources; fisheries, and wetlands; cultural resources; vegetation and wildlife; air quality and noise; endangered and threatened species; public safety; and cumulative impacts.

We will also evaluate possible alternatives to the planned project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission’s pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EA.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we
may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate with us in the preparation of the EA.4 Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation’s implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the Minnesota State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project’s potential effects on historic properties.5 We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission’s regulations) who are potential right-of-way grantees, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version, you can request a copy by calling (866) 208–3676, or for TTY, contact (202) 502–8659. The Environmental Mailing List under section 106.

Becoming an Intervenor

Once Northern files its application with the Commission, you may want to become an “intervenor” which is an official party to the Commission’s proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission’s final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Motions to intervene are more fully described at http://www.ferc.gov/resources/guides/how-to/intervene.asp. Instructions for becoming an intervenor are in the “Document-less Intervention Guide” under the “e-filing” link on the Commission’s Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project.

Additional Information

Additional information about the project is available from the Commission’s Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (www.ferc.gov) using the eLibrary link. Click on the eLibrary link, click on “General Search” and enter the docket number, excluding the last three digits in the Docket Number field (i.e., PF15–33). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of 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. Go to www.ferc.gov/docs-filing/esubscription.asp.

Finally, public meetings or site visits will be posted on the Commission’s calendar located at www.ferc.gov/EventCalendar/EventsList.aspx along with other related information.

Dated: April 11, 2016.
Kimberly D. Bose,
Secretary.

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FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0743]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: 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; the accuracy of the Commission’s burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a
collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before May 18, 2016. 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, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email Nicholas_A_Fraser@omb.eop.gov; and to Nicole Ongele, FCC, via email PRA@fcc.gov and to Nicole.Ongele@fcc.gov. Include in the comments the OMB control number as shown in the “Supplementary Information” section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page http://www.reginfo.gov/public/do/PRAMain, (2) look for the section of the Web page called “Currently Under Review,” (3) click on the downward-pointing arrow in the “Select Agency” box below the “Currently Under Review” heading, (4) select “Federal Communications Commission” from the list of agencies presented in the “Select Agency” box, (5) click the “Submit” button to the right of the “Select Agency” box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:
OMB Control Number: 3060–0743.
Form Number: N/A.
Type of Review: Extension of a currently approved collection.
Respondents: Business or other profit entities and state, local and tribal government.
Number of Respondents and Responses: 4,471 respondents; 10,071 responses.
Estimated Time per Response: 11.730414 hours.
Frequency of Response: On occasion, quarterly and monthly reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 276 of the Telecommunications Act of 1996, as amended.
Total Annual Burden: 118,137 hours.
Total Annual Cost: No cost.
Privacy Impact Assessment: No impact(s).
Nature and Extent of Confidentiality: The Commission is not requesting that respondents submit confidential information to the FCC. If the Commission requests respondents to submit information which respondents believe is confidential, they may request confidential treatment of such information under 47 CFR 0.459 of the Commission’s rules.

Needs and Uses: In CC Docket No. 96–128, the Commission promulgated rules and requirements implementing Section 276 of the Telecommunications Act of 1996. Among other things, the rules (1) establish fair compensation for every completed intrastate and interstate payphone call; (2) discontinue intrastate and interstate access charge payphone service elements and payments, and intrastate and interstate payphone subsidies from basic exchange services; and (3) adopt guidelines for use by the states in establishing public interest payphones to be located where there would otherwise not be a payphone. The information collected under LEC Provision of Emergency Numbers to Carrier-Payers would enable us to ensure that interexchange carriers, payphone service providers (“PSP”), LECs, and the states, comply with their obligations under the 1996 Act.

Federal Communications Commission.
Gloria J. Miles,
Register Liaison Officer. Office of the Secretary.
[FR Doc. 2016–08890 Filed 4–15–16; 8:45 am]
BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION
[OMB 3060–0166, 3060–0076]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority
AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: 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; the accuracy of the Commission’s burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 17, 2016. 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, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email to PRA@fcc.gov and to Nicole.Ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:
OMB Control Number: 3060–0166.
Title: Part 42, Sections 42.5, 42.6, and 42.7, Preservation of Records of Communications Common Carriers.
Form Number: N/A.
Type of Review: Extension of a currently approved collection.
Respondents: Business or other profit entities.
Number of Respondents and Responses: 50 respondents; 50 responses.
Estimated Time per Response: 2 hours.
Frequency of Response: Occasional reporting requirement, recordkeeping requirement, and third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in Section 220 of the Communications Act of 1934, as amended, 47 U.S.C. 220.

Total Annual Burden: 100 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The respondents are instructed on the appropriate procedures to follow to safeguard information deemed confidential under 47 CFR 0.457 of the Commission’s rules, which details the type of records that are not routinely available for public inspection. Section 0.459 of the Commission’s rules contains procedures for requesting that material and information submitted to the Commission be withheld from public inspection.

Needs and Uses: FCC Report 395, Common Carrier Annual Employment Report, is a data collection mechanism to implement the FCC’s Equal Employment Opportunity (EEO) rules. All common carrier licensees or permittees with sixteen (16) or more full-time employees are required to file the Annual Employment Report. Each common carrier is also obligated to file with this Commission copies of all exhibits, letters, and documents pertaining to all equal employment opportunity statements and annual reports on complaints regarding violations of equal employment provisions of Federal, State, Territorial, or local law. Section 22.321(f), 47 CFR, requires each licensee to maintain these documents for a period of two years. The Annual Employment Report identifies each filer’s staff by gender, race, color, and/or national origin in each of ten major job categories. The report and all other EEOC documents are filed with the Commission to detail the applicant’s compliance with the Commission’s EEO rules. Those documents are available for public inspection at a designated area located in the FCC’s Industry Analysis and Technology Division.

Federal Communications Commission.

Gloria J. Miles,
Federal Register Liaison Officer. Office of the Secretary.

[FR Doc. 2016–08889 Filed 4–15–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, March 15, 2016 at 10:00 a.m. and Wednesday, March 16, 2016 at the conclusion of the Open Meeting.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

Federal Register notice of previous announcement—81 FR 12731.

CHANGE IN THE MEETING: This meeting was continued on April 12, 2016.

PERSON TO CONTACT FOR INFORMATION:
Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,
Deputy Secretary.

[FR Doc. 2016–09035 Filed 4–14–16; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting


TIME AND DATE: April 20, 2016–10 a.m.

PLACE: 800 North Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The meeting will be held in Open Session.

MATTERS TO BE CONSIDERED:

Open Session

1. Supply Chain Innovation Team Update
2. Briefing on Upgrade to FMC Online Agreement Library
3. Optional Method of Filing Ocean Common Carrier and Marine Terminal Operator Agreements
4. Presentation of Evidence in Commission Adjudicatory Proceedings

CONTACT PERSON FOR MORE INFORMATION:
Karen V. Gregory, Secretary, (202) 523 5725.
Karen V. Gregory,
Secretary.

[FR Doc. 2016–09002 Filed 4–14–16; 4:15 pm]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board’s Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments
must be received not later than May 2, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. Douglas M. Taylor, Bemidji, Minnesota, individually and as trustee of Citizens State Bank Midwest 401(k) Profit Sharing Plan, Bemidji, North Dakota (“Profit Sharing Plan”), and as part of a group acting in concert with the Profit Sharing Plan, Nancy R. Helling, Saint Cloud, Minnesota, and Ramona D. Taylor Vosper, Neche, North Dakota; to acquire voting shares of Pembina County Banksshares, Ltd., and thereby indirectly acquire voting shares of Citizens State Bank—Midwest, both in Cavalier, North Dakota.

Board of Governors of the Federal Reserve System, April 12, 2016.

Michael J. Lewandowski, Associate Secretary of the Board.

[BILLING CODE 6210–01–P]

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 13, 2016.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:


Board of Governors of the Federal Reserve System, April 13, 2016.

Michael J. Lewandowski, Associate Secretary of the Board.

[BILLING CODE 6210–01–P]
FEDERAL TRADE COMMISSION

Enforcement Policy Statement on Deceptively Formatted Advertisements

AGENCY: Federal Trade Commission.

ACTION: Commission policy statement.

SUMMARY: The Federal Trade Commission has issued an Enforcement Policy Statement on Deceptively Formatted Advertisements. The Statement describes the underlying consumer protection principles that guide the Commission’s enforcement actions, advisory opinions, and other guidance addressing various forms of deceptively formatted advertising, including advertising and promotional messages integrated into and presented as non-commercial content.

DATES: The Commission announced the issuance of the Statement on December 22, 2015.


SUPPLEMENTARY INFORMATION:

Enforcement Policy Statement on Deceptively Formatted Advertisements

The Federal Trade Commission issues this enforcement policy statement regarding advertising and promotional messages integrated into and presented as non-commercial content. The statement summarizes the principles underlying the Commission’s enforcement actions, advisory opinions, and other guidance over many decades addressing various forms of deceptively formatted advertising.

Section 5 of the FTC Act prohibits “unfair or deceptive acts or practices in or affecting commerce.” As the Commission set forth in its 1983 Policy Statement on Deception, a representation, omission, or practice is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and is material to consumers—that is, it would likely affect the consumer’s conduct or decisions with regard to a product or service. In determining whether an advertisement, including its format,

misleads consumers, the Commission considers the overall “net impression” it conveys. Any qualifying information necessary to prevent deception must be disclosed prominently and unambiguously to overcome any misleading impression created. The Commission has long held the view that advertising and promotional messages that are not identifiable as advertising to consumers are deceptive if they mislead consumers into believing they are independent, impartial, or, not from the sponsoring advertiser itself. Knowing the source of an advertisement or promotional message typically affects the weight or credibility consumers give it. Such knowledge also may influence whether and to what extent consumers choose to interact with content containing a promotional message. Over the years, the Commission has challenged as deceptive a wide variety of advertising and other commercial message formats, including “advertorials” that appeared as news stories or feature articles, direct-mail ads disguised as book reviews, infromercials presented as regular television or radio programming, in-person sales practices that misled consumers as to their true nature and purpose, mortgage relief ads designed to look like solicitations from a government agency, emails with deceptive headers that appeared to originate from a consumer’s bank or mortgage company, and paid endorsements offered as the independent opinions of impartial consumers or experts.

With the emergence of digital media and changes in the way publishers monetize content, online advertising known as “native advertising” or “sponsored content,” which is often indistinguishable from news, feature articles, product reviews, editorial, entertainment, and other regular content, has become more prevalent. In digital media, a publisher, or an authorized third party, can easily and inexpensively format an ad so it matches the style and layout of the content into which it is integrated in ways not previously available in traditional media. The effect is to mask the signals consumers customarily have relied upon to recognize an advertising or promotional message. At the same time, the business models of many publishers also have undergone significant change, as, increasingly, consumers are able to skip or block digital ads while watching digitized programming or browsing publisher content. Consequently, many publishers have begun to offer advertisers formats and techniques that are closely integrated with and less distinguishable from regular content so that they can capture the attention and clicks of advertising consumers.

Regardless of the medium in which an advertising or promotional message is disseminated, deception occurs when consumers acting reasonably under the circumstances are misled about its nature or source, and such misleading impression is likely to affect their decisions or conduct regarding the advertised product or the advertising. This statement sets forth generally applicable standards on which the Commission relies in making such a determination.

I. Deceptive Advertising Formats

The principle that advertising and promotional messages should be identifiable as advertising is found in Commission and staff policy guidance, specific cases challenging deceptive advertising in a wide range of media, and Congressional policy with regard to telemarketing calls and commercial email. As set forth below, over the years, the Commission and staff have addressed the potential for consumers to be deceived by various categories of advertising formats, such as ads appearing in a news or feature story format, deceptive endorsements, undisclosed sponsorship of advertising and promotional messages, and ads in search results.

A. Advertisements Appearing in a News Format or That Otherwise Misrepresent Their Source or Nature

The Commission first addressed the issue of print advertisements appearing in a news format in a 1967 press release and subsequent 1968 advisory opinion. A newspaper column, advertising the cuisine of local restaurants, was written in narrative form, with each write-up discussing such details as how a meal was prepared, the name of the chef and/ or head waiter, cocktail service offered,


whether dancing was permitted, hours, and the price range of the meal. The Commission found that the column "use[d] the format and ha[d] the general appearance of a news feature and/or article for public information which purport[ed] to give an independent, impartial and unbiased view of the cuisine facilities of a particular restaurant." The Commission also explained that the inclusion of the exact price of the meal advertised or listing a range of prices for other meals would not alter this impression.

The Commission concluded that a clear and conspicuous disclosure that the column was an advertisement was necessary to prevent consumers from being deceived. Specifically, the Commission suggested placing "ADVERTISEMENT," in clear type, sufficiently large to be readily noticed, in close proximity to the ad. The Commission, however, noted that in some instances, "the format of [an] advertisement may so exactly duplicate a news or feature article as to render the caption 'ADVERTISEMENT' meaningless and incapable of curing the deception." 9

Two decades later, in a case against a bookseller, the Commission applied this same analysis and concluded there was reason to believe that the bookseller violated the FTC Act through a deceptive direct-mail ad formatted to appear as if it were a book review torn out of a magazine, with a personalized note attached. The Commission alleged that the ad's format communicated a misleading claim that it was "a book review written by an independent journalist or reviewer, containing the independent opinions of the journalist or reviewer, and was disseminated in a magazine or other independent publication." The Commission observed that the ad was printed on glossy stock and had a ripped, left edge, and included other elements, such as the header "REVIEW," a byline, a publication date, and page numbers, and part of an unrelated article on the reverse side, which, when together, made it look like a published review of the book advertised. In evaluating what the ad communicated to consumers, the Commission also considered that affixed to each ad was a small, stick-on note containing what appeared to be a personalized, handwritten message, with the recipient's first name and saying, "Try this. It works!"

During the 1980s, after the Federal Communications Commission removed its ban on program-length commercials, such advertisements, known as infomercials, began to air on television and radio. 11 Concerned about the increasingly blurred line between advertising and non-promotional content, the Commission brought cases alleging that deception occurs when infomercials are presented as regular television or radio programming, such as a news report or talk show. In the Commission's first such case in 1989, the Commission challenged a television infomercial that opened with the statement, "Welcome to 'Consumer Challenge,' hosted by Jonathan Goldsmith." and went on to describe the program as one that "examines popular new products for you," with the help of investigative reporters. 12 It then announced that the day's program would investigate a particular brand of sunglasses, posing the question to viewers: "Is it innovation or consumer rip-off?" In evaluating the sunglasses infomercial, the Commission asserted that its format was likely to mislead consumers into believing that it was "an independent consumer program . . . that conducts independent and objective investigations of consumer products," including for the company's sunglasses. Since bringing that case, the FTC has charged that numerous other television and radio infomercials were deceptively formatted. In nearly every such case, the Commission has issued an order requiring a clear and prominent disclosure, at the beginning of an infomercial and again each time ordering instructions are given, informing consumers that the program is a "PAIDADVERTISEMENT" for the particular product or service advertised. 13

More recently, the Commission has brought a series of cases concerning ads disguised to look like news reports on weight-loss pills and other products, where a purported journalist tested the advertised product and authored the story. 14 The ads used devices such as news-related names and headlines suggestive of a local television station, trademarks of established news companies, reporter by-lines, and reader comment sections to create that false impression. In one case, the Commission alleged the format was deceptive despite the presence of a small-print disclaimer "Advertorial" in the top border of some Web sites. 15 Consumers reached all these fake news Web sites by clicking on ads presented as attention-getting news headlines, which frequently appeared on legitimate news Web sites.

In another recent case, the Commission challenged as deceptive a Web site purported to originate from an independent scientific organization. The Commission alleged that dietary supplement marketers misrepresented that their Web site promoting the health benefits of their children's supplements was an independent, objective resource for scientific and other information on creating a specific health condition, and that they failed to disclose their relationship to the Web site. 16

The Commission also has challenged advertisements misrepresenting that a government agency endorsed or was

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9 Advisory Opinion on Ads in News Formats, 73 F.T.C. at 1307.
10 Statement on Ads in Feature Article Format.
15 See Complaint at 6, FTC v. Circa Direct LLC; see also Memorandum in Support of Plaintiff's Motion for a TRO at 14, FTC v. Circa Direct LLC (Apr. 18, 2011). Similarly, in a Securities and Exchange Commission case concerning paid promotions of stocks that appeared in a news format, a court held that, "[t]he 'advertorial' label . . . simply does not convey to the reader that the articles, which appear in a news-item format, were indeed purchased by the subject companies; this label does not provide investors with the material information regarding the publishers' bias." SEC v. Corp. Relations Grp., Inc., No. 06-cv-1223, 2003 U.S. Dist. LEXIS 24926, at *26–27 (M.D. Fla. Mar. 28, 2003).
affiliated with a product or service. For example, one such case against a seller of mortgage relief services concerned radio ads formatted to appear as public service announcements from the United States government, which began, “Please stay tuned for this important public announcement for those in danger of losing their home” and prominently featured the word “federal.” 17 A federal district court found these radio ads deceived consumers, observing that the defendants “intended to cause consumers to associate [those responsible for the ads] with the federal government so that consumers would be more likely to believe that [they] were credible and stable.” 18 The Commission similarly has alleged that direct mail mortgage loan modification ads sent in official-looking brown envelopes with a mortgage loan modification ad may be deceptive.19

In 2002, when online search was a relatively new medium, FTC staff issued guidance concerning the potential for consumers to be deceived by paid ads formatted to appear as the regular search results. Consumers might take ads that appear at the top of the search results to be the most relevant, and thus more likely to be useful, even if the information they contain is misleading. The guidance made clear: “advertising results are not based on the relevance of the content of the ad but rather on the payment made to appear at the top of the results.”20

The Commission concurs with the staff’s conclusion, as articulated in the 2002 guidance and updated guidance issued in 2013,21 that consumers ordinarily would expect a search engine to return results based on relevance to a search query, as determined by impartial criteria, not based on payment from a third party. Knowing when search results are included or ranked higher based on payment and not on impartial criteria likely would influence consumers’ decisions with regard to a search engine and the results it delivers. Thus, failing to clearly and prominently disclose the paid nature of such advertising results is deceptive.

B. Misleading Door Openers

Other formats that mislead consumers about a commercial message’s nature or purpose also have been alleged or found to be deceptive, such as misleading sales visits and calls with emails and with falsified sender information. An early example of such a challenge was a 1976 case against an encyclopedia seller.22 A salesperson would “disguise his role as a salesman and appear as a surveyor engaged in advertising research” or salespeople would “approach prospects’ homes in the guise of delivering . . . gifts or prizes without identifying themselves as salesmen, or that the purpose of their visit is to sell an encyclopedia.” 23 The Commission order required the respondents’ sales representatives to present a card that clearly disclosed the purpose of the visit before entering a prospect’s home.24 Subsequently, the Commission’s Deception Policy Statement categorized this practice as a “misleading door opener,” citing it for the general proposition that, “when the first contact between the seller and a buyer occurs through a deceptive practice, the law may be violated, even if the truth is subsequently made known to the purchaser.”25

In 1994, concerned about deception and abuse occurring in the telemarketing of goods and services, Congress enacted the Telemarketing Fraud Act,26 which prohibited the use of deceptive door-openers in telemarketing. That Act, among other things, outlawed as an abusive practice a telemarketer’s failure to “promptly and clearly disclose . . . that the purpose of the call is to sell goods or services” when that is the case.27 The Commission implemented Congress’s intent to prohibit this practice when it promulgated the Telemarketing Sales Rule.28 In enforcing that Rule, the Commission has brought cases against telemarketers who misrepresented that calls were from, or made on behalf of, companies with which consumers had done business, such as banks and credit card companies.29

When Congress passed the CAN-SPAM Act,30 among the practices the law was intended to address were emails that “mislead recipients as to the source or content of such mail.”31 Specifically, Congress concluded that “[m]any senders of unsolicited commercial electronic mail purposefully disguise the source of such mail” and “include misleading information in the messages’ subject lines in order to induce the recipients to view the messages,” and that the recipients of such mail “incur costs for the . . . time spent accessing, reviewing, and discarding such mail . . . .”32 The CAN-SPAM Act therefore effectively prohibited deceptive door-openers in commercial email. The Act outlawed the sending of emails containing falsified header information.
including sender or subject information, and made doing so a violation of the FTC Act.\textsuperscript{33} Even prior to the law’s passage, in a case against an email marketer, the Commission alleged it was deceptive to forge an email’s header information so as to make recipients believe a well-known bank or mortgage company sent it.\textsuperscript{34}

\textbf{G. Deceptive Endorsements That Do Not Disclose a Sponsoring Advertiser}

Consumers may also be misled about an advertisement’s nature or source as a result of an advertiser’s use of consumer and other endorsements. As the Commission stated in the Endorsement Guides, “When there exists a connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement (i.e., the connection is not reasonably expected by the audience), such connection must be fully disclosed. . . . clearly and conspicuously . . . .”\textsuperscript{35} In revising the Guides in 2009, the Commission specifically addressed paid endorsements in non-traditional forms of advertising, such as user-generated social media, personal blogs, online comment sections, or television talk show interviews.\textsuperscript{36} The Commission’s advice was based on the principle that when the content in which an endorsement is disseminated is not identifiable by consumers as advertising, consumers would not ordinarily expect an endorser to be speaking on behalf of a sponsoring advertiser and such connection must be disclosed to avoid deceiving consumers.

Since revising the Endorsement Guides, the Commission has brought a number of cases underscoring this principle.\textsuperscript{37} For example, in a case against an app developer, employees of a public relations firm hired by the developer posted reviews about its games in the iTunes app store, without disclosing their relationship to the company.\textsuperscript{38} The Commission asserted that the posted reviews were misrepresented as independent reviews reflecting the opinions of ordinary consumers, and that the failure to disclose the reviewers’ material connection to the app company was deceptive. Another case concerned a home security firm’s hiring of spokespersons who appeared on television and radio programs as impartial expert reviewers but failed to make known their connection to the company.\textsuperscript{39}

\textbf{II. Commission Policy on Deceptively Formatted Advertising}

The recent proliferation of natively formatted advertising in digital media has raised questions about whether these advertising formats deceive consumers by blurring the distinction between advertising and non-commercial content. Natively formatted advertising encompasses a broad range of advertising and promotional messages that match the design, style, and behavior of the digital media in which it is disseminated. The ads can appear in a wide variety of forms, including written narratives, videos, infographics, images, animations, in-game modules, and playlists on streaming services. Often natively formatted ads are inserted into the stream of regular content a publisher offers,\textsuperscript{40} generally referred to in this statement as a “publisher site,” such as news and news aggregator sites and social media platforms.\textsuperscript{41} In some instances, publishers place these ads on their sites and, in other instances, advertising networks operating ad content-recommendation engines do so. Advertising and promotional messages

\textsuperscript{33} Id. at section 7704(a)(1) and (2). In certain circumstances, materially falsifying header information also can be a crime punishable by a fine, imprisonment, or both, and enforceable by the United States Department of Justice. See 18 U.S.C. 1037.


\textsuperscript{35} Guides Concerning Use of Endorsements and Testimonials in Advertising (hereinafter “Endorsement Guides”), 16 CFR 255.5 (Disclosure of material connection).

\textsuperscript{36} Id. Examples 3, 7, 8, 9.


\textsuperscript{38} Reverb Connec’ns, Inc., 150 F.T.C. 782, 783–84 (2010) (consent).

\textsuperscript{39} Complaint at 1–5, ADT LLC.

\textsuperscript{40} Commonly, when a natively formatted ad appears on a publisher site, it consists of headline text, a short description, and a thumbnail image, which, if clicked, lead to additional content.

\textsuperscript{41} The term “publisher site” refers to any media platform on which consumers consume content and media creators and curators publish content. The content may be delivered by publishers through various means, including the web and mobile applications, and may be accessed by consumers on different devices, including computers, smartphones, tablets, and televisions.

\textsuperscript{42} By product or advertising claims, the Commission generally means any representations about the benefits or attributes of a product, type of product, or category of products, including disparaging claims about a competitor’s products.

\textsuperscript{43} The Commission has challenged advertising formats as deceptive without challenging product claims made in advertisements. See, e.g., Complaint, ADT LLC; Georgetown Publ’g House Ltd., No. CV13–00001 (C.D. Cal. Apr. 27, 2015) (stipulated order for civil penalties).
impartial restaurant reviews.45 In a case against a bookseller, the Commission’s complaint noted a number of elements, including the challenged ad’s printing on magazine-like paper, a ripped left edge, page numbering, inclusion of a publication date and byline, and an affixed personalized sticky note, in alleging that the overall impression created was that the ad was an independent book review.46 Thus, in evaluating whether an ad’s format is misleading, the Commission will scrutinize the entire ad, examining such factors as its overall appearance, the similarity of its written, spoken, or visual style to non-advertising content offered on a publisher’s site, and the degree to which it is distinguishable from such other content.

Any determination of whether an advertisement’s format misleads as to the ad’s nature or source depends on how reasonable consumers would interpret the ad in a particular situation. To be reasonable, an interpretation or response of consumers to a particular ad must be the only one nor be shared by a majority of consumers.47 Interpretations that advertisers intend to convey about an advertisement’s nature or source are presumed reasonable.48 In digital media, consumers can encounter natively formatted ads in a wide variety of situations, including in the news feed or main page of a publisher site, or through other means, such as posts in social media, in search results, and in email. In evaluating whether reasonable consumers would recognize ads as such, the Commission will consider the particular circumstances in which the ads are disseminated, including customary expectations based on consumers’ prior experience with the media in which it appears and the impression communicated by the ad’s format.49 For instance, if a natively formatted ad appearing as a news story is inserted into the content stream of a publisher site that customarily offers news and feature articles, reasonable consumers are unlikely to recognize it as an ad.

The target audience of an ad also may affect whether it is likely to mislead reasonable consumers about its nature or source. Increasingly, in digital media, advertisers can target natively formatted ads to individual consumers and even tailor the ads’ messaging to appeal to the known preferences of those consumers.50 The propensity of an ad to mislead as to its nature or source may be different when considered from the perspective of its target audience. To the extent that an advertisement is targeted to a specific audience, the Commission will consider the effect of the ad’s format on reasonable or ordinary members of that targeted group.51 Certain ads that are natively formatted like the non-advertising content with which they are presented, however, may be unlikely to mislead consumers acting reasonably. Some ads by the very nature of their promotional message communicated may be inherently obvious as advertising to consumers. For instance, if a natively formatted ad with an image of a particular sports car and the headline “Come and Drive [X] today” were inserted into the news stream of a publisher site, that ad likely would be identifiable as an ad to consumers, even though it was presented in the same visual manner as news stories in the stream.

Finally, in determining the overall impression communicated by an ad, the Commission also will consider any qualifying information contained in the ad.52 Advertisements may include disclosures to inform consumers of their commercial nature, including text labels, audio disclosures, or visual cues distinguishing the ad from other content into which it is integrated. Any disclosure used must be “sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression.”53 A disclosure’s adequacy ultimately will be measured by whether reasonable consumers perceive the ad as advertising.54 A disclosure must be made in “simple, unequivocal” language, so that consumers comprehend what it means.55 For example, in infomercial cases, the Commission has required the use of the words “Paid Advertisement.”56 In its Advisory Opinion on Ads in a News Format, the Commission suggested use of the term “Advertisement” to prevent consumers from being deceived by those particular advertising formats.57 Disclosures also must be made in the same language as the predominant language in which ads are communicated.58

The conspicuousness of the disclosure will depend on the method of delivery and placement within the ad. Depending on the circumstances, a disclosure in the text may not remedy a misleading impression created by the headline because reasonable consumers might glance only at the headline.59 In Commission cases and Rules addressing audio ads, the Commission has required audible disclosures to be delivered in a volume, cadence, and speed sufficient

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45 Advisory Opinion on Ads in News Formats, 73 F.T.C. at 1307–08.
46 Georgetown Publ’g House Ltd. P’ship, 122 F.T.C. at 393–96.
47 Deception Policy Statement, 103 F.T.C. at 177 n.20. “A material practice that misleads a significant minority of reasonable consumers is deceptive.” Id.
48 Id. at 178.
49 For example, consumers’ customary use of and prior experience with search engines are relevant to the need to distinguish paid from regular search results. See Updated Search Engine Letter, at note 2 and accompanying text.
50 There may be a host of data collection and use activities associated with natively formatted ads disseminated programmatically in digital media, some of which may not be transparent to consumers. This enforcement policy statement is not intended to address the legal and policy implications of such practices. Existing Commission and staff guidance address the privacy issues raised by digital advertising and consistently recommend that companies provide truthful and prominent information and choices to consumers about their data collection, use, and sharing practices. See, e.g., FTC, Protecting Consumer Privacy in an Era of Rapid Change: Recommendations For Businesses and Policymakers (Mar. 2012), available at https:// www.ftc.gov/sites/default/files/documents/reports/ federal-trade-commission-report-protecting- consumer-privacy-era-rapid-change- recommendations/20120320privacyreport.pdf (recommending a framework for addressing consumer privacy, including transparency and simplified choice regarding the online collection and use of consumer data for marketing purposes); FTC Staff Report: Self-Regulatory Principles For Online Behavioral Advertising; Tracking, Targeting, and Technology (Feb. 2009), available at www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-staff-report-self- regulatory-principles-online-behavioral- advertising/805406beheavardreport.pdf (setting forth proposed principles related to online behavioral advertising).
51 Deception Policy Statement, 103 F.T.C. at 177–78. For example, special considerations may be relevant in determining whether a natively formatted ad directed to children would be misleading. Id. at 177; cf. Commission Enforcement Policy Statement in regard to Conceivable and Conspicuous Disclosure in Television Advertising, CCH Trade Regulation Reporter, ¶ 7596.09 (Oct. 21, 1970) available at www.ftc.gov/system/files/documents/public_stories/288851701201avad- pp.pdf (disclosures in television ads that are intended to qualify misleading claims, communicated to children “must be written and presented in a manner that would be understood by them and have the capacity to attract their attention”).
52 Deception Policy Statement, 103 F.T.C. at 180.
for ordinary consumers to hear and understand them.60

To be effective, a disclosure also generally must be made contemporaneously with the misleading claim it is intended to qualify. For example, disclosures that subsequently inform consumers of a natively formatted ad’s commercial nature after they have clicked on and arrived at another page will not cure any misleading impression created when the ad is presented in the stream of a publisher site. This approach also reflects and is consistent with longstanding public policy, as codified in the CAN-SPAM Act61 and Telemarketing Fraud Act62 and found in Commission cases,63 that material misrepresentations as to the nature or source of a commercial communication are deceptive, even if the truth is subsequently made known to consumers.

B. Misleading Claims About the Nature or Source of Advertising Are Likely Material

Deception occurs when an ad misleads consumers about a material fact.64 Material facts are those that are important to consumers’ choices or conduct regarding a product.65 Misleading representations or omissions about an advertisement’s true nature or source, including that a party other than the sponsoring advertiser is the source of the advertised product or the

advertisement.66 Consumers with such a misleading impression, for example, are likely to give added credence to advertising messages communicated and to interact with advertising content with which they otherwise would have decided not to interact.67

The Commission presumes that claims made expressly and claims the advertiser intended to make are material.68 The Commission also considers certain misleading formats to be presumptively material. Depending on the facts, false claims that advertising and promotional messages reflect the independent, impartial views, opinions, or experiences of ordinary consumers or experts are presumed material.69 Similarly, the Commission views as material any misrepresentations that advertising content is a news or feature article,70 independent product review,71 investigative report,72 or scientific research or other information from a scientific or other organization.73 Commercial communications that mislead consumers that they are from the government,74 a legitimate business, such as a well-known bank,75 or a marketing surveyor76 also are presumed to be material.

III. Conclusion

Although digital media has expanded and changed the way marketers reach consumers, all advertisers, including digital advertisers, must comply with the same legal principles regarding deceptive conduct the Commission has long enforced. This statement sets forth principles of general applicability on which the Commission will rely in determining whether any particular advertising format is deceptive, in violation of Section 5 of the FTC Act. The Commission will find an advertisement deceptive if the ad misleads reasonable consumers as to its nature or source, including that a party other than the sponsoring advertiser is its source. Misleading representations of this kind are likely to affect consumers’ decisions or conduct regarding the advertised product or the advertisement, including by causing consumers to give greater credence to advertising claims or to interact with advertising content with which they otherwise would not have interacted.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2016–08813 Filed 4–15–16; 8:45 am]
BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0097; Docket 2016–0053; Sequence 6]

Submission for OMB Review; Taxpayer Identification Number Information

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).
ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Taxpayer Identification Number Information. A notice was published in the Federal Register at 81 FR 6514 on February 8, 2016. No comments were received.

DATES: Submit comments on or before May 18, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0097, Taxpayer Identification Number Information.

Instructions: Please submit comments only and cite Information Collection 9000–0097, Taxpayer Identification Number Information, in all correspondence related to this collection. Comments received generally will be posted without change to http://www.regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Contract Policy Division, GSA, 202–501–1448 or email at curtis.glover@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose
In accordance with 31 U.S.C. 7701(c), a contractor doing business with a Government agency is required to furnish its Tax Identification Number (TIN) to that agency. Also, 31 U.S.C. 3325(d) requires the Government to include, with each certified voucher prepared by the Government payment office and submitted to a disbursing official, the TIN of the contractor receiving payment under the voucher. 26 U.S.C. 6050M, as implemented in the Department of Treasury, Internal Revenue Service (IRS) regulations at Title 26 of the Code of Federal Regulations (CFR), requires heads of Federal executive agencies to report certain information to the IRS. 26 U.S.C. 6041 and 6041A, as implemented in 26 CFR, in part, requires payors, including Government agencies, to report to the IRS, on form 1099, payments made to certain contractors.

To comply with the requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the IRS in 26 CFR, FAR clause 52.204–3, Taxpayer Identification, requires a potential Government contractor to submit, among other information, its TIN. The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the contractor’s relationship with the Government. A contractor is not required to provide its TIN on each contract in accordance with FAR clause 52.204–3, Taxpayer Identification, when FAR clause 52.204–7, Central Contractor Registration, is inserted in contracts. FAR clause 52.204–7 requires a potential Federal contractor to provide its TIN in the Central Contractor Registration (CCR) system.

B. Annual Reporting Burden

Respondents: 39,428.
Responses Per Respondent: 3.
Total Responses: 118,284.
Hours Per Response: 10.
Total Burden Hours: 1,182,820.

C. Public Comments
Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0097, Taxpayer Identification Number Information, in all correspondence.

Dated: April 13, 2016.

Lorin S. Curtis,
Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–08871 Filed 4–15–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0175; Docket 2016–0053; Sequence 5]

Submission for OMB Review; Use of Project Labor Agreements for Federal Construction Projects

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement regarding Use of Project Labor Agreements for Federal Construction Projects. A notice published in the Federal Register at 81 FR 6516 on February 8, 2016. No comments were received.

DATES: Submit comments on or before May 18, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect
of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEDOB, Washington, DC 20503.

Additionally submit a copy to GSA by any of the following methods:
- Regulations.gov: http://www.regulations.gov. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link “Submit a Comment” that corresponds with “Information Collection 9000–0175, Use of Project Labor Agreements for Federal Construction Projects”. Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “Information Collection 9000–0175, Use of Project Labor Agreements for Federal Construction Projects” on your attached document.

Instructions: Please submit comments only and cite Information Collection 9000–0175, Use of Project Labor Agreements for Federal Construction Projects, in all correspondence related to this collection. Comments received generally will be posted without change to http://www.regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, Office of Governmentwide Acquisition Policy, at telephone 202–501–0650 or via email to edward.loeb@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR 22.501 prescribes policies and procedures to implement Executive Order 13502, February 6, 2009 which encourages Federal agencies to consider the use of a project labor agreement (PLA), as they may decide appropriate, on large-scale construction projects, where the total cost to the Government is more than $25 million, in order to promote economy and efficiency in Federal procurement. A PLA is a pre-hire collective bargaining agreement with one or more labor organizations that establishes the terms and conditions of employment for a specific construction project. FAR 22.503(b) provides that an agency may, if appropriate, require that every contractor and subcontractor engaged in construction on the project agree, for that project, to negotiate or become a party to a project labor agreement with one or more labor organizations if the agency decides that the use of project labor agreements will—

1. Advance the Federal Government’s interest in achieving economy and efficiency in Federal procurement, producing labor-management stability, and ensuring compliance with laws and regulations governing safety and health, equal employment opportunity, labor and employment standards, and other matters; and,

2. Be consistent with law.

B. Annual Reporting Burden

Respondents: 70.

Responses per Respondent: 1.

Annual Responses: 70.

Hours per Response: 1.

Total Burden Hours: 70.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0175, Use of Project Labor Agreements for Federal Construction Projects, in all correspondence.

Dated: April 13, 2016.

Lorin S. Curit,
Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–08873 Filed 4–15–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES

ADMINISTRATION

NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION

[OMB Control No. 9000–0060; Docket 2016–0053; Sequence 5]

Submission for OMB Review; Accident Prevention Plans and Recordkeeping

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension of an information collection requirement regarding an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Accident Prevention Plans and Recordkeeping. A notice published in the Federal Register at 81 FR 6517 on February 8, 2016. No comments were received.

DATES: Submit comments on or before May 18, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEDOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- Regulations.gov: http://www.regulations.gov. Submit comments via the Federal eRulemaking portal by searching for Information Collection 9000–0060, Accident Prevention Plans and Recordkeeping. Select the link “Comment Now” that corresponds with “Information Collection 9000–0060, Accident Prevention Plans and Recordkeeping”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 9000–0060, Accident Prevention Plans and Recordkeeping” on your attached document.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Contract Policy Division, GSA, telephone 202–501–1448 or email at curtis.glover@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR clause at 52.236–13, Accident Prevention, requires Federal construction contractors to keep records of accidents incident to work performed under the contract that result in death, traumatic injury, occupational disease or damage to property, materials, supplies or equipment. Records of personal inquiries are required by the Department of Labor’s (DOL) Occupational Safety and Health Administration regulations (OSHA). The records maintained by the contractor are used to evaluate compliance and may be used in workmen’s compensation cases. The Federal Acquisition Regulation (FAR) requires records of damage to property, materials, supplies or equipment to provide background information when claims are brought against the Government.

If the contract involves work of a long duration, or hazardous nature, the contracting officer shall insert the clause with its alternate that requires the contractor to submit a written proposed plan for implementing the clause. The plan shall include an analysis of the significant hazards to life, limb, and property inherent in performing the contract and a plan for controlling the hazards. The Accident Prevention Plan (APP) is analyzed by the contracting officer along with the agency safety representatives to determine if the proposed plan will meet the requirements of safety regulations and applicable statutes.

B. Annual Reporting Burden

Respondents: 215.
Responses per Respondent: 1.
Annual Responses: 215.
Hours per Response: 22.

Total Burden Hours: 4,730

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals:
Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0060, Accident Prevention Plans and Recordkeeping, in all correspondence.

Dated: April 13, 2016.

Lorin S. Curit,
Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–08870 Filed 4–15–16; 8:45 am]
BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0159; Docket 2016–0053; Sequence 4]

Submission for OMB Review; Central Contractor Registration

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning the Central Contractor Registration database. A notice was published in the Federal Register at 81 FR 6515 on February 8, 2016. No comments were received.

DATES: Submit comments on or before May 18, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

• Regulations.gov: http://www.regulations.gov. Submit comments via the Federal eRulemaking portal by searching for the OMB control number. Select the link “Submit a Comment” that corresponds with “Information Collection 9000–0159, Central Contractor Registration.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “Information Collection 9000–0159, Central Contractor Registration” on your attached document.

• Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0159, Central Contractor Registration.

Instructions: Please submit comments only and cite Information Collection 9000–0159, Central Contractor Registration, in all correspondence related to this collection. Comments received generally will be posted without change to http://www.regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).
Both current and potential Federal Government vendors are required to register in CCR in order to be awarded contracts by the Federal Government. Vendors are required to complete a one-time registration to provide basic information relevant to procurement and financial transactions. Vendors must update or renew their registration at least once per year to maintain an active status.

The CCR validates the vendor information and electronically shares the secure and encrypted data with Federal agency finance offices to facilitate paperless payments through electronic funds transfer. Additionally, CCR shares the data with Federal Government procurement and electronic business systems.

### B. Annual Reporting Burden

<table>
<thead>
<tr>
<th>Respondents:</th>
<th>110,350.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responses per Respondent:</td>
<td>1.</td>
</tr>
<tr>
<td>Annual Responses:</td>
<td>110,350.</td>
</tr>
<tr>
<td>Hours per Response:</td>
<td>1.7141.</td>
</tr>
<tr>
<td>Total Burden Hours:</td>
<td>189,151.</td>
</tr>
</tbody>
</table>

### C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please citeOMB Control Number 9000–0159, Central Contractor Registration, in all correspondence.

Dated: April 13, 2016.

Lorin S. Carri

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–08872 Filed 4–15–16; 8:45 am]

BILLING CODE 6820–EP–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Agency for Healthcare Research and Quality

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “Making It Easier for Patients to Understand Health Information and Navigate Health Care Systems: Developing Quality Improvement Measures.” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the Federal Register on February 10, 2016 and allowed 60 days for public comment. AHRQ received no substantive comments of the public. The purpose of this notice is to allow an additional 30 days for public comment.

**DATES:** Comments on this notice must be received by May 18, 2016.

**ADDRESSES:** Written comments should be submitted to: AHRQ’s OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ’s desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ’s desk officer).

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@ahrq.hhs.gov.

### SUPPLEMENTARY INFORMATION:

#### Proposed Project

**Making It Easier for Patients To Understand Health Information and Navigate Health Care Systems: Developing Quality Improvement Measures**

A goal of Healthy People 2020 is to increase Americans’ health literacy, defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” The effects of limited health literacy are numerous and serious, including medication non-adherence resulting from patients’ inability to read and comprehend medication labels; underuse of preventive measures, such as vaccines; poor self-management of conditions such as asthma and diabetes; and higher utilization of inpatient and emergency department care. According to the 2003 National Assessment of Adult Literacy, 88% of US adults have significant difficulties understanding widely used health information. By adopting “health literacy universal precautions,” health care providers and organizations can create an environment in which all patients—regardless of health literacy level—can successfully (1) understand health information, (2) navigate the health care system, (3) engage in medical decision-making, and (4) manage their health.

Numerous resources have been developed to support health care organizations in their attempts to address limitations in patient health literacy. However, little work has been done to establish valid quality improvement measures that organizations can use to monitor the impact of initiatives aimed at improving patient understanding, navigation, engagement, and self-management.

Absent such measures, organizations may be unable to accurately assess whether their initiatives are effective.

This research has the following goals:

1. Identify existing quality improvement measures and gather proposals for additional measures (not generated from patient survey data) that organizations may use to monitor progress related to enhancing patient understanding, navigation, engagement, and self-management; and

2. Identify a set of quality improvement measures that reflects patient priorities, has expert support, and can be recommended for more formal measurement and testing.

This project is being conducted by AHRQ through its contractor, Board of Regents of the University of Colorado, pursuant to AHRQ’s statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

### Method of Collection

Environmental Scan Interviews: Representatives from 25 health care organizations engaged in relevant quality improvement efforts will be interviewed to obtain information about the quality improvement measures they
use in assessing their work to improve patient understanding, navigation, engagement, and self-care.

The planned environmental scan interviews will provide the information needed to:

• Identify and document the characteristics of relevant quality improvement measures that are already in use; and
• Identify additional measures that would be useful to stakeholders in the field.

The findings from these interviews will be used, along with the results from other activities (i.e., input from a Technical Expert Panel, literature review, a Request for Information published in the Federal Register, and focus groups with patients), to identify and document a set of quality improvement measures that can be recommended for rigorous testing and validation. Measures that are assessed to be valid and reliable will be eligible to be disseminated by AHRQ to support health care organizations in their efforts to improve patient understanding of health information, navigation of the health care system, engagement in medical decision making, and management of their health.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in Environmental Scan Interviews. The Environmental Scan Interviews will be completed by 50 respondents (2 representatives from each of the 25 organizations targeted for participation).

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Scan Interviews</td>
<td>50</td>
<td>1</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>50</strong></td>
<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Exhibit 2 shows the estimated annual cost burden associated with the respondents’ time to participate in this information collection. The annual cost burden for the Environmental Scan Interviews is estimated to be $4,984.

<table>
<thead>
<tr>
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<td><strong>100</strong></td>
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**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for neuropathic pain associated with peripheral neuropathies. Patient-Focused Drug Development is part of FDA’s performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of neuropathic pain associated with peripheral neuropathies, patient views on treatment approaches, and decision factors taken into account when selecting a treatment.

**DATES:** The public meeting will be held on June 10, 2016, from 10 a.m. to 4 p.m. Registration to attend the meeting must be received by June 3, 2016 (see Supplementary Information for instructions). Submit electronic or
written comments to the public docket by August 10, 2016.

**Addresses:** You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** [http://www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [http://www.regulations.gov](http://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 [http://www.regulations.gov](http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–1110 for “Public Meeting on Patient-Focused Drug Development for Neuropathic Pain Associated with Peripheral Neuropathy.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at [http://www.regulations.gov](http://www.regulations.gov) or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**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.” The Agency 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 [http://www.regulations.gov](http://www.regulations.gov). Submit both copies to the Division of Dockets Management. 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 comments 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 docket, see 80 FR 56469, September 18, 2015, or access the information at: [http://www.fda.gov/regulatoryinformation/dockets/default.htm](http://www.fda.gov/regulatoryinformation/dockets/default.htm).

**Dockets:** For access to the docket to read background documents or the electronic and written/paper comments received, go to [http://www.regulations.gov](http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at: [http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm](http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm).

**For Further Information Contact:** Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–6525, FAX: 301–847–8443, Meghana.Chalasani@fda.hhs.gov.

**Supplementary Information:**

**I. Background on Patient-Focused Drug Development**

FDA has selected neuropathic pain associated with peripheral neuropathy as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for that condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). The full set of performance commitments is available at [http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf](http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf).

FDA committed to obtain the patient perspective on at least 20 disease areas during the course of PDUFA V. For each disease area, the Agency is conducting a public meeting to discuss the disease and its impact on patients’ daily lives, the types of treatment benefit that matter most to patients, and patients’ perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the *Federal Register* (78 FR 21613) announcing the disease areas for meetings in fiscal years (FYs) 2013–2015, the first 3 years of the 5-year PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency’s proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA initiated a second public process for determining the disease areas for FY 2016–2017, and published a notice in the *Federal Register* on July 2, 2015 (80 FR 38216), announcing the selection of eight disease areas. More information, including the list of disease areas and a general schedule of meetings, is posted at [http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm](http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm).

**II. Public Meeting Information**

**A. Purpose and Scope of the Meeting**

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on the impacts of neuropathic pain associated with peripheral neuropathies. Peripheral neuropathy is a neurological disorder that develops as a result of damage to the peripheral nerves and is
associated with both a physical and psychological burden. Nerve damage can be caused by diseases such as diabetes, physical injury, or exposure to drugs or toxins. The pain associated with neuropathies of sensory nerves may be characterized as a pins and needles sensation, as sharp, jabbing, or burning, or as an exaggeratedly intense or distorted pain response to typically nonpainful touch. While there is currently no cure, treatments for the pain associated with peripheral neuropathy include prescription medications and other approaches such as transcutaneous electrical nerve stimulation, braces, and behavioral therapies. FDA is interested in the perspectives of patients with peripheral neuropathy specifically: (1) The impact of neuropathic pain associated with peripheral neuropathy and (2) treatment approaches for the neuropathic pain associated with peripheral neuropathy.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see ADDRESSES).

**Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients**

1. How would you describe your neuropathic pain associated with peripheral neuropathy? What terms would you use to describe the most bothersome aspects of pain? (Examples may include stabbing sensations, electric shocks, burning or tingling, etc.)
2. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your neuropathic pain? (Examples of activities may include sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
3. How do your neuropathic pain and its negative impacts affect your daily life on the best days? On the worst days?
4. How has your neuropathic pain changed over time?
5. What worries you most about your condition?

**Topic 2: Patients’ Perspectives on Current Approaches to Treatment**

1. What are you currently doing to help treat your neuropathic pain associated with peripheral neuropathy? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies). How has your treatment regimen changed over time, and why?
2. How well does your current treatment regimen control your neuropathic pain?
   a. How well have these treatments worked for you as your condition has changed over time?
   b. Would you define your condition today as being well managed?
3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, going to the hospital or clinic for treatment, time devoted to treatment, restrictions on driving, etc.)
4. Assuming there is no complete cure for your neuropathic pain, what specific things would you look for in an ideal treatment for your neuropathic pain? What would you consider to be a meaningful improvement in your condition (for example, specific symptom improvements or functional improvements) that a treatment could provide?
5. If you had the opportunity to consider participating in a clinical trial studying experimental treatments for neuropathic pain, what things would you consider when deciding whether or not to participate? (Examples may include how severe your neuropathic pain is, how well current treatments are working for you, your concern about risks, etc.)

**B. Meeting Attendance and Participation**

If you wish to attend this meeting, visit https://PeripheralNeuropathyPIDD.eventbrite.com. Please register by June 3, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Meghana Chalasani (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to PatientFocused@fda.hhs.gov a brief summary of responses to the topic questions by May 27, 2016. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

**Docket Comments:** Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to topics 1 and 2 to the public docket (see ADDRESSES) by August 10, 2016. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

**Transcripts:** As soon as a transcript is available, FDA will post it at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm.

Dated: April 13, 2016.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–08881 Filed 4–15–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2016–N–1097]

**AbbVie Inc.: Withdrawal of Approval of New Drug Applications for ADVICOR and SIMCOR**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug applications (NDAs) for ADVICOR (niacin extended-release [ER] and lovastatin) tablets and SIMCOR (niacin ER and simvastatin) tablets. The holder of these two applications, AbbVie Inc.,...
has requested that FDA withdraw approval of the applications and has waived its opportunity for a hearing. The Agency has also determined that ADVICOR and SIMCOR were withdrawn from sale for reasons of safety and effectiveness, and FDA will not accept or approve abbreviated new drug applications (ANDAs) that reference ADVICOR or SIMCOR.

DATES: The effective date is April 18, 2016.

ADDRESSES: For access to the dockets to read background documents, go to http://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 Division of Dockets Management (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jay Siltani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6282, Silver Spring, MD 20993–0002, 301–796–5202.

SUPPLEMENTARY INFORMATION:

I. Background

FDA approved NDA 021249 for ADVICOR on December 17, 2001. ADVICOR is a fixed-combination drug product containing niacin ER and lovastatin in tablet form. The drug is approved in four strengths of niacin ER and lovastatin, respectively: (1) 500 mg, 20 mg; (2) 500 mg, 40 mg; (3) 750 mg, 20 mg; (4) 1 g, 20 mg; and (5) 1 g, 40 mg. SIMCOR is approved for the following indications:

• To reduce TC, LDL–C, apolipoprotein B, non-HDL–C, triglycerides (TG), or to increase HDL–C in patients with primary hypercholesterolemia and mixed dyslipidemia when treatment with simvastatin monotherapy or niacin ER monotherapy is considered inadequate
• To reduce TG in patients with hypertriglyceridemia when treatment with simvastatin monotherapy or niacin ER monotherapy is considered inadequate

The labeling includes the following Limitation of Use in the Indications and Usage section of the labeling:

• No incremental benefit of SIMCOR on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin monotherapy and niacin monotherapy has been established.

II. Withdrawal Under Section 505(e) of the FD&C Act

Based on the collective evidence from several large cardiovascular outcome trials (Refs. 1–3.), the Agency has concluded that the totality of the scientific evidence no longer supports the conclusion that a drug-induced reduction in triglyceride levels and/or increase in HDL-cholesterol levels in statin-treated patients results in a reduction in the risk of cardiovascular events. Consistent with this conclusion, FDA has determined that the benefits of ADVICOR and SIMCOR no longer outweigh the risks, and approval should be withdrawn.

FDA requested that AbbVie Inc. voluntarily discontinue marketing of ADVICOR and SIMCOR, and AbbVie Inc. agreed to do so. AbbVie Inc. also has requested in writing that FDA withdraw approval of NDA 021249 and NDA 022078 and waived its opportunity for a hearing.

Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Director of the Center for Drug Evaluation and Research by the Commissioner of Food and Drugs, approval of ADVICOR and SIMCOR is withdrawn. Introduction or delivery for introduction of these products without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The Agency is required to publish a list of all approved drugs (see section 505(j)(7) of the FD&C Act (21 U.S.C. 355(j)(7)). FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.161 and 314.162(a)(2)). For the reasons summarized in this document, the Agency has determined that ADVICOR and SIMCOR were voluntarily withdrawn from sale for reasons of safety or effectiveness. FDA will remove NDA 021249 for ADVICOR and NDA 022078 for SIMCOR from the list of products published in the Orange Book and will not accept or approve ANDAs that reference either drug product.

III. References

The following references are on display in the Division of Dockets Management (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 http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


Dated: April 13, 2016.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–08894 Filed 4–15–16; 8:45 am]

BILLING CODE 4164–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2016–D–0271]

Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled “Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act.” This guidance describes how FDA intends to apply the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to drugs compounded by licensed pharmacists or physicians in State-licensed hospital or health system pharmacies.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work to finalize the guidance, submit either electronic or written comments on this draft guidance by July 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–0271 for “Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• 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.” The Agency 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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 comments 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background
FDA is announcing the availability of a draft guidance for industry entitled “Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act.” Pharmacies located within a hospital or standalone pharmacies that are part of a health system frequently provide compounded drug products for administration within the hospital or health system. Some of these compounds have registered with FDA as outsourcing facilities under section 503B of the FD&C Act (21 U.S.C. 353b) and others are State-licensed pharmacies subject to section 503A of the FD&C Act (21 U.S.C. 353a).

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

• Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements);
• section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and
• section 505 (21 U.S.C. 355) (concerning the approval of drugs under
new drug applications (NDAs) or abbreviated new drug applications (ANDAs).

The guidance describes how FDA intends to apply section 503A of the FD&C Act to drugs compounded by licensed pharmacists or physicians in State-licensed hospital or health system pharmacies.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: April 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–08679 Filed 4–15–16; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0238]

Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” Section 503B defines an outsourcing facility, in part, as “a facility at one geographic location or address.” FDA has received questions from outsourcing facilities and other stakeholders about the meaning of this term, such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards. FDA is issuing this draft guidance to answer these questions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–0238 for “Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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”. The Agency 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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 comments 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the “SUPPLEMENTARY INFORMATION” section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation
This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the meaning of the term “facility at one geographic location or address” under section 503B of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: April 12, 2016.

Leslie Kux, Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1127]

AbbVie Inc. et al; Withdrawal of Approval of Indications Related to the Coadministration With Statins in Applications for Niacin Extended-Release Tablets and Fenofibric Acid Delayed-Release Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the indications related to the coadministration with a statin for niacin extended-release (ER) tablets and fenofibric acid delayed-release (DR) capsules. Affected applications include one new drug application (NDA) and seven abbreviated new drug applications (ANDAs) for niacin ER tablets, and one NDA and three ANDAs for fenofibric acid DR capsules. The holders of these applications have requested that FDA withdraw approval of the indications and have waived their opportunities for a hearing.

DATES: The effective date is April 18, 2016.

ADDRESSES: For access to the docket to read background documents, go to http://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 Division of Dockets Management (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jay Sitlani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6282, Silver Spring, MD 20993–0002, 301–796–5202.

SUPPLEMENTARY INFORMATION:

I. Background

A. Applications for Niacin ER Tablets

FDA first approved NDA 020381 for Niaspan (niacin extended-release) tablets for several indications on July 28, 1997. On March 26, 2009, FDA approved a revised indication that read as follows:

• Niaspan in combination with simvastatin or lovastatin is indicated for the treatment of primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIA and IIb) when treatment with Niaspan, simvastatin, or lovastatin monotherapy is considered inadequate.

In addition, the following Limitation of Use was added to the Indications and Usage section of the labeling:

• No incremental benefit of Niaspan coadministered with simvastatin or lovastatin on cardiovascular morbidity and mortality over and above that demonstrated for niacin, simvastatin, or lovastatin monotherapy has been established. Niaspan has not been studied in Fredrickson Type I and III dyslipidemias.

This indication was revised between March 26, 2009, and April 27, 2015, at which time it was removed from the approved labeling. The Limitation of Use currently reads:

• Addition of Niaspan did not reduce cardiovascular morbidity or mortality among patients treated with simvastatin in a large, randomized controlled trial (AIM–HIGH).

There are seven approved ANDAs that cited Niaspan as the reference listed drug (RLD) and that are approved for the same indications as Niaspan (see table 1).
II. Withdrawal Under Section 505(e) of the FD&C Act

Based on the collective evidence from several large cardiovascular outcome trials (Refs. 1–3), the Agency has concluded that the totality of the scientific evidence no longer supports the conclusion that a drug-induced reduction in triglyceride levels and/or increase in HDL-cholesterol levels in statin-treated patients results in a reduction in the risk of cardiovascular events. Consistent with this conclusion, FDA has determined that the benefits of niacin ER tablets and fenofibric acid DR capsules for coadministration with statins no longer outweigh the risks, and the approvals for this indication should be withdrawn.

FDA requested that the application holders voluntarily discontinue marketing of niacin ER tablets and fenofibric acid DR capsules for these indications. The NDA and ANDA holders identified above have requested in writing that FDA withdraw approval of these indications and waived their opportunity for a hearing.

Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Director of the Center for Drug Evaluation and Research by the Commissioner of Food and Drugs, the approvals for the indications related to coadministration with statins for the applications listed in tables 1 and 2 are withdrawn. Introduction or delivery for introduction of these products with these indications in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

III. References

The following references are on display in the Division of Dockets Management (HFA 305), Food and Drug Administration, 5600 Fishers Lane, Rm. 2025–2026, Rockville, MD 20852, 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 http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


Dated: April 13, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–08987 Filed 4–15–16; 8:45 am]

BILLING CODE 4164–01–P

Table 1—Affected Niacin Products

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Application holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 020381</td>
<td>Niaspan (niacin extended-release tablets)</td>
<td>AbbVie.</td>
</tr>
<tr>
<td>ANDA 076250</td>
<td>Niacin extended-release tablets</td>
<td>Barr.</td>
</tr>
<tr>
<td>ANDA 076378</td>
<td>Niacin extended-release tablets</td>
<td>Barr.</td>
</tr>
<tr>
<td>ANDA 090446</td>
<td>Niacin extended-release tablets</td>
<td>Lupin Ltd.</td>
</tr>
<tr>
<td>ANDA 090860</td>
<td>Niacin extended-release tablets</td>
<td>Lupin Ltd.</td>
</tr>
<tr>
<td>ANDA 090892</td>
<td>Niacin extended-release tablets</td>
<td>Lupin Ltd.</td>
</tr>
<tr>
<td>ANDA 200484</td>
<td>Niacin extended-release tablets</td>
<td>Sun Pharma Global.</td>
</tr>
<tr>
<td>ANDA 201273</td>
<td>Niacin extended-release tablets</td>
<td>Sun Pharma Global.</td>
</tr>
</tbody>
</table>

Table 2—Affected Fenofibric Acid Products

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Application holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 022224</td>
<td>Trilipix (fenofibric acid) delayed-release capsules</td>
<td>AbbVie.</td>
</tr>
<tr>
<td>ANDA 201573</td>
<td>Fenofibric acid delayed-release capsules</td>
<td>Anchen Pharmaceuticals.</td>
</tr>
<tr>
<td>ANDA 200750</td>
<td>Fenofibric acid delayed-release capsules</td>
<td>Lupin Ltd.</td>
</tr>
<tr>
<td>ANDA 200913</td>
<td>Fenofibric acid delayed-release capsules</td>
<td>Mylan Pharmaceuticals Inc.</td>
</tr>
</tbody>
</table>

B. Applications for Fenofibric Acid DR Capsules

FDA approved NDA 022224 for Trilipix (fenofibric acid) DR capsules on December 15, 2008, for several indications, including the following:

- Trilipix is indicated as an adjunct to diet in combination with a statin to reduce TG and increase HDL–C in patients with mixed dyslipidemia and CHD (coronary heart disease) or a CHD risk equivalent who are on optimal statin therapy to achieve their LDL–C goal.
- CHD risk equivalents comprise:
  - Other clinical forms of atherosclerotic disease (peripheral arterial disease, abdominal aortic aneurysm, and symptomatic carotid artery disease);
  - Diabetes; and
  - Multiple risk factors that confer a 10-year risk for CHD >20 percent.

The following Limitation of Use was included in the Indications and Usage section of the labeling:

- No incremental benefit of Trilipix on cardiovascular morbidity and mortality over and above that demonstrated for statin monotherapy has been established.

Both this indication and the Limitation of Use were removed from the labeling on April 27, 2015.

There are three approved ANDAs that cited Trilipix as the RLD and that are approved for the same indications as Trilipix (see table 2).
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1112]

Public Meeting on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a regional public meeting entitled “U.S. Food and Drug Administration and Health Canada Joint Public Consultation on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).” The meeting will take place on the FDA campus and also be broadcast on the Internet. The goal of this meeting is to provide information and receive comments on the ICH, as well as information related to the upcoming ICH meetings in Lisbon, Portugal, in June 2016. The topics to be discussed in the regional public meeting are the topics for discussion at the forthcoming ICH Assembly Meeting. The purpose of this regional public meeting is to solicit public input prior to the next Assembly and Expert Working Group meetings in Lisbon, Portugal, scheduled for June 11 through 16, 2016, at which the discussion of the topics underway and ICH reforms will continue to progress.

DATES: The public meeting will be held on May 6, 2016, from 9 a.m. to 12 p.m., EST. Registration to attend the Webcast and requests for oral presentations must be received by May 4, 2016. Interested persons may submit either electronic or written comments to the public docket (see ADDRESSES) by June 6, 2016.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://www.regulations.gov.
• If you wish 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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fithers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–1112 for “The U.S. Food and Drug Administration and Health Canada Joint Public Consultation on International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.
• 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.” The Agency 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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 comments 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Amanda Roache, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring MD, 20903, 301–796–4548, Amanda.Roache@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The ICH, formerly known as the International Conference on Harmonisation, was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness. In 2015, the ICH was reformed to make the ICH a true global initiative that expands beyond the previous ICH members. More involvement from
regulators around the world is expected, as they will join their counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH Regulatory Members. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development, and their regulation. Additionally, the reforms strengthen ICH as the leading platform for global pharmaceutical regulatory harmonization, and brings together in a transparent manner all key regulatory authorities and industry stakeholders.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. Members of the ICH Management Committee include the European Union; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; Swissmedic; the World Health Organization; and International Federation of Pharmaceutical Manufacturers and Associations (as Observers). The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following Web site: http://www.ich.org. (FDA has verified the Web site addresses as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.)

II. Webcast Attendance and Participation

A. Registration

If you wish to attend this meeting, visit http://ichpublicconsult2016.eventbrite.com. Please register by May 4, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast on the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration must also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Amanda Roache (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the Webcast.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public Webcast. Public oral presentations will be scheduled between approximately 11:30 a.m. and 12 p.m. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Amanda Roache (see FOR FURTHER INFORMATION CONTACT) by April 29, 2016, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation. The agenda for the public Webcast will be made available on the Internet at http://www.fda.gov/Drugs/NewsEvents/ucm488618.htm.

Dated: April 13, 2016.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–08880 Filed 4–15–16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2065]

Radiation Biodosimetry Medical Countermeasure Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled “Radiation Biodosimetry Medical Countermeasure Devices.” FDA has developed this guidance to provide industry and Agency staff with recommendations for the types of information that should be submitted to support marketing authorization for radiation biodosimetry medical countermeasure devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted marked and identified, as confidential,
This guidance provides recommendations for the types of information that should be submitted to support marketing authorization (e.g., the clearance or approval) for radiation biodosimetry medical countermeasure devices (referred to as “biodosimetry devices” or “biosimeters” throughout this document).

This guidance applies to premarket submissions for medical device systems intended to measure biological responses to unintended (non-therapeutic) radiation absorption. Biodosimetry devices are devices used for the purpose of reconstructing the ionizing radiation dose received by individuals or populations using physiological, chemical, or biological markers of exposure found in humans. Biodosimetry technologies may be used at various stages during triage, including both early mass casualty triage and subsequent clinical evaluation. Such exposures could be the result of intentional harm or as a consequence of a disaster. Devices may be designed to give quantitative outputs or qualitative information around a clinical decision making cut-point. Likewise, devices may be designed for use in field triage settings, at patient bedside, or in Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578) certified clinical laboratories. FDA considered both high-throughput and single-use devices in developing this guidance document.

This guidance only applies to validation of diagnostic biodosimetry devices intended to be used to assess radiation absorption that occurs as a result of non-therapeutic or accidental exposures (e.g., a deliberate attack, such as use of an improvised nuclear device, or a natural disaster), and does not apply to medical devices intended to be used to measure doses delivered as a result of radiation therapy nor to devices that measure effects from long-term radiation exposure. In addition, dosimeters, which are devices that detect radiation exposure on a physical substrate rather than through a biological response and are worn by people who might be exposed to radiation during the course of their normal work (such as film badges), are not addressed in this guidance document. Finally, biological assays that might be used to detect the presence of ingested radioisotopes in sputum or urine are not considered in this guidance document.

This guidance document does not provide specific study designs; it describes design principles for studies that may be used to establish a reasonable assurance of the safety and effectiveness of biodosimetry devices.

In the Federal Register of December 30, 2014 (79 FR 78448), the Agency announced the issuance of the draft guidance entitled “Radiation Biodosimetry Medical Countermeasure Devices; Draft Guidance for Industry and Food and Drug Administration Staff.” In the Federal Register of May 28, 2015 (80 FR 30466), FDA reopened and extended the comment period on the draft guidance. The Agency has considered the comments, as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Radiation Biodosimetry Medical Countermeasure Devices.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of “Radiation Biodosimetry Medical Countermeasure Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400045 to identify the document you are requesting.
IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in the guidance document entitled “Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable” have been approved under OMB control number 0910–0582; the collections of information in the guidance document entitled “Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization” have been approved under OMB control number 0910–0607; and the collections of information in the guidance document entitled “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910–0756.

Dated: April 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–08899 Filed 4–15–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2016–D–0269]

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” This guidance sets forth FDA’s policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work to finalize the guidance, submit either electronic or written comments on this draft guidance by July 18, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–0269 for “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• 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.” The Agency 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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 comments 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 docket, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to oira_submission@omb.eop.gov. All comments should be identified with the title, “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Collection of Information.”

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Room 5197, Silver Spring, MD, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” Section 503A (21 U.S.C. 353a), added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or by a licensed physician, to be exempt from applicable statutes and regulations.

- Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements);
- section 352(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and
- section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

A compounded drug product may be eligible for the exceptions under section 503A of the FD&C Act only if it is, among other things, compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. Among other conditions, to qualify for the exemptions under section 503A of the FD&C Act, the drug product must be compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a)).

This guidance sets forth FDA's policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the FD&C Act. It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the prescription requirement under section 503A of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document. With respect to the collection of information associated with this document, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under the draft guidance, if it is not obvious from a prescription order that the prescription is for a compounded drug product, a compounding pharmacist to consult with the prescriber to determine whether the patient needs a compounded drug and make an appropriate notation on the prescription order. To serve as a basis for compounding under section 503A of the FD&C Act, a notation must document the prescriber's determination that a compounded drug is necessary for the identified patient. FDA recommends using the following statement: "[type of communication] with [name of prescriber] on [date], [name of prescriber] has advised that compounded [name of drug] is necessary for the treatment of [name of patient]."

We estimate that annually a total of approximately 3,444 licensed pharmacists and licensed physicians (“number of respondents” in table 1) will make a notation with this statement on approximately 172,200 prescription orders (“total annual disclosures” in table 1). We estimate that the consultation between the compounding pharmacist and the prescriber and adding the written statement to each prescription will take approximately 5 minutes per prescription order.

In addition, the licensed pharmacist or licensed physician seeking to compound a drug product under section 503A should maintain records of valid prescription orders received for compounded drug products to demonstrate compliance with the prescription requirement in section 503A(a)(1) of the FD&C Act. For example, this includes records of valid prescription orders and of prescription orders bearing notations that the compounded drug product is necessary for the identified individual patient as described in section III.A of this guidance and section 503A(a)(1) of the FD&C Act. Because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by licensed pharmacists and licensed physicians in the normal course of their activities, it is excluded from the definition of
“burden” under 5 CFR 1220.3(b)(2). FDA understands that maintaining records of prescriptions for compounded drug products is part of the usual course of the practice of compounding and selling drugs and is required by States’ pharmacy laws and other State laws governing record keeping by health care professionals and health care facilities.

Under the guidance, licensed pharmacists and licensed physicians should also maintain records of the calculations performed to determine the limited quantities of drug products compounded before the receipt of valid prescription orders under the enforcement policy described in section III.B.2 of this guidance and section 503A(a)(2) of the FD&C Act. These records should clearly reflect the quantity of a particular drug product compounded in advance of receiving prescription orders for identified individual patients that the compounder has kept on hand as stock for distribution, and the basis for the quantity the compounder kept in stock. Under the enforcement policy described in section III.B.2 of this guidance, this would include the quantity of the drug product distributed under prescription orders for identified individual patients during the reference period that the licensed pharmacist or licensed physician selected (i.e., a 30-day period within the last year).

We estimate that annually a total of 10,332 licensed pharmacists and licensed physicians (“number of recordkeepers” in table 2) will maintain approximately 103,320 records (“total annual records” in table 2). We estimate that maintaining the records will take approximately 5 minutes per record.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of reporting</td>
</tr>
<tr>
<td>Consultation between the licensed pharmacist or licensed physician and the prescriber and adding a notation to document the prescriber’s determination that a compounded drug is necessary for an identified patient.</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

<table>
<thead>
<tr>
<th>TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of reporting</td>
</tr>
<tr>
<td>Records of calculations performed to determine “limited quantities”.</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

### III. Electronic Access


Dated: April 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2016–08877 Filed 4–15–16; 8:45 am]
BILLING CODE 4164–01–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration**

[Docket No. FDA–2012–N–0427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Inspection by Accredited Persons Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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:** Fax written comments on the collection of information by May 18, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0510. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, 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.

**Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—OMB Control Number 0910–0510—Extension**

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA added a new paragraph (g) to section 704 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. FDA’s guidance document entitled “Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002;
Accreditation Criteria” provides information for those interested in participating in this voluntary program. In the Federal Register of October 21, 2015 (80 FR 63806), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for accreditation</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>80</td>
<td>80</td>
</tr>
</tbody>
</table>

*There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 12, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–08893 Filed 4–15–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1109]

Tobacco Farm Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing an invitation for participation in its voluntary Tobacco Farm Site Tours Program. This program is intended to give CTP staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers and the processes involved in curing and preparing tobacco intended for sale to tobacco product manufacturers. This program is not an FDA regulatory inspection, and tobacco farms are not regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer. The purpose of this notice is to invite parties interested in participating in the Tobacco Farm Site Tours Program to submit requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by June 17, 2016. See section IV of this document for information on requests for participation.

ADDRESSES: If your farm is interested in offering a site visit, please submit a request either electronically to http:// www.regulations.gov or in writing to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Allison Hoffman, Office of Science, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 5426, Silver Spring, MD 20993–0002, 1–877–287–1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing.

CTP’s Office of Science is conducting the Tobacco Farm Site Tours Program to provide its staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers (a “tobacco product manufacturer” is defined as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished tobacco product for sale or distribution in the United States (section 900(20) of the FD&C Act (21 U.S.C. 387(20))). Although farms that grow tobacco are not FDA-regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer (see section 901(c)(2) of the FD&C Act (21 U.S.C. 387a(c)(2))), tobacco farm site visits will aid the Agency in gaining a better understanding of tobacco farming and the processes involved in curing and preparing tobacco leaf intended for sale to tobacco product manufacturers.

The goal for the Tobacco Farm Site Tours Program is for CTP staff to gain firsthand exposure to tobacco farming practices, including cultivation, harvesting, curing, and preparation for sale of tobacco leaf to tobacco product manufacturers.

II. Description of Tobacco Farm Site Tours Program

In the Tobacco Farm Site Tours Program, small groups of CTP staff plan to observe the operations of farms that grow tobacco for sale to tobacco product manufacturers. Please note that FDA does not regulate these farms and the Tobacco Farm Site Tours Program is not an inspection of facilities to determine compliance with the FD&C Act; rather, this program is meant to educate CTP staff and improve their understanding of tobacco farming. It is anticipated that the tobacco farm site tours will take place in the fall of 2016.

III. Site Selection

CTP hopes to be able to tour small, medium, and large farms, and farms that grow tobacco for different kinds of tobacco products. Final site selections will be based on the availability of funds and resources for the relevant fiscal year as well as the desire to visit a wide variety of types of tobacco farms. FDA plans on visiting nine or fewer farms. All FDA travel expenses associated with the farm site tours will be the responsibility of FDA.

IV. Requests for Participation

To aid in site selection, your request for participation should include the following information:

- A description of your farm, including the size of the farm;
- A list of the type(s) of tobacco grown and the kinds of tobacco product manufacturers to whom you sell tobacco;
- The physical address(es) of the site(s) for which you are submitting a request; and
- A proposed 1-day tour agenda.

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than June 17, 2016.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N–39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Black Lung Clinics Program Performance Measures

OMB No. 0915–0292—Extension.

Abstract: The Federal Office of Rural Health Policy (FORHP), HRSA, conducts an annual data collection of user information for the Black Lung Clinics Program, which has been ongoing with OMB approval since 2004. The purpose of the Black Lung Clinics Program is to reduce the morbidity and mortality associated with occupationally related coal mine dust lung disease through the screening, diagnosis, and treatment of active, inactive, retired, and/or disabled coal miners. Collecting this data provides HRSA with information on how well each grantee is meeting the needs of these miners in their communities.

Need and Proposed Use of the Information: Data from the annual report provides quantitative information about the clinics, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type); (b) the characteristics of services provided (medical encounters, non-medical encounters, benefits counseling, and outreach); and, (c) the number of patients served. This assessment enables HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It also ensures that funds are effectively used to provide services that meet the target population needs. HRSA does not plan to make any changes to the performance measures at this time.

Likely Respondents: Black Lung Clinics Program Grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total responses</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black Lung Clinics Program Measures</td>
<td>15</td>
<td>1</td>
<td>15</td>
<td>10</td>
<td>150</td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
<td>1</td>
<td>15</td>
<td>10</td>
<td>150</td>
</tr>
</tbody>
</table>

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,
Director, Division of the Executive Secretariat.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C.,
as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, Household Air Pollution Health Outcomes Trial (UM1).

**Date:** May 10, 2016.

**Time:** 11:00 a.m. to 3:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

**Contact Person:** Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301–496–2434, kristen.page@nih.gov.

**Catalogue of Federal Domestic Assistance Program Nos.** 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS.

Dated: April 12, 2016.

**Anna Snouffer,**
**Deputy Director, Office of Federal Advisory Committee Policy.**

[FR Doc. 2016–08800 Filed 4–15–16; 8:45 am]

**BILLING CODE 4140–01–P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Member Conflicts and Continuous Submissions.

**Date:** April 28, 2016.

**Time:** 11:00 a.m. to 3:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

**Contact Person:** Chee Lin, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 4128, Bethesda, MD 20892, 301–435–1850, limc4@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.


Dated: April 12, 2016.

**Anna Snouffer,**
**Deputy Director, Office of Federal Advisory Committee Policy.**

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) 276–1243.

**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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

**Agency Information Collection Activities: Proposed Collection; Comment Request**

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) is requesting approval for the revision of data collection associated with the previously-approved Monitoring of the National Suicide Prevention Lifeline (OMB No. 0930–0274; Expiration, July 31, 2016). The current request will continue previously-cleared efforts to evaluate process and impacts of follow-up services provided to suicidal individuals through the National Suicide Prevention Lifeline Crisis Center Follow-Up (NSPL Follow-Up) program.

The NSPL, or Lifeline, is SAMHSA’s 24-hour crisis hotline (1–800–273–TALK [8255]) that serves as a central switchboard, seamlessly connecting callers from anywhere in the U.S. to the closest of its 165 crisis centers within the Lifeline network. Since its inception, the Lifeline has helped more than 6 million people. In 2008, SAMHSA launched the NSPL Follow-up program and began awarding cooperative agreements to crisis centers in the Lifeline network to reconnect with suicidal callers to offer emotional support and ensure they followed up with referrals to treatment. In 2013, the program was expanded to include crisis center follow-up with any suicidal individual referred from a partnering emergency department (ED) or inpatient hospital.

While previous evaluations of the NSPL demonstrated that suicidal callers experienced a reduction in hopelessness and suicidal intent after contacting the Lifeline, 43% of suicidal callers participating in follow-up assessments reported some recurrence of suicidality (e.g., ideation, plan, or attempt) since their crisis call (Gould et al., 2007). Even so, only about 35% of suicidal callers set up an appointment and even fewer had been seen by the behavioral health care system to which they were referred (Gould et al., 2007; Kalafat et al., 2007). Similarly, while several randomized, controlled trials have demonstrated that following up by telephone or letter with patients discharged from inpatient or ED settings can reduce rates of repeat suicide attempts (Vaiva et al., 2006), as well as completions (Fleischman et al., 2008; Motto & Bostron, 2001), suicidal individuals discharged from EDs rarely link to ongoing care. As many as 70% of suicide attempters either never attend their first appointment or drop out of...
treatment after a few sessions (Knesper et al., 2010). Thus, it is imperative that EDs and inpatient settings link these individuals to follow-up care.

SAMHSA is addressing this need through the NSPL Follow-Up program. The Monitoring of the NSPL will continue to assess whether the NSPL Follow-Up program achieves its intended goals. This revision of the Monitoring of the NSPL represents SAMHSA’s desire to expand this process and impacts evaluation to assess follow-up with clients referred to the Lifeline from partnering inpatient hospitals and EDs and continue to improve the methods and standards of service delivery to suicidal individuals receiving crisis center services. This effort will build on information collected through previous and ongoing NSPL evaluations; expand our understanding of the outcomes associated with the NSPL Follow-Up program; and continue to contribute to the evidence base.

This revision requests approval for the removal of one previously-approved instrument and the continuation and renaming of five previously-approved activities. Six crisis centers funded through the NSPL Follow-Up program in FY 2016 will participate in this effort.

Instrument Removal
Due to the completion of the motivational interviewing/safety planning (MI/SP) training and the fulfillment of data collection goals, the currently-approved MI/SP Counselor Attitudes Questionnaire and its associated burden will be removed.

Instrument and Consent Revisions
Each of the five instruments and consents associated with the Monitoring of the NSPL was previously approved by OMB (No. 0930–0274; Expiration: July 31, 2016). Revisions include the following: (1) The term “caller” will be replaced with “client” to reflect the change in respondent type to clients referred from partnering EDs and inpatient hospitals rather than callers, and (2) MI/SP will be removed from the titles of all instruments and consents.

No other changes are being made.

The MI/SP Caller Follow-up Interview will be renamed “Client Follow-up Interview.”

The MI/SP Initial Script will be renamed “Client Initial Script.”

The MI/SP Consent Script will be renamed “Client Follow-up Consent Script.”

The MI/SP Follow-up Questionnaire will be renamed “Counselor Follow-up Questionnaire.”

The MI/SP Follow-up Consent will be renamed “Counselor Consent.”

The estimated response burden to collect this information associated with the Monitoring of the NSPL annualized over the requested 3-year approval period is presented below:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Responses per respondent</th>
<th>Total number of responses</th>
<th>Burden per response (hours)</th>
<th>Annual burden (hours)</th>
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<tbody>
<tr>
<td>Client Initial Script</td>
<td>217</td>
<td>1</td>
<td>217</td>
<td>.08</td>
<td>17</td>
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<tr>
<td>Client Initial Refusals</td>
<td>53</td>
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<td>53</td>
<td>.02</td>
<td>1</td>
</tr>
<tr>
<td>Client Follow-up Consent Script</td>
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<td>161</td>
<td>.17</td>
<td>27</td>
</tr>
<tr>
<td>Client Follow-up Consent Refusals</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>.03</td>
<td>1</td>
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<tr>
<td>Client Follow-up Interview</td>
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<td>.67</td>
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<tr>
<td>Counselor Consent</td>
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<td>3</td>
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<tr>
<td>Counselor Follow-up Questionnaire</td>
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<td>15</td>
<td>630</td>
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<td>685</td>
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<td>1,274</td>
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<td>264</td>
</tr>
</tbody>
</table>

* Rounded to the nearest whole number with 0 rounded to 1.

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–B, Rockville, MD, 20857 OR email her a copy at summer.king@samhsa.hhs.gov. Written comments should be received by June 17, 2016.

Summer King, Statistician.

[FR Doc. 2016–08864 Filed 4–15–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs And Border Protection

Accreditation of Dixie Services Inc., as a Commercial Laboratory


ACTION: Notice of accreditation of Dixie Services, Inc., as a commercial laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Dixie Services, Inc., has been accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 9, 2015.

DATES: The accreditation of Dixie Services, Inc., as commercial laboratory became effective on September 9, 2015. The next triennial inspection date will be scheduled for September 2018.


SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 that Dixie Services, Inc., 1706 First St., Galena Park, TX 77547, has been accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12.

Dixie Services, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):...
DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Oiltest, Inc., as a Commercial Gauger and Laboratory


ACTION: Notice of accreditation and approval of Oiltest, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Oiltest, Inc., has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Oiltest, Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

<table>
<thead>
<tr>
<th>API chapters</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Tank gauging.</td>
</tr>
<tr>
<td>7</td>
<td>Temperature determination.</td>
</tr>
<tr>
<td>8</td>
<td>Sampling.</td>
</tr>
<tr>
<td>12</td>
<td>Calculations.</td>
</tr>
<tr>
<td>17</td>
<td>Maritime measurement.</td>
</tr>
</tbody>
</table>

Oiltest, Inc. is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

<table>
<thead>
<tr>
<th>CBPL No.</th>
<th>ASTM</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>27–03</td>
<td>ASTM D 4006</td>
<td>Standard test method for water in crude oil by distillation.</td>
</tr>
<tr>
<td>27–04</td>
<td>ASTM D 4928</td>
<td>Standard test method for water in petroleum products and bituminous materials by distillation.</td>
</tr>
<tr>
<td>27–50</td>
<td>ASTM D 93</td>
<td>Standard test methods for flash point by Pensky-Martens Closed Cup Tester.</td>
</tr>
</tbody>
</table>

Anyone wishing to employ this entity to conduct laboratory analyses should request and receive written assurances from the entity that it is accredited by the U.S. Customs and Border Protection to conduct the specific test requested. Alternatively, inquiries regarding the specific test this entity is accredited to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://www.cbp.gov/about/labs--scientific/commercial-gaugers-and-laboratories

Dated: April 11, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–08930 Filed 4–15–16; 8:45 am]

BILLING CODE 9111–14–P

<table>
<thead>
<tr>
<th>CBPL No.</th>
<th>ASTM</th>
<th>Title</th>
</tr>
</thead>
</table>
Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.

Ira S. Reese,
Executive Director, Laboratories and Scientific Services Directorate.

Dated: April 12, 2016.

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Prior Disclosure


ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Prior Disclosure. This is a proposed extension of information collection requirements that were previously approved. CBP is proposing these requirements be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before May 18, 2016 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oira_submission@omb.eop.gov or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register (81 FR 4326) on January 26, 2016, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Abstract: The Prior Disclosure program establishes a method for a potential violator to disclose to CBP that they have committed an error or a violation with respect to the legal requirements of entering merchandise into the United States, such as underpaid tariffs or duties, or misclassified merchandise. The procedure for making a prior disclosure is set forth in 19 CFR 162.74 which requires that respondents submit information about the merchandise involved, a specification of the false statements or omissions, and what the true and accurate information should be. A valid prior disclosure will entitle the disclosing party to the reduced penalties pursuant to 19 U.S.C. 1592(c)(4).

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 3,500.

Estimated Number of Annual Responses: 3,500.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 3,500.

Dated: April 13, 2016.

Tracey Denning,
Agency Clearance Officer, U.S. Customs and Border Protection.

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0058, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a Federal Register notice, with a 60-day comment period soliciting comments, of the following collection of information on February 10, 2016 (81 FR 7139). The information collection activity provides a means to gather qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery.
DATEs: Send your comments by May 18, 2016. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to oira_submission@omb.eop.gov or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email TSA/PRA@dhs.gov.

SUPPLEMENTARY INFORMATION:
Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available via the link in the footer of http://www.reginfo.gov. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Type of Request: Extension.

OMB Control Number: 1652–0058.

Form(s): NA.

Affected Public: Individuals, Households, Businesses, Organizations, and State, Local or Tribal Governments.

Abstract: The information collection activity provides a means to gather qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery.

From TSA’s perspective, qualitative feedback from customers and stakeholders is information that provides useful insights on their perceptions, experiences, opinions, and expectations regarding TSA products or services, provides TSA with an early warning of issues with service, and focuses attention on areas where changes regarding communication, training, or operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between TSA and its customers and stakeholders. They will also allow feedback to contribute directly to the improvement of program management. The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered by TSA. If this information is not collected, vital feedback from customers and stakeholders on TSA’s services will be unavailable.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature. Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of TSA (if released, TSA must indicate the qualitative nature of the information). Feedback collected under this generic clearance provides useful qualitative information, but it does not yield data that can be generalized to the overall population. Qualitative information is not designed or expected to yield statistically reliable or actionable results; it will not be used for quantitative information collections. Depending on the degree of influence the results are likely to have, there may be future information collection submissions for other generic mechanisms that are designed to yield quantitative results.

Below we provide the Transportation Security Administration’s projected average estimates for the next three years:

Number of Respondents: 7,094,500.

Estimated Annual Burden Hours: An estimated 3,547,250 hours annually.

Dated: April 12, 2016.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2016–08835 Filed 4–15–16; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615—NEW]

Agency Information Collection Activities: Application for Travel Document (Carrier Documentation), Form I–131A; New Collection


ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the Federal Register on October 2, 2015, at 80 FR 59805, allowing for a 60-day public comment period. USCIS did receive two comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until May 18, 2016. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at oira_submission@omb.eop.gov. Comments may also be submitted via fax at (202) 395–5806 (This is not a toll-free number). All submissions received must include the agency name, the OMB Control Number 1615—NEW in the subject box and Docket ID USCIS–2015–0004.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy,
Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377. (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at http://www.uscis.gov or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: http://www.regulations.gov and enter USCIS—2015–0004 in the search box. Written comments and suggestions from the public and affected agencies 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 Request: New Collection.

(2) Title of the Form/Collection: Application for Travel Document Request:

(3) Agency form number, if any, and the applicable component of the DHS sponsoring the collection: Form I–131A; USCIS.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. Certain lawful permanent residents may file Form I–131A to obtain documentation that will allow a commercial carrier to board the lawful permanent resident on a vessel or aircraft destined for the United States without transportation carrier liability.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 15,000 respondents submitting Form I–131A at .92 hours; 15,000 respondents providing biometrics at 1.17 hours.

(6) An estimate of the total public burden (in hours) associated with the collection: 31,300 annual burden hours.

(7) An estimate of the total public burden (in cost) associated with the collection: $7,350,000.

Dated: April 12, 2016.

Samantha Deshommes,

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5858–N–02]

Housing Counseling Federal Advisory Committee; Charter Reestablishment

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of Charter Reestablishment for Housing Counseling Federal Advisory Committee.

SUMMARY: The Department of Housing and Urban Development announces the charter renewal of the Housing Counseling Federal Advisory Committee, a federal advisory committee established pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act and the Federal Advisory Committee Act. This charter renewal will take effect on May 1, 2016, and will expire after 2 years.

FOR FURTHER INFORMATION CONTACT: Marjorie George, Housing Program Technical Specialist, Office of Housing Counseling, U.S. Department of Housing and Urban Development, 200 Jefferson Avenue, Suite 300, Memphis, TN 38103; telephone number 1–901–544–4228 (this is not a toll-free number); email marjorie.a.george@hud.gov. For hearing and speech-impaired persons, this number may be accessed via TTY by calling the Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Background and Authority

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), HUD is giving notice to reestablish the charter for the Housing Counseling Federal Advisory Committee (HCFAC). The HCFAC was established to advise HUD’s Office of Housing Counseling (OHC) to meet its mission to provide individuals and families with the knowledge they need to obtain, sustain, and improve their housing through a strong national network of HUD-approved housing counseling agencies and HUD-certified counselors. The HCFAC, however, shall have no role in reviewing or awarding of OHC housing counseling grants and procurement contracts. See the HCFAC Web site for details at https://www.hudexchange.info/programs/housing-counseling/federal-advisory-committee/.

Dated: April 12, 2016.

Edward L. Golding,
Principal Deputy Assistant Secretary for Housing.

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV500000 L58530000.E40000 241A; N–80613; 10–08807; MO# 4500090192; TAS:14X5232]

Notice of Realty Action: Recreation and Public Purposes Act Classification, Clark County, NV (N–80613)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) has examined and found suitable for classification under the Taylor Grazing Act, and for lease and conveyance under the provisions of the Recreation and Public Purposes (R&PP) Act, as amended, approximately 17.5 acres of public land in Clark County, Nevada. Clark County proposes to use the land for a community park. The 17.5-acre park will help meet future expanding needs in the southwestern part of Las Vegas Valley.

DATES: Interested parties may submit written comments regarding the proposed classification for lease and conveyance of the land until June 2, 2016.
In accordance with the R&PP Act, Clark County has filed an application in which it proposes to develop the above-described land as a community park with children’s playground area, perimeter walking path, picnic shade areas, restroom facilities, athletic facilities, and ancillary equipment. Additional detailed information pertaining to this application, plan of development, and site plan is located in case file N–80613, which is available for review at the BLM Las Vegas Field Office at the above address. Clark County is a political subdivision of the State of Nevada and is therefore a qualified applicant under the R&PP Act.

Subject to limitations prescribed by law and regulation, prior to patent issuance, the holder of any right-of-way grant within the lease area may be given the opportunity to amend the right-of-way grant for conversion to a new term, including perpetuity, if applicable.

The land identified is not needed for any Federal purpose. The lease and conveyance is consistent with the BLM Las Vegas Resource Management Plan dated October 5, 1998, and would be in the public interest. Clark County has not applied for more than the 640 acre limitation for public purpose uses in a year and has submitted a statement in compliance with the regulations at 43 CFR 2741.4(b).

The lease and conveyance, when issued, will be subject to the provisions of the R&PP Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945); and
2. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

Any lease and/or conveyance will also be subject to valid existing rights, will contain any terms or conditions required by law (including, but not limited to, any terms or conditions required by 43 CFR 2741.4), and will contain an appropriate indemnification clause protecting the United States from claims arising out of the lessee’s/patentee’s use, occupancy, or operations on the leased/patented lands. It will also contain any other terms and conditions deemed necessary and appropriate by the Authorized Officer.

Any lease and conveyance will also be subject to all valid and existing rights.

Upon publication of this notice in the Federal Register, the land described above will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease and conveyance under the R&PP Act, leasing under the mineral leasing laws and disposals under the mineral material disposal laws.

Interested parties may submit written comments on the suitability of the land for a public park in the Enterprise area. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Interested parties may also submit written comments regarding the specific use proposed in the application and plan of development, and whether the BLM followed proper administrative procedures in reaching the decision to lease and convey under the R&PP Act.

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. Only written comments submitted to the Field Manager, BLM Las Vegas Field Office, will be considered properly filed. Any adverse comments will be reviewed by the BLM Nevada State Director, who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, the decision will become effective on June 17, 2016. The lands will not be available for lease and conveyance until after the decision becomes effective.

Authority: 43 CFR 2741.5.

Vanessa L. Hice,
Assistant Field Manager, Division of Lands.

DEPARTMENT OF THE INTERIOR
Bureau of Land Management

Notice of Availability of the Final Environmental Impact Statement for the Continental Divide-Creston Natural Gas Development Project, Wyoming

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Rawlins Field Office has prepared a final environmental impact statement (EIS) for the proposed Continental Divide-Creston Natural Gas Development Project (CD–C) in Rawlins, Wyoming, and by this notice announces its availability.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days of the date that the Environmental Protection Agency (EPA) publishes this notice in the Federal Register.

DEPARTMENT OF THE INTERIOR
Bureau of Land Management

Notice of Availability of the Final Environmental Impact Statement for the Continental Divide-Creston Natural Gas Development Project, Wyoming

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Rawlins Field Office has prepared a final environmental impact statement (EIS) for the proposed Continental Divide-Creston Natural Gas Development Project (CD–C) in Rawlins, Wyoming, and by this notice announces its availability.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days of the date that the Environmental Protection Agency (EPA) publishes this notice in the Federal Register.

ADDRESS: The CD–C Final EIS is available for public review at the BLM Rawlins Field Office, 1300 North Third Street, Rawlins, Wyoming; the BLM High Desert District Office, 280 Highway 191 North, Rock Springs, Wyoming; and the BLM Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming. The Final EIS may also be reviewed online at www.blm.gov/wy/st/en/info/NEPA/documents/rfo/cd_creston.html.
Street, Rawlins, WY 82301; or jfleuret@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The IRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: BP America Production Company (BP) and 20 other companies propose to expand development of natural gas resources and condensate (oil) within the existing Continental Divide/Wamsutter II and Creston Blue Gap natural gas fields. More than 4,700 wells have been drilled in the project area since the 1950s under previous authorizations. Existing surface disturbance from natural gas and oil development in the project area is approximately 49,218 acres, including nearly 8,500 acres of long-term disturbance.

The CD–C project would drill and develop up to 8,950 additional natural gas wells (some of which would also produce condensate (oil)), including 100 to 500 coaled methane wells, using a combination of vertical and directional drilling techniques over an estimated 15-year period. The total estimated life of the project is 30 to 40 years and includes approximately 47,200 additional acres of disturbance. Planned facilities would include well pads, gas, condensate and water collection pipelines, compressor stations, water disposal systems, an access road network, and an electrical distribution system. All surface facilities would be removed when the project is completed and the land would be re-contoured to near pre-disturbance condition and re-vegetated with native plant communities.

The project is located in the following area:

**Sixth Principal Meridian**

<table>
<thead>
<tr>
<th>T.</th>
<th>N.</th>
<th>R. W.</th>
<th>Secs. 6, 7, secs. 17 to 20, inclusive, and secs. 29 to 32, inclusive.</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>N.</td>
<td>91 W.</td>
<td>T. 18 N., R. 91 W., Secs. 3 to 10, inclusive, secs. 15 to 21, inclusive, and secs. 28 to 32, inclusive.</td>
</tr>
<tr>
<td>15</td>
<td>N.</td>
<td>92 W.</td>
<td>T. 19 N., R. 91 W., Secs. 1 to 23, inclusive, and secs. 26 to 34, inclusive.</td>
</tr>
<tr>
<td>16</td>
<td>N.</td>
<td>92 W.</td>
<td>T. 20 N., R. 91 W., Secs. 6, 7, 18, 19, 30, and 31.</td>
</tr>
<tr>
<td>21</td>
<td>N.</td>
<td>91 W.</td>
<td>T. 22 N., R. 91 W., Secs. 4 to 9, inclusive, secs. 16 to 21, inclusive, and secs. 28 to 33, inclusive.</td>
</tr>
<tr>
<td>23</td>
<td>N.</td>
<td>91 W.</td>
<td>T. 24 N., R. 91 W., Secs. 4 to 9, inclusive, secs. 16 to 21, inclusive, and secs. 28 to 33, inclusive.</td>
</tr>
<tr>
<td>14</td>
<td>N.</td>
<td>92 W.</td>
<td>T. 15 N., R. 92 W., Secs. 3 to 10, inclusive, secs. 14 to 23, inclusive, and secs. 25 to 36, inclusive.</td>
</tr>
<tr>
<td>16</td>
<td>N.</td>
<td>92 W.</td>
<td>T. 17 N., R. 92 W., Secs. 4 to 8, inclusive, secs. 18, 19, and secs. 29 to 33, inclusive.</td>
</tr>
<tr>
<td>17</td>
<td>N.</td>
<td>92 W.</td>
<td>Tps. 1 to 23, inclusive, and secs. 27 to 34, inclusive.</td>
</tr>
<tr>
<td>18</td>
<td>N.</td>
<td>92 W.</td>
<td>Tps. 18 to 23 N., R. 92 W.</td>
</tr>
<tr>
<td>19</td>
<td>N.</td>
<td>92 W.</td>
<td>Tps. 17 to 23 N., R. 94 W.</td>
</tr>
<tr>
<td>16</td>
<td>N.</td>
<td>95 W.</td>
<td>Secs. 1 to 14, inclusive, secs. 23 to 26, inclusive, secs. 35 and 36.</td>
</tr>
<tr>
<td>17</td>
<td>N.</td>
<td>95 W.</td>
<td>Secs. 1, 2, 3, and secs. 10 to 15, inclusive, secs. 22 to 27, inclusive, secs. 34, 35, and 36.</td>
</tr>
<tr>
<td>18</td>
<td>N.</td>
<td>95 W.</td>
<td>Tps. 16 to 23 N., R. 93 W.</td>
</tr>
<tr>
<td>19</td>
<td>N.</td>
<td>94 W.</td>
<td>Tps. 17 to 23 N., R. 94 W.</td>
</tr>
<tr>
<td>16</td>
<td>N.</td>
<td>95 W.</td>
<td>Secs. 1 to 14, inclusive, secs. 23 to 26, inclusive, secs. 35 and 36.</td>
</tr>
<tr>
<td>17</td>
<td>N.</td>
<td>95 W.</td>
<td>Secs. 1 to 15, inclusive, secs. 22 to 27, inclusive, secs. 34, 35, and 36.</td>
</tr>
<tr>
<td>18</td>
<td>N.</td>
<td>95 W.</td>
<td>Tps. 18 to 24 N., R. 95 W.</td>
</tr>
<tr>
<td>19</td>
<td>N.</td>
<td>95 W.</td>
<td>Tps. 19 to 24 N., R. 93 W.</td>
</tr>
<tr>
<td>16</td>
<td>N.</td>
<td>95 W.</td>
<td>Secs. 1 to 4, inclusive, and secs. 9 to 16, inclusive, those portions of secs. 17, 19, and 20 lying south of the right-of-way granted to the Union Pacific Railroad Company by the United States, serial number WYE–05871; secs. 21 to 36, inclusive.</td>
</tr>
<tr>
<td>20</td>
<td>N.</td>
<td>97 W.</td>
<td>Secs. 1 to 4, inclusive, secs. 9 to 16, inclusive, secs. 21 to 28, inclusive, and secs. 33 to 36, inclusive.</td>
</tr>
<tr>
<td>22</td>
<td>N.</td>
<td>97 W.</td>
<td>Secs. 1, 2, 3, and secs. 10 to 15, inclusive.</td>
</tr>
<tr>
<td>23</td>
<td>N.</td>
<td>97 W.</td>
<td>Secs. 1 to 4, inclusive, secs. 9 to 16, inclusive, secs. 21 to 28, inclusive, and secs. 33 to 36, inclusive.</td>
</tr>
<tr>
<td>24</td>
<td>N.</td>
<td>97 W.</td>
<td>Secs. 8, SE1/4; Sec. 9, S1/2; Sec. 10, S1/2; Sec. 11, S1/2; Sec. 12, S1/2; Secs. 13 to 16, inclusive; Sec. 17, E1/2; Sec. 20, E1/2; Secs. 21 to 28, inclusive; Sec. 29, E1/2; Secs. 33 to 36, inclusive.</td>
</tr>
<tr>
<td>19</td>
<td>N.</td>
<td>98 W.</td>
<td>Those portions of secs. 23 and 24 lying south of the right-of-way granted to the Union Pacific Railroad Company by the United States, serial number WYE–05871; Sec. 25; Those portions of secs. 26 to 31, inclusive, lying south of the right-of-way granted to the Union Pacific Railroad Company by the United States, serial number WYE–05871; Secs. 32 to 36, inclusive.</td>
</tr>
</tbody>
</table>

The CD–C project area includes about 1.1 million acres, or 1,672 square miles, in Carbon and Sweetwater counties, Wyoming. Approximately 626,932 acres (58.6 percent) are administered by the BLM Rawlins Field Office, approximately 48,684 acres (4.5 percent) are State of Wyoming owned and approximately 394,470 acres (36.9 percent) are privately-owned. The project area is bisected by Interstate 80 and extends from 25 miles west of Rawlins, Wyoming, to 50 miles east of Rock Springs, Wyoming.

Cooperating agencies for this EIS include the State of Wyoming, with active participation from many state agencies including the State Planning Office, Wyoming Game and Fish Department, State Historic Preservation Office, the Wyoming Department of Environmental Quality and the Wyoming Department of Agriculture. Regional cooperating agencies include Sweetwater and Carbon counties and the Little Snake River and Sweetwater County conservation districts.

The Notice of Intent to prepare the EIS was published on September 8, 2005 (70 FR 53381), and again on March 3, 2006 (71 FR 10989). Public scoping meetings were held in Rawlins, Wyoming, on October 13, 2005, and on April 6, 2006. Fifty comment letters, faxes and emails were received during the extended scoping period. Key issues identified during scoping include:

- **Air quality:** Potential project and cumulative impacts on air quality, including air quality-related values.
- **Cultural resources:** The impact on the historical trails and historical travel routes in the project area.
- **Hydrology:** Potential degradation of surface and/or groundwater quality by project construction and drilling activities.
- **Land ownership:** The majority of the project area is in the checkerboard pattern of mixed public and private land ownership, complicating landscape scale mitigation on public lands where adjacent sections are nonpublic lands not subject to BLM regulations and requirements.
- **Non-native, invasive plant species:** The effect of current and projected infestations of non-native, invasive species.
- **Rangeland management:** Loss of livestock forage and the impact of project-associated hazardous conditions to area livestock operators.
- **Special-status species:** The impact from project activities upon threatened and endangered and sensitive wildlife species.
- **Socioeconomics:** The impact of the project on traditional socioeconomic indicators.
SUMMARY: The National Park Service has prepared and approved a Record of Decision for the Final Environmental Impact Statement for the Development Concept Plans (DCP) for Katherine Landing and Cottonwood Cove. Approval of the DCP concludes an extensive conservation planning and environmental impact analysis effort that began during 2008.

ADDRESSES: Those wishing to review the Record of Decision may obtain a copy by request to the Superintendent, Lake Mead National Recreation Area, 601 Nevada Way, Boulder City, Nevada 89005 or via telephone request at (702) 293–8978.

FOR FURTHER INFORMATION CONTACT: Michael Boyles, Acting Chief, Resource Management and Visitor Services, (702) 293–8978.

SUPPLEMENTARY INFORMATION: The National Park Service has prepared and approved a Record of Decision for the Final Environmental Impact Statement for the DCP for Cottonwood Cove and Katherine Land. This process was conducted pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4332 et seq.) and the implementing regulations promulgated by the Council on Environmental Quality (40 CFR part 1505.2). The requisite no-action “wait period” was initiated on November 14, 2014, with the Environmental Protection Agency’s Federal Register announcement of the filing of the Final EIS.

Three alternatives, all including mitigation measures, were evaluated during the DCP process. The “agency preferred” Alternative 3 Enhance Visitor Experience and Park Operations has been selected as the approved DCP. All primary project components of the selected alternative will be

DEPARTMENT OF THE INTERIOR

National Park Service

[74 FR 73049], opening a 90-day public comment period. A public meeting was held on January 15, 2013, and the public comment period closed on March 7, 2013. Over 8,000 individual comment letters were received and identified issues such as the lack of a preferred alternative and concerns associated with each of the alternatives, including feasibility, sufficiency of the analysis and impacts to specific resources as a result of each alternative. Comments were considered and incorporated as appropriate into the Final EIS; however, the analysis of the alternatives and the identified impacts did not significantly change.

The Final EIS differs from the Draft EIS by:

• Dropping Alternative A, 100-Percent Vertical Drilling, from consideration due to public comments on feasibility and the magnitude of total disturbance;

• Redefining the No Action Alternative to include an analysis of impacts associated with development on state and private mineral estate in addition to potential development on Federal mineral estate; and

• Including Alternative F, Agency-Preferred Alternative—This alternative responds to Draft EIS scoping concerns and comments by limiting development to eight wellpads per square mile section, requiring that wellpads be placed in the most environmentally suited areas, and creating a CD–C consultation and coordination group to response to evolving energy issues and concerns relating to the project. This alternative is a reconfiguration of elements of alternatives that were analyzed in the Draft EIS. The CD–C consultation and coordination group and protection measures of Alternative F were originally analyzed in the DEIS under Alternative B; and the emphasis on directional drilling was analyzed in Alternative D.

The Final EIS includes potential landscape scale mitigation strategies. Consistent with Secretarial Order No. 3330 and the BLM’s obligations under the Federal Land Policy and Management Act, BLM Wyoming drafted a landscape-scale mitigation appendix, Appendix S, for inclusion in the Final EIS. The appendix has been reviewed by the Washington Office and the cooperating agencies.

Upon conclusion of the 30-day public availability period following the date the EPA publishes the NOA in the Federal Register, the BLM will prepare and sign the record of decision (ROD) to announce its final decision on the Continental Divide-Creston Natural Gas Development Project. Availability of the ROD will be announced to the local media and placed on the project mailing list, and the ROD itself will be posted on the project Web page.
implemented as staffing and funding allow. Key actions include the following:

**Cottonwood Cove**

- Develop new day-use areas (picnic and no-boat areas) in Ski Cove, and designate trail to Cotton Tail Cove; existing day-use areas in Cottonwood Cove remain.
- Phase out trailer village near the end of the next concession contract pending an economic feasibility analysis. Redevelop site for RV use or concession operated overnight accommodations.
- Expand motel as needed; additional structures double capacity and include meeting space (for hosting meetings and other events).
- Maintain character of Mission 66 structures while responding to changing needs to the extent possible.
- Construct engineered system of diversion dikes and concrete channels to convey the 500 year flood to better protect Mission 66 structures while responding to changing needs.
- Maintain the Early Warning Detection System, install flood warning signs, and develop evacuation plan.

**Katherine Landing**

- Remove motel; redevelop site for expanded visitor parking near lake. Provide other forms of overnight accommodations (e.g., RV park with pull-through parking).
- Phase out trailer village near the end of the next concession contract pending an economic feasibility analysis. The site would be redeveloped as part of an expanded, accessible campground that would be concessioner-run and would accommodate larger vehicles (larger sites with pull-through parking and hookups, etc.). Some portion of the campground would retain its current configuration for tent/car camping. Cabins may be part of the mix (exact mix of accommodations to be determined).
- Develop new paved loop serving both north and south areas of the development (housing/administration area to campground loop D).
- Consolidate NPS offices and operations (law enforcement/ emergency, interpretation offices, etc.) in the vicinity of the NPS maintenance area; retain NPS maintenance area in same location.
- Construct engineered system of diversion dikes, channels, and detention basin to convey predicted maximum flood flows through North and South Katherine Washes.
- Install Early Warning Detection System for Katherine Landing; place flood warning signs and develop an evacuation plan for Katherine Landing and North and South Arizona Telephone Coves.

**Princess Cove, Cabinsite Point, and North and South Arizona Telephone Cove**

- Develop new picnic facilities at Cabinsite Point and provide additional parking and allow backcountry camping at some of the former cabin sites.
- Develop picnic area at North Arizona Telephone Cove and design access roads to eliminate or greatly reduce exposure to flood hazards at both North and South Arizona Telephone Coves.
- If launch capacity at Katherine Landing is reduced due to flood control, the park may consider paving and formalizing more of the overflow parking area at Princess Cove and improving the launch at North Arizona Telephone Cove or at Cabinsite Point, to align with established capacity levels set by the Lake Management Plan. The approved development concept plan/environmental impact statement is a programmatic document covering both Cottonwood Cove and Katherine Landing areas. More detailed information will be developed during the individual project design stage.
- Based on this further design information, additional natural and cultural resource surveys and further Section 106 and NEPA compliance will be tiered from this document.

Dated: March 25, 2016.

Patricia L. Neubacher,
Acting Regional Director, Pacific West Region.

[F] [FR Doc. 2016–08837 Filed 4–15–16; 8:45 am]

BILLING CODE 4312–FF–P

**DEPARTMENT OF THE INTERIOR**

**National Park Service**

[NPS–PWR–PWRO–19326; PXPD0004214G001]

**Record of Decision for the Channel Islands National Park General Management Plan/Wilderness Study, Santa Barbara County, California**

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of availability.

**SUMMARY:** The National Park Service (NPS) has prepared and approved a Record of Decision for the Final Environmental Impact Statement (EIS) and General Management Plan/Wilderness Study (GMP/WS) for Channel Islands National Park. Approval of the GMP/WS culminates an extensive public engagement and environmental impact analysis effort that began in 2001.

**ADDRESSES:** Those wishing to review the Record of Decision may obtain a copy by submitting their request to the Superintendent, Channel Islands National Park, 1901 Spinnaker Drive, Ventura, CA 93001.

**FOR FURTHER INFORMATION CONTACT:** Russell Galipeau, Superintendent, telephone (805) 508–5702 or email chis_superintendent@nps.gov.

**SUPPLEMENTARY INFORMATION:** This process was conducted pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and the regulations promulgated by the Council on Environmental Quality (40 CFR part 1505.2). The original Notice of Intent (NOI) initiating the conservation planning and environmental impact analysis process appeared in the Federal Register on November 8, 2001 (66 FR 56575, column 1)—a revised NOI expanding GMP scope to include a wilderness study was published April 8, 2009 (74 FR 16006, column 2). Based on information obtained from extensive public outreach, three alternatives were developed. The NPS consulted with park partners; traditionally associated American Indian tribes and groups; the State Historic Preservation Officer; and other federal and state agencies. The Draft EIS was released on November 14, 2013 (78 FR 68469, column 2), for an extended 90-day review and comment period. Two public meetings were conducted to share information and gather feedback, one of which also included a public hearing on the wilderness study. Overall 1,620 pieces of correspondence were received during the public review period. The Final EIS was released on April 17, 2015. The legally required 30-day “wait period” was initiated on April 17, 2015, with the Environmental Protection Agency’s Federal Register publication of filing of the Final EIS.

The NPS evaluated the environmental consequences of two action alternatives and a no-action alternative. These alternatives described varying means to provide appropriate types and levels of access for visitors and authorized users, preserve wilderness character, protect cultural and natural resources, and adhere to legally required management and preservation objectives. Alternative 3 (agency-preferred) has been selected for implementation. This is also the environmentally-preferred course of action, which emphasizes resource stewardship and preservation while also placing more attention on expanding education and recreational opportunities and accommodations to...
provide diverse visitor experiences on the islands. Wilderness designation is proposed for 1,298 acres on Anacapa, Santa Barbara, Santa Cruz, and Santa Rosa Islands, and additionally on Santa Cruz and Santa Rosa Islands 65,278 acres are identified as potential wilderness.

For a park that includes five remote islands spanning 2,228 square miles of land and sea, the new Channel Islands National Park GMP defines a clear direction for resource preservation and visitor experience over the next 20 to 40 years. The GMP provides a framework for proactive decision making, which will allow park managers to effectively address future opportunities and problems. The approved GMP will also serve as the basis for future detailed management documents, such as five-year strategic plans and project implementation plans.

Dated: September 14, 2015.

Martha J. Lee,
Acting Regional Director, Pacific West Region.

Editorial Note: This document was received for publication by the Office of the Federal Register on April 12, 2016. [FR Doc. 2016–08841 Filed 4–15–16; 8:45 am]

BILLING CODE 4312–FF–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1070B (Second Review)]

Certain Tissue Paper Products From China; Cancellation of Hearing for Full-Five-Year Review


ACTION: Notice.

DATES: Effective Date: April 12, 2016.

FOR FURTHER INFORMATION CONTACT: Justin Enck (202) 205–3363), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov). The public record for this review may be viewed on the Commission’s electronic docket (EDIS) at http://edis.usitc.gov.

SUPPLEMENTARY INFORMATION: Effective January 6, 2016, the Commission established a schedule for the conduct of this review (81 FR 1643, January 13, 2016). Subsequently, counsel for the domestic interested parties filed a request to appear at the hearing and for consideration of cancellation of the hearing. Counsel indicated a willingness to submit written testimony and responses to any Commission questions in lieu of an actual hearing. No other party has entered an appearance in this review. Consequently, the public hearing in connection with this review, scheduled to begin at 9:30 a.m. on Thursday, April 28, 2016, at the U.S. International Trade Commission Building, is cancelled. Parties to this review should respond to any written questions posed by the Commission in their posthearing briefs, which are due to be filed on May 5, 2016.

For further information concerning this review see the Commission’s notice cited above and the Commission’s Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission’s rules.

By order of the Commission.
Issued: April 12, 2016.

Lisa R. Barton,
Secretary to the Commission.
[FR Doc. 2016–08797 Filed 4–15–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–930]

Certain Laser Abraded Denim Garments; Commission Determination To Review Order No. 43, and on Review Vacating That Order as Moot; Termination of the Investigation


ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to review Order No. 43 issued by the presiding administrative law judge (“ALJ”). On review, the Commission has determined to vacate Order No. 43 because the law firm disqualification at issue has become moot. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov). The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at http://edis.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: The Commission instituted this investigation on September 23, 2014, based on a complaint filed by RevoLaze, LLC and TechnoLines, LLC, both of Westlake, Ohio (collectively, “RevoLaze”), 79 Fed Reg. 56828 (Sept. 23, 2014). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, by reason of the importation into the United States, the sale for importation, and the sale within the United States after importation of certain laser abraded denim garments. The complaint alleged the infringement of seventy-one claims of six United States patents. The notice of institution named twenty respondents, including The Gap, Inc. of San Francisco, California (“Gap”), who, one-by-one were terminated from the investigation. On November 3, 2015, the Commission terminated the last remaining respondents from the investigation on the basis of settlement and withdrawal of the complaint. 80 FR Reg. 73209, 73210 (Nov. 24, 2015).

However, previously in the investigation, the then-presiding ALJ disqualified complainants’ counsel Dentons US LLP (“Dentons US”) in an order that was not an initial determination (“ID”). Order No. 43 (May 7, 2015). Subsequently, the ALJ granted (as an ID) Dentons US’s motion to intervene regarding its disqualification, Order No. 82 (Aug. 7, 2013), but denied (as an order) its motion for reconsideration of Order No. 43 as well as its request for leave to seek interlocutory review before the Commission. Order No. 103 (Aug. 7, 2015); see 19 CFR 210.24 (interlocutory review by the Commission). The
Commission determined not to review Order No. 82, Notice (Aug. 26, 2015).

On October 27, 2015, in response to the issuance of an ID (Order No. 106), which terminated the investigation before the ALJ, Dentons US filed a petition for Commission review of Order Nos. 43 and 83. See 19 CFR 210.24 (rulings by the ALJ “on motions may not be appealed to the Commission prior to the administrative law judge’s issuance of an initial determination”). On November 3, 2015, and November 9, 2015, the Office of Unfair Import Investigations and Gap, respectively, opposed Dentons’ petition.

The Commission has determined to review Order No. 43, and, on review, has determined to vacate the disqualification decision as moot. In view of the final disposition of the investigation as to all respondents, the issue of Dentons US’s disqualification has no practical effect on this investigation.

Although the Commission has the discretion to address issues that have become moot, it has determined not to do so here. The disqualification in this investigation turns on whether Dentons US and Dentons Canada LLP as members of Salans FMC Denton Group (“Dentons Verein”) should be treated as a single law firm under the American Bar Association’s Model Rules of Professional Conduct (”Model Rules”) in this investigation. Answering that question would require further proceedings, and potentially additional factfinding. In particular, Comment 2 to Model Rule 1.0 sets forth several factors to consider in determining whether a group of lawyers constitute a law firm, including (1) how the lawyers present themselves to the public, (2) whether the lawyers conduct themselves as a law firm, (3) the terms of any formal agreement among the lawyers, and (4) whether the lawyers have mutual access to client information. Here, the record lacks sufficient evidence on these factors, especially as to the third factor, because the Dentons Verein organizational agreements have not been made part of the record of the investigation. The Commission has decided that the added delay, burdens, and expenses that would be incurred by the parties and the Commission in resolving these issues are unjustified given the termination of the investigation as to all respondents.

Accordingly, the Commission has determined to review and vacate Order No. 43, without deciding whether the disqualification in this investigation was appropriate. The reasoning in support of the Commission’s decision will be set forth more fully in a forthcoming opinion.

In light of its determination above, the Commission has determined not to review Order No. 83, which denied as untimely a motion of Dentons US and Revolaze for reconsideration of Order No. 43 or for interlocutory review by the Commission.

The Commission notes that in April 2016, it received several submissions from RevoLaze and Dentons US after the deadlines for submissions set forth in 19 CFR 210.43 had passed. The Commission rejects these submissions as untimely and procedurally improper, and did not consider them in making its determination.


Issued: April 12, 2016.

By order of the Commission.

Lisa R. Barton,
Secretary to the Commission.

DEPARTMENT OF JUSTICE
Antitrust Division


Notice is hereby given that, on March 18, 2016, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. (“the Act”), IMS Global Learning Consortium, Inc. (“IMS Global”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Baltimore City Public Schools, Baltimore, MD; Broward Community College, Fort Lauderdale, FL; exploration, Montreal, Quebec, CANADA; its learning, Bergen, NORWAY; Katy Independent School District, Katy, TX; and Purdue University, West Lafayette, IN, have been added as parties to this venture. Also, EUN Partnership AISBL, Brussels, BELGIUM; Open Universiteit Nederland, Hooren, THE NETHERLANDS; D.E. Solution sprl, Brussels, BELGIUM; Poway Unified School District, Poway, CA; American Institutes for Research, Washington, DC; University of Bridgeport, Bridgeport, CT; and Gutenberg Technology, Cambridge, MA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and IMS Global intends to file additional written notifications disclosing all changes in membership.

On April 7, 2000, IMS Global filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to section 6(b) of the Act on September 13, 2000 (65 FR 55283).

The last notification was filed with the Department on December 29, 2015. A notice was published in the Federal Register pursuant to section 6(b) of the Act on January 22, 2016 (81 FR 3820).

Patricia A. Brink,
Director of Civil Enforcement, Antitrust Division.

DEPARTMENT OF JUSTICE
Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on March 23, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. (“the Act”), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Arista Networks, Santa Clara, CA; Cisco International Limited, Feltham, UNITED KINGDOM; Coveloz Technologies, Inc., Kanata, CANADA; Masstech Innovations, Markham, Ontario, CANADA; Iain Collins (individual member), London, UNITED KINGDOM; Gabor Forgacs (individual member), Budapest, HUNGARY; Laurence Hughes
DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Cody Laboratories, Inc.

ACTION: Notice of registration.

SUMMARY: Cody Laboratories, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Cody Laboratories, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated December 4, 2015, and published in the Federal Register on December 10, 2015, 80 FR 76709, Cody Laboratories, Inc., 601 Yellowstone Avenue, Cody, Wyoming 82414 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cody Laboratories, Inc. to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the company’s compliance with state and local laws, and reviewing the company’s background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydromorphine (9145)</td>
<td>I</td>
</tr>
<tr>
<td>Amphetamine (1100)</td>
<td>II</td>
</tr>
<tr>
<td>Methamphetamine (1105)</td>
<td>II</td>
</tr>
<tr>
<td>Methylphenidate (1724)</td>
<td>II</td>
</tr>
<tr>
<td>Amobarbital (2125)</td>
<td>II</td>
</tr>
<tr>
<td>Pentobarbital (2270)</td>
<td>II</td>
</tr>
<tr>
<td>Secobarbital (2315)</td>
<td>II</td>
</tr>
<tr>
<td>4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333)</td>
<td>II</td>
</tr>
<tr>
<td>Phenylacetonine (8501)</td>
<td>II</td>
</tr>
<tr>
<td>Cocaine (9041)</td>
<td>II</td>
</tr>
<tr>
<td>Codeine (9050)</td>
<td>II</td>
</tr>
<tr>
<td>Dihydrocodeine (9120)</td>
<td>II</td>
</tr>
<tr>
<td>Oxycodone (9143)</td>
<td>II</td>
</tr>
<tr>
<td>Hydromorphone (9150)</td>
<td>II</td>
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<tr>
<td>Diphenoxylate (9170)</td>
<td>II</td>
</tr>
<tr>
<td>Egonine (9180)</td>
<td>II</td>
</tr>
<tr>
<td>Hydrocodone (9193)</td>
<td>II</td>
</tr>
<tr>
<td>Meperidine (9230)</td>
<td>II</td>
</tr>
<tr>
<td>Methadone (9250)</td>
<td>II</td>
</tr>
<tr>
<td>Methadone intermediate (9254)</td>
<td>II</td>
</tr>
<tr>
<td>Morphine (9300)</td>
<td>II</td>
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<tr>
<td>Thebaine (9333)</td>
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<tr>
<td>Oxymorphone (9652)</td>
<td>II</td>
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<tr>
<td>Alfentanil (9737)</td>
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</tr>
<tr>
<td>Remifentanil (9739)</td>
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<tr>
<td>Sufentanil (9740)</td>
<td>II</td>
</tr>
<tr>
<td>Tapentadol (9780)</td>
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</tr>
<tr>
<td>Fentanyl (9801)</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans to manufacture the listed controlled substances in bulk for sale to its customers.

Dated: April 11, 2016.

Louis J. Milone,
Deputy Assistant Administrator.

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Registration: Research Triangle Institute

[Docket No. DEA–392]

ACTION: Notice of registration.

SUMMARY: Research Triangle Institute applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Research Triangle Institute registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated July 29, 2015, and published in the Federal Register on August 4, 2015, 80 FR 46330, Research Triangle Institute, Kenneth S. Rehder, Hermann Building East Institute Drive, Room 106, Research Triangle Park, North Carolina 27709–2194 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Research Triangle Institute to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the company’s compliance with state and local laws, and reviewing the company’s background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB—PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide) (7023)</td>
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<tr>
<td>AB—CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide) (7031)</td>
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<tr>
<td>AM–2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl indole) (7201)</td>
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<td>Controlled substance</td>
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<td>AM–694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole) (7694)</td>
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<td>JW–018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl) indole) (7118)</td>
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<td>JW–073 (1-Butyl-3-(1-naphthoyl) indole) (7173)</td>
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<td>JW–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl) indole) (7200)</td>
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<td>JW–290 (1-Pentyl-3-(2-methoxyphenylacetyl) indole) (6250)</td>
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<td>JW–019 (1-Hexyl-3-(1-naphthoxyl) indole) (7019)</td>
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<td>JW–081 (1-Pentyl-3-(1-(4-methoxy naphthoyl) indole) (7081)</td>
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<td>JW–122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole) (7122)</td>
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<td>JW–203 (1-Pentyl-3-(2-chlorophenylacetyl) indole) (7203)</td>
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<td>JW–398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole (7398)</td>
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<td>THU–2201 (1-(5-Fluoropentyl)-1H-indazol-3-yl)naphthalen-1-yl)methanone (7024)</td>
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<td>1-1-Phenylcyclohexyl)pyrrolidin (7458)</td>
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<td>1-1-(2-Thienyl)cyclohexyl)piperidin (7470)</td>
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<td>1-Methyl-4-phenyl-4-propionoxyiperidin (9661)</td>
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<td>1-(2-Phenylethyl)-4-phenyl-4-acetoxyiperidin (9663)</td>
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<td>2,5-Dimethoxy-4-(n-propyl) phenethylamine (2C–T–7) (7348)</td>
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<td>2,5-Dimethoxy-4-ethylamphetamine (7399)</td>
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<td>2,5-Dimethoxyamphetamine (7396)</td>
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<td>2-(2,5-Dimethoxy-4-ethyl) phenylamine (2C–E) (7509)</td>
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<td>2-(2,5-Dimethoxyphenyl) ethanamine (2C–H) (7517)</td>
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<td>2-(2,5-Dimethoxy-2-nitro-phenyl) ethanamine (2C–N) (7521)</td>
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<td>2-(2,5-Dimethoxy-4-n-propylphenyl) ethanamine (2C–P) (7524)</td>
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<td>2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine (2C–I) (7518)</td>
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<td>2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (2C–C) (7519)</td>
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<td>3,4,5-Trimethoxyamphetamine (7390)</td>
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<td>Racemoramide (9645)</td>
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<td>SR-18 (Also known as RCS-8) (1-Cyclohexyl-1-piperidinyl(2-methoxyphenethyl) indole) (1704)</td>
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<td>SR-19 (Also known as RCS-4) (1-Pentyl-3-(4-methoxy)-benzoyl indole) (1704)</td>
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<td>Controlled substance</td>
<td>Schedule</td>
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<td>Tetrahydrocannabinols (7370)</td>
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<td>1-Piperidinocyclohexaneuronitrile (8603)</td>
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<td>4-Anilino-N-phenethyl-4-piperidine (ANPP) (9333)</td>
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<td>Alfentanil (9737)</td>
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<tr>
<td>Phenmetrazine (1631)</td>
<td>II</td>
</tr>
<tr>
<td>Phenylacetone (8501)</td>
<td>II</td>
</tr>
<tr>
<td>Pininodine (9730)</td>
<td>II</td>
</tr>
<tr>
<td>Ractemethorphan (9732)</td>
<td>II</td>
</tr>
<tr>
<td>Racemorphor (9735)</td>
<td>II</td>
</tr>
<tr>
<td>Remifanital (9738)</td>
<td>II</td>
</tr>
<tr>
<td>Secobarbital (2315)</td>
<td>II</td>
</tr>
<tr>
<td>Sufentanil (9740)</td>
<td>II</td>
</tr>
<tr>
<td>Tapentadol (9780)</td>
<td>II</td>
</tr>
<tr>
<td>Thebaie (9333)</td>
<td>II</td>
</tr>
</tbody>
</table>
The company plans to import small quantities of the listed controlled substances for the National Institute on Drug Abuse (NIDA) for research activities.

The company plans to import analytical reference standards for distribution to its customers for research and analytical purposes. Placement of these drug codes onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: April 11, 2016.

Louis J. Milione,
Deputy Assistant Administrator.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Johnson Matthey, Inc.

ACTION: Notice of registration.

SUMMARY: Johnson Matthey, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Johnson Matthey, Inc. registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated December 21, 2015, and published in the Federal Register on December 29, 2015, 80 FR 81367, Johnson Matthey, Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey 08066–1742 applied to be registered as an importer of certain basic classes of controlled substances. Comments and request for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007). Also no comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Johnson Matthey, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the company’s compliance with state and local laws, and reviewing the company’s background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coca Leaves (9040)</td>
<td>II</td>
</tr>
<tr>
<td>Thebaine (9933)</td>
<td>II</td>
</tr>
<tr>
<td>Opium, raw (9600)</td>
<td>II</td>
</tr>
<tr>
<td>Noroxymorphone (9668)</td>
<td>II</td>
</tr>
<tr>
<td>Poppy Straw Concentrate (9670)</td>
<td>II</td>
</tr>
<tr>
<td>Fentanyl (9801)</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans to import thebaine derivatives and fentanyl as reference standards.

The company plans to import the remaining listed controlled substances as raw materials, to be used in the manufacture of bulk controlled substances, for distribution to its customers. Placement of these drug codes onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances.

Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: April 11, 2016.

Louis J. Milione,
Deputy Assistant Administrator.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Meridian Medical Technologies

ACTION: Notice of registration.

SUMMARY: Meridian Medical Technologies applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Meridian Medical Technologies registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION: By notice dated November 27, 2015, and published in the Federal Register on December 3, 2015, 80 FR 75691, Meridian Medical Technologies, 2555 Hermelin Drive, Saint Louis, Missouri 63144 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Meridian Medical Technologies to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the company’s compliance with state and local laws, and reviewing the company’s background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of morphine (9300), a basic class of controlled substance listed in schedule II.

The company manufactures a product containing morphine in the United States. The company exports this product to customers around the world. The company has been asked to ensure that its product, which is sold to European customers, meets the standards established by the European Pharmacopoeia, administered by the Directorate for the Quality of Medicines (EDQM). In order to ensure that its product will meet European specifications, the company seeks to import morphine supplied by EDQM for use as reference standards.

This is the sole purpose for which the company will be authorized by the DEA to import morphine.

Dated: April 11, 2016.

Louis J. Milione,
Deputy Assistant Administrator.
DEPARTMENT OF JUSTICE
[CPCL Order No. 001–2016]

Privacy Act of 1974; System of Records

AGENCY: Federal Bureau of Prisons, Department of Justice.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, 5 U.S.C. 552a, and Office of Management and Budget (OMB) Circular No. A–130, notice is hereby given that the Federal Bureau of Prisons (Bureau or BOP), Department of Justice (Department or DOJ) proposes to amend an existing Bureau system of records notice titled, “Inmate Central Records System, JUSTICE/BOP–005”, last modified at 77 FR 24982, on April 26, 2012. The Bureau is amending routine use (i) to notify the public that the Bureau will be sharing federal inmate records with the U.S. Department of Veterans Affairs (VA) for matching purposes broader than are covered specifically under 38 U.S.C. 5106, Public Law 94–432.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), the public is given a 30-day period in which to comment. Therefore, please submit any comments by May 18, 2016.

FOR FURTHER INFORMATION CONTACT: Wanda Hunt, Privacy Officer, Bureau of Prisons, 320 First Street NW., Washington, DC 20530, or by facsimile at (202) 307–0693.

SUPPLEMENTARY INFORMATION: The Bureau last published a modified Bureau of Prisons Privacy Act system of records notice on April 26, 2012, titled “Inmate Central Records System,” JUSTICE/BOP–005, to reflect a number of changes to the notice, including changes reflecting the overall modernization and technological changes of the Bureau’s electronic information systems. This system of records is maintained by the Bureau to cover records relating to the care, classification, subsistence, protection, discipline, and programs of federal inmates. In this modification, the Bureau proposes to modify an existing routine use, paragraph “(i),” which was also modified pursuant to the April 26, 2012, system of records notice modification, to allow records from the Inmate Central Records System to be disclosed to any United States Veterans Administration entity or official for the purpose of matching those Bureau records against VA records to determine the eligibility or potential eligibility of Bureau inmates to receive benefits and/or services. The modification will enable BOP to more efficiently: (1) Identify inmates who may potentially be eligible for VA services upon release, (2) assist those inmates while in custody by providing to them information useful for seeking VA services upon release, and (3) evaluate which inmates may be in greater need than the general BOP population for certain BOP-provided inmate services while in custody. The modification will also remove the requirement stating “the VA is to erase the Bureau data after the match has been made” for two reasons. First, this erasure clause may unnecessarily force the VA to immediately erase data, creating difficulty for validation, auditing, and other legitimate purposes. Second, the VA is required to protect the records under the Privacy Act, and erase the data as required by the applicable disposition schedule approved by the National Archives. This system of records notice modification will not affect the existing Privacy Act exemption regulations claimed by the Attorney General.

In accordance with 5 U.S.C.552a(r), the Department has provided a report to OMB and Congress on this modified system of records.

Dated: April 8, 2016.

Erika Brown Lee,
Chief Privacy and Civil Liberties Officer,
United States Department of Justice.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

(i) To the United States Department of Veterans Affairs (VA), for the purpose of matching the records against VA records to determine the eligibility or potential eligibility of Bureau inmates to receive veterans’ benefits and/or services.

DEPARTMENT OF JUSTICE
[Docket No. ODAG 160]

National Commission on Forensic Science Solicitation of Applications for Additional Commission Membership To Support Digital Evidence

AGENCY: Department of Justice.

ACTION: Notice of solicitation of applications for additional commission membership for the National Commission on Forensic Science specifically to fill a current vacancy to support digital evidence.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, this notice announces the solicitation of applications for additional Commission membership to fill a current vacancy to support digital evidence.

DATES: Applications must be received on or before May 18, 2016.

ADDRESS: All applications should be submitted to: Jonathan McGrath, Designated Federal Official, 810 Seventh St. NW., Washington, DC 20531, or by email at Jonathan.McGrath@usdoj.gov.

FOR FURTHER INFORMATION CONTACT: Jonathan McGrath, Designated Federal Official, 810 Seventh St. NW., Washington, DC 20531, by email at Jonathan.McGrath@usdoj.gov, or by phone at (202) 514–6277.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. App.), this notice announces the solicitation of applications for additional Commission membership on the National Commission on Forensic Science to fill current vacancies. The National Commission on Forensic Science was chartered on April 23, 2013 and the charter was renewed on April 23, 2015. There is currently a Commissioner vacancy to support digital evidence. This notice announces the solicitation of applications for Commission membership to fill the digital evidence vacancy.

The Commission is co-chaired by the Department of Justice and National Institute of Standards and Technology. The Commission provides recommendations and advice to the Department of Justice concerning national methods and strategies for: Strengthening the validity and reliability of the forensic sciences (including medicolegal death investigation); enhancing quality assurance and quality control in forensic science laboratories and units; identifying and recommending scientific guidance and protocols for
Each application should include: (1) A statement of interest describing the applicant’s relevant experience; and (3) a statement of support from the applicant’s employer. Potential candidates may be asked to provide detailed information as necessary regarding financial interests, employment, and professional affiliations to evaluate possible sources of conflicts of interest. The application period will remain open through May 18, 2016. The applications must be sent in one complete package, by email, to Andrew Bruck (contact information above) with the subject line of the email entitled, “NCFS Membership 2016.” Other sources, in addition to the Federal Register notice, may be utilized in the solicitation of applications.

Dated: April 12, 2016.

Andrew Bruck,
Senior Counsel, Office of the Deputy Attorney General.

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Program Year (PY) 2016 Workforce Innovation and Opportunity Act (WIOA) Allotments; PY 2016 Wagner-Peyser Act Final Allotments and PY 2016 Workforce Information Grants

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This notice announces allotments for PY 2016 for WIOA Title I Youth, Adults and Dislocated Worker Activities programs; final allotments for Employment Service (ES) activities under the Wagner-Peyser Act for PY 2016 and Workforce Information Grants allotments for PY 2016.

WIOA allotments for States and the State final allotments for the Wagner-Peyser Act are based on formulas defined in their respective statutes. WIOA requires allotments for the outsourcing areas to be competitively based rather than based on a formula determined by the Secretary of Labor (Secretary) as occurred under the Workforce Investment Act (WIA). For PY 2016, the Consolidated Appropriations Act, 2016 waives the competition requirement, and the Secretary is using the discretionary formula rationale and methodology for allocating PY 2016 funds for the outsourcing areas (American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, and the United States Virgin Islands) that was published in the Federal Register at 65 FR 8236 (Feb. 17, 2000). WIOA specifically included the Republic of Palau as an outsourcing area, except during any period for which the Secretary of Labor and the Secretary of Education determine that a Compact of Free Association is in effect and contains provisions for training and education assistance prohibiting the assistance provided under WIOA; no such determinations prohibiting assistance have been made. The formula that the Department of Labor (Department) used for PY 2016 is the same formula used in PY 2015 and is described in the section on Youth Activities program allotments.

Comments are invited on the formula used to allot funds to the outsourcing areas.

DATES: Comments on the formula used to allot funds to the outsourcing areas must be received at the designated place by the date specified above.

ADDRESSES: Submit written comments to the Employment and Training Administration (ETA), Office of Financial Administration, 200 Constitution Avenue NW., Room N–4702, Washington, DC 20210, Attention: Ms. Anita Harvey, email: harvey.anita@ dol.gov.

Commenters are advised that mail delivery in the Washington area may be delayed due to security concerns. Hand-delivered comments will be received at the above address. All overnight mail will be considered to be hand-delivered and must be received at the designated place by the date specified above.

Please submit your comments by only one method. The Department will not review comments received by means other than those listed above or that are received after the comment period has closed.

Comments: The Department will retain all comments on this notice and will release them upon request via email to any member of the public. The Department also will make all the comments it receives available for public inspection by appointment during normal business hours at the above address. If you need assistance to review the comments, the Department will provide you with appropriate aids such as readers or print magnifiers. The Department will make copies of this notice available, upon request, in large print, Braille and electronic file. The Department also will consider providing the notice in other formats upon request. To schedule an appointment to review the comments and/or obtain the notice in an alternative format, contact Ms. Harvey using the information provided above. The Department will
retain all comments received without making any changes to the comments, including any personal information provided. The Department therefore cautions commenters not to include their personal information such as Social Security Numbers, personal addresses, telephone numbers, and email addresses in their comments; this information would be released with the comment if the comments are requested. It is the commenter’s responsibility to safeguard his or her information.

**FOR FURTHER INFORMATION CONTACT:**
WIOA Youth Activities allotments—Evan Rosenberg at (202) 693–3593 or LaSharn Youngblood at (202) 693–3606; WIOA Adult and Dislocated Worker Activities and ES final allotments—Robert Kight at (202) 693–3937; Workforce Information Grant allotments—Donald Haughton at (202) 693–2784. Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

**SUPPLEMENTARY INFORMATION:** The Department is announcing WIOA allotments for PY 2016 for Youth Activities, Adults and Dislocated Worker Activities, Wagner-Peyser Act PY 2016 final allotments, and PY 2016 Workforce Information Grant allotments. This notice provides information on the amount of funds available during PY 2016 to States with an approved WIOA Title I and Wagner-Peyser Act Strategic Plan for PY 2016, and information regarding allotments to the outlying areas.

On December 18, 2015, the Consolidated Appropriations Act, 2016, Public Law 114–113 was signed into law (“the Act”). The Act, Division H, Title I, Section 107 of the Act allows the Secretary of Labor (Secretary) to set aside up to 0.75 percent of most operating funds for evaluations. The evaluation provision is consistent with the Federal government’s priority on evidence-based policy and programming and provides important opportunities to expand evaluations and demonstrations in the Department to build solid evidence about what works best. In the past, funds for ETA evaluations and demonstrations were separately appropriated and managed by ETA. That separate authority has been replaced by the set aside provision. Funds are transferred to the Department’s Chief Evaluation Office to implement formal evaluations and collaborations with ETA. For 2016, the Secretary set aside .25 percent of the Training and Employment Services (TES) and State Unemployment Insurance and Employment Services Operations (SUESO) appropriations. ETA spread the amount to be set aside for each appropriation among the programs funded by that appropriation with more than $100 million in funding. This includes WIOA Adult, Youth and Dislocated Worker and Wagner-Peyser Employment Service program budgets.

We also have attached tables listing the PY 2016 allotments for programs under WIOA Title I Youth Activities (Table A), Adult and Dislocated Workers Employment and Training Activities (Tables B and C, respectively), and the PY 2016 Wagner-Peyser Act final allotments (Table D). We also have attached the PY 2016 Workforce Information Grant table (Table E).

**Youth Activities Allotments.** The appropriated level for PY 2016 for WIOA Youth Activities totals $873,416,000. After reducing the appropriation by $2,485,000 for evaluations, $855,722,367 is available for Youth Activities. Table A includes a breakdown of the Youth Activities program allotments for PY 2016 and provides a comparison of these allotments to PY 2015 Youth Activities allotments for all States, and outlying areas. For the Native American Youth program, the total amount available is 1.5 percent of the total amount for Youth Activities (after the evaluations set aside), in accordance with WIOA section 127. The total funding available for the outlying areas was reserved at 0.25 percent of the amount appropriated for Youth Activities (after the evaluations set aside) after the amount reserved for Native American Youth (in accordance with WIOA section 127(b)(1)(B)(ii)). On December 17, 2003, Pub. L. 108–188, the Compact of Free Association Amendments Act of 2003 (“the Compact”), was signed into law. The Compact specified that the Republic of Palau remained eligible for WIA Title I funding. See 48 U.S.C. 1921(d)(1)(B)(ix). WIOA section 132(b)(2)[A](i) regarding funding to outlying areas (e.g., American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, and the United States Virgin Islands). For PY 2016, the Department used the same methodology used since PY 2000 (i.e., we distribute funds among the outlying areas by formula based on relative share of the number of unemployed, a minimum of 90 percent of the prior year allotment percentage, a $75,000 minimum, and a 130 percent stop-gain of the prior year share). For the relative share calculation in PY 2016, the Department continued to use the data obtained from the 2010 Census for American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the United States Virgin Islands. For the Republic of Palau, the Department continued to use data from Palau’s 2005 Census.

After the Department calculated the amount for the outlying areas and the Native American program, it was determined that the amount available for PY 2016 allotments to the States is $855,722,367. This total amount was below the required $1 billion threshold specified in WIOA section 127(b)(1)(C)(iv)(IV); therefore, the Department did not apply the WIOA additional minimum provisions. Instead, as required by WIOA, the Department used the Job Training Partnership Act (JTPA) (Pub. L. 97–300), section 262(b)(2) (as amended by section 207 of the Job Training Reform Amendments of 1992, Pub. L. 102–367) minimums of 90 percent of the prior year allotment percentage and 0.25 percent State minimum floor. WIOA also provides that no State may receive an allotment that is more than 130 percent of the allotment percentage for the State for the previous year. The three data factors required by WIOA for the PY 2016 Youth Activities State formula allotments are:

1. The average number of unemployed individuals for Areas of Substantial Unemployment (ASUs) for the 12-month period, July 2014–June 2015;
2. Number of excess unemployed individuals or the ASU excess (depending on which is higher) averages for the same 12-month period used for ASU unemployed data; and
3. Number of economically disadvantaged Youth (age 16 to 21, excluding college students in the workforce and military) from special tabulations of data from the American Community Survey (ACS), which the Department obtained from the Bureau in 2012. The Bureau collected the data used in the special tabulations for...

For purposes of identifying ASUs for the within-state Youth Activities allocation formula, States should continue to use the data made available by BLS (as described in the Local Area Unemployment Statistics (LAUS) Technical Memorandum No. S–15–13). For purposes of determining the number of economically disadvantaged Youth for the statutory within-state allocation formula, States should continue to use the special tabulations of ACS data made available to them in 2013 and available at http://www.doleta.gov/budget/disadvantagedYouthAdults.cfm.

See TEGL No. 21–12 for further information.

**Adult Employment and Training Activities Allotments.** The total appropriated funds for Adult Activities in PY 2016 is $815,556,000. After reducing the appropriated amount by $2,321,000 for evaluations, $813,235,000 remains for Adult Activities, of which $811,201,912 is for States and $2,033,088 is for outlying areas. Table B shows the PY 2016 Adult Employment and Training Activities allotments and a State by State comparison of the PY 2016 allotments to PY 2015 allotments.

In accordance with WIOA, the Department reserved the total available for the outlying areas at 0.25 percent of the full amount appropriated for Adult Activities (after the evaluations set aside). As discussed in the Youth Activities section above, in PY 2016 the Department will distribute the Adult Activities funding for the outlying areas, using the same principles, formula and data as used for outlying areas for Youth Activities. After determining the amount for the outlying areas, the Department used the statutory formula to distribute the remaining amount available for allotments to the States. The Department did not apply the WIOA minimum provisions for the PY 2016 allotments because the total amount available for the States was below the $960 million threshold required for Adult Activities in WIOA section 132(b)(1)(B)(iv)(IV). Instead, as required by WIOA, the Department calculated minimum allotments using the JTPA section 202(b)(2) (as amended by section 202 of the Job Training Reform Amendments of 1992) minimums of 90 percent of the prior year allotment percentage and 0.25 percent State minimum floor. WIOA also provides that no State may receive an allotment that is more than 130 percent of the allotment percentage for the State for the previous year. The three formula data factors for the Adult Activities program are the same as those used for the Youth Activities formula, except the Department used data for the number of economically disadvantaged Adults (age 18 to 72, excluding college students in the workforce and military).

As noted above, updated data for within-state ASU calculations is available from the Bureau of Labor Statistics (BLS), and States should continue to use the economically disadvantaged Adults data made available to States by the Department in 2013.

**Dislocated Worker Employment and Training Activities Allotments.** The amount appropriated for Dislocated Worker activities in PY 2016 totals $1,241,719,000. The total appropriation includes formula funds for the States, while the National Reserve is used for National Dislocated Worker Grants, technical assistance and training, demonstration projects, and the outlying areas’ Dislocated Worker allotments. After reducing the appropriated amount by $3,533,000 for evaluations, a total of $1,238,186,000 remains available for Dislocated Worker activities. The amount available for outlying areas is $3,095,465, leaving $217,135,535 for the National Reserve and a total of $1,017,955,000 available for States. Like the Adult program, Table C shows the PY 2016 Dislocated Worker activities allotments and a State by State comparison of the PY 2016 allotments to PY 2015 allotments.

Like the Adult Activities program, the Department reserved the total available for the outlying areas at 0.25 percent of the full amount appropriated for Dislocated Worker Activities (after the evaluations set aside). Similar to Youth and Adult funds, instead of competition, in PY 2016 the Department will use the same pro rata share as the areas received for the PY 2016 WIOA Adult Activities program to distribute the outlying areas’ Dislocated Worker funds, the same methodology used in PY 2015. The three data factors required in WIOA for the PY 2016 Dislocated Worker State formula allotments are:

1. Number of unemployed, averages for the 12-month period, October 2014–September 2015;
2. Number of excess unemployed, averages for the 12-month period, October 2014–September 2015; and

In PY 2016, under WIOA the Dislocated Worker formula adopted minimum provisions. No State may receive an allotment that is less than 90 percent of the State’s prior year allotment percentage or more than 130 percent of the State’s prior year allotment percentage.

**Wagner-Peyser Act ES Final Allotments.** The appropriated level for PY 2016 for ES grants totals $680,000,000. After reducing the appropriated amount by $1,845,000 for evaluations, a total of $678,155,000 remains available for ES programs. After determining the funding for outlying areas, the Department calculated allotments to States using the formula set forth at section 6 of the Wagner-Peyser Act (29 U.S.C. 49e). The Department based PY 2016 formula allotments on each State’s share of calendar year 2015 monthly averages of the civilian labor force (CLF) and unemployment. Section 6(b)(4) of the Wagner-Peyser Act requires the Secretary to set aside up to three percent of the total funds available for ES to ensure that each State will have sufficient resources to maintain statewide ES activities. In accordance with this provision, the Department included the three percent set-aside funds in this total allotment. The Department distributed the set-aside funds in two steps to States that have experienced a reduction in their relative share of the total resources available this year from their relative share of the total resources available the previous year.

In Step 1, States that have a CLF below one million and are also below the median CLF density were maintained at 100 percent of their relative share of prior year resources. ETA calculated the median CLF density based on CLF data provided by the BLS for calendar year 2015. All remaining set-aside funds were distributed on a pro-rata basis in Step 2 to all other States experiencing reductions in relative share from the prior year but not meeting the size and density criteria for Step 1. The distribution of ES funds (Table D) includes $676,501,894 for States, as well as $1,653,106 for outlying areas.

Under section 7(a), 50 percent of funds must be used for labor exchange services and other career services such as job search and placement services to job seekers; appropriate recruitment services for employers; program evaluations; developing and providing labor market and occupational information; developing management information systems; and administering the work test for unemployment insurance claimants. Under section 7(b) of the Wagner-Peyser Act, ten percent of the total sums allotted to each State shall be reserved for use by the Governor to provide performance incentives for ES offices, services for groups with special needs, and for the
Workforce Information Grants

Allotments. Total PY 2016 funding for Workforce Information Grants allotments to States is $322,000,000. The allotment figures for each State are listed in Table E. Funds are distributed by administrative formula, with a reserve of $176,800 for Guam and the United States Virgin Islands. Guam and the United States Virgin Islands allotment amounts are partially based on CLF data. The Department distributes the remaining funds to the States with 40 percent distributed equally to all States and 60 percent distributed based on each State’s share of CLF for the 12 months ending September 2015.

### Table A—U.S. Department of Labor Employment and Training Administration WIOA Youth Activities State Allotments

[Comparison of PY 2016 allotments vs PY 2015 allotments]

<table>
<thead>
<tr>
<th>State</th>
<th>PY 2015</th>
<th>PY 2016</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total with Evaluations</td>
<td>$831,842,000</td>
<td>$873,416,000</td>
<td>$41,574,000</td>
<td>5.00</td>
</tr>
<tr>
<td>Total (WIOA Youth Activities)</td>
<td>$829,547,000</td>
<td>$870,931,000</td>
<td>$41,384,000</td>
<td>4.99</td>
</tr>
<tr>
<td>Alabama</td>
<td>10,793,635</td>
<td>13,242,811</td>
<td>2,449,176</td>
<td>20.68</td>
</tr>
<tr>
<td>Alaska</td>
<td>2,037,653</td>
<td>2,296,191</td>
<td>258,538</td>
<td>12.69</td>
</tr>
<tr>
<td>Arizona</td>
<td>18,380,399</td>
<td>20,040,831</td>
<td>1,660,432</td>
<td>9.03</td>
</tr>
<tr>
<td>Arkansas</td>
<td>7,694,400</td>
<td>7,839,730</td>
<td>145,330</td>
<td>1.89</td>
</tr>
<tr>
<td>California</td>
<td>120,708,644</td>
<td>128,766,566</td>
<td>8,057,922</td>
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</tr>
<tr>
<td>Colorado</td>
<td>11,835,030</td>
<td>11,182,905</td>
<td>652,125</td>
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<tr>
<td>Connecticut</td>
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<td>10,313,964</td>
<td>679,283</td>
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</tr>
<tr>
<td>Delaware</td>
<td>2,037,653</td>
<td>2,139,306</td>
<td>101,653</td>
<td>4.99</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>2,329,955</td>
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<td>42,774,978</td>
<td>49,787,759</td>
<td>7,012,781</td>
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<td>27,630,735</td>
<td>30,707,363</td>
<td>3,076,648</td>
<td>11.13</td>
</tr>
<tr>
<td>Hawaii</td>
<td>2,037,653</td>
<td>2,139,306</td>
<td>101,653</td>
<td>4.99</td>
</tr>
<tr>
<td>Idaho</td>
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<td>42,336,174</td>
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<td>17,064,726</td>
<td>861,069</td>
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</tr>
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<td>7.04</td>
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</tr>
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<td>12,961,737</td>
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<td>9,110,017</td>
<td>12,548,488</td>
<td>3,438,471</td>
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<td>3,214,985</td>
<td>3,208,693</td>
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<td>14,375,433</td>
<td>2,011,431</td>
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</tr>
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<td>16,504,685</td>
<td>15,595,256</td>
<td>(909,429)</td>
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</tr>
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<td>29,709,018</td>
<td>(1,541,086)</td>
<td>-4.93</td>
</tr>
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<td>8,577,825</td>
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<td>9,151,084</td>
<td>10,193,683</td>
<td>1,042,599</td>
<td>11.36</td>
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<td>16,472,508</td>
<td>2,244,069</td>
<td>15.77</td>
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<td>2,152,782</td>
<td>2,139,306</td>
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<td>-0.63</td>
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<td>2,291,470</td>
<td>(133,626)</td>
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<td>9,034,617</td>
<td>9,531,729</td>
<td>497,112</td>
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<td>101,653</td>
<td>4.99</td>
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<td>24,898,651</td>
<td>1,616,374</td>
<td>6.94</td>
</tr>
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<td>6,167,206</td>
<td>917,430</td>
<td>17.48</td>
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<td>54,003,637</td>
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</tr>
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<td>26,347,165</td>
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<td>(1,111,795)</td>
<td>-4.22</td>
</tr>
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<td>2,139,306</td>
<td>101,653</td>
<td>4.99</td>
</tr>
<tr>
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<td>28,162,375</td>
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<td>-1.51</td>
</tr>
<tr>
<td>Oklahoma</td>
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<td>6,558,618</td>
<td>(382,462)</td>
<td>-5.51</td>
</tr>
<tr>
<td>Oregon</td>
<td>10,431,168</td>
<td>11,441,241</td>
<td>1,010,073</td>
<td>9.68</td>
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<tr>
<td>Pennsylvania</td>
<td>30,984,178</td>
<td>29,662,886</td>
<td>(1,321,292)</td>
<td>-4.30</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>19,489,676</td>
<td>23,096,083</td>
<td>3,606,407</td>
<td>18.50</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>4,106,989</td>
<td>3,880,689</td>
<td>(226,300)</td>
<td>-5.51</td>
</tr>
<tr>
<td>South Carolina</td>
<td>11,474,747</td>
<td>14,636,640</td>
<td>3,161,893</td>
<td>27.56</td>
</tr>
<tr>
<td>South Dakota</td>
<td>2,037,653</td>
<td>2,139,306</td>
<td>101,653</td>
<td>4.99</td>
</tr>
<tr>
<td>Tennessee</td>
<td>17,503,627</td>
<td>18,111,472</td>
<td>607,845</td>
<td>3.51</td>
</tr>
<tr>
<td>Texas</td>
<td>54,514,867</td>
<td>51,888,988</td>
<td>(2,625,879)</td>
<td>-5.11</td>
</tr>
<tr>
<td>Utah</td>
<td>3,928,231</td>
<td>3,711,780</td>
<td>(216,451)</td>
<td>-5.11</td>
</tr>
<tr>
<td>Vermont</td>
<td>2,037,653</td>
<td>2,139,306</td>
<td>101,653</td>
<td>4.99</td>
</tr>
<tr>
<td>Virginia</td>
<td>13,325,559</td>
<td>15,728,252</td>
<td>2,402,693</td>
<td>18.03</td>
</tr>
<tr>
<td>Washington</td>
<td>15,945,865</td>
<td>18,966,351</td>
<td>3,020,486</td>
<td>18.94</td>
</tr>
<tr>
<td>West Virginia</td>
<td>3,887,564</td>
<td>5,350,384</td>
<td>1,462,820</td>
<td>34.18</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>14,041,859</td>
<td>13,268,135</td>
<td>(773,724)</td>
<td>-5.51</td>
</tr>
<tr>
<td>Wyoming</td>
<td>2,037,653</td>
<td>2,139,306</td>
<td>101,653</td>
<td>4.99</td>
</tr>
<tr>
<td><strong>State Total</strong></td>
<td>815,061,036</td>
<td>855,722,367</td>
<td>40,661,331</td>
<td>4.99</td>
</tr>
<tr>
<td><strong>American Samoa</strong></td>
<td>217,678</td>
<td>228,951</td>
<td>11,273</td>
<td>5.18</td>
</tr>
<tr>
<td><strong>Guam</strong></td>
<td>738,863</td>
<td>777,128</td>
<td>38,265</td>
<td>5.18</td>
</tr>
<tr>
<td><strong>Northern Marianas</strong></td>
<td>403,686</td>
<td>424,593</td>
<td>20,907</td>
<td>5.18</td>
</tr>
<tr>
<td><strong>Palau</strong></td>
<td>75,000</td>
<td>75,000</td>
<td>0</td>
<td>0.00</td>
</tr>
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</table>
### TABLE A—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION WIOA YOUTH ACTIVITIES STATE ALLOTMENTS—Continued

[Comparison of PY 2016 allotments vs PY 2015 allotments]

<table>
<thead>
<tr>
<th>State</th>
<th>PY 2015</th>
<th>PY 2016</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virgin Islands</td>
<td>607,532</td>
<td>638,996</td>
<td>31,464</td>
<td>5.18</td>
</tr>
<tr>
<td>Outlying Areas Total</td>
<td>2,042,759</td>
<td>2,144,688</td>
<td>101,909</td>
<td>4.99</td>
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<td>Native Americans</td>
<td>12,443,205</td>
<td>13,063,965</td>
<td>620,760</td>
<td>4.99</td>
</tr>
<tr>
<td>Evaluations set aside</td>
<td>2,295,000</td>
<td>2,485,000</td>
<td>190,000</td>
<td>8.28</td>
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### TABLE B—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION WIOA ADULT ACTIVITIES STATE ALLOTMENTS

[Comparison of PY 2016 allotments vs PY 2015 allotments]

<table>
<thead>
<tr>
<th>State</th>
<th>PY 2015</th>
<th>PY 2016</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total with Evaluations</td>
<td>$776,736,000</td>
<td>$815,556,000</td>
<td>$38,820,000</td>
<td>5.00</td>
</tr>
<tr>
<td>Total (WIOA Adult Activities)</td>
<td>$774,593,000</td>
<td>$813,235,000</td>
<td>$38,642,000</td>
<td>4.99</td>
</tr>
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<td>Alaska</td>
<td>10,701,084</td>
<td>12,855,265</td>
<td>2,154,181</td>
<td>20.13</td>
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<td>17,323,692</td>
<td>18,879,837</td>
<td>1,556,145</td>
<td>8.98</td>
</tr>
<tr>
<td>Arkansas</td>
<td>19,348,672</td>
<td>7,479,394</td>
<td>11,869,278</td>
<td>102.24</td>
</tr>
<tr>
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<td>123,210,917</td>
<td>7,632,691</td>
<td>6.60</td>
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<td>Colorado</td>
<td>10,974,957</td>
<td>10,370,217</td>
<td>(604,740)</td>
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</tr>
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<td>8,856,853</td>
<td>9,481,516</td>
<td>624,663</td>
<td>7.05</td>
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<td>Delaware</td>
<td>1,931,641</td>
<td>2,028,005</td>
<td>96,364</td>
<td>4.99</td>
</tr>
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<td>District of Columbia</td>
<td>2,119,523</td>
<td>2,829,641</td>
<td>710,118</td>
<td>33.50</td>
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<td>6,713,752</td>
<td>15.69</td>
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<td>2,909,814</td>
<td>10.98</td>
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<td>76,723</td>
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<td>4,279,457</td>
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<td>28,780,666</td>
<td>27,194,798</td>
<td>(1,585,868)</td>
<td>-5.51</td>
</tr>
<tr>
<td>Minnesota</td>
<td>7,764,825</td>
<td>7,336,969</td>
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<td>-5.51</td>
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<tr>
<td>Mississippi</td>
<td>8,730,734</td>
<td>9,714,582</td>
<td>983,848</td>
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</tr>
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<td>15,350,715</td>
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<td>4.99</td>
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<td>476,669</td>
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<td>96,364</td>
<td>4.99</td>
</tr>
<tr>
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<td>5,913,046</td>
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<td>17.21</td>
</tr>
<tr>
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<td>52,214,166</td>
<td>1,792,515</td>
<td>3.56</td>
</tr>
<tr>
<td>North Carolina</td>
<td>25,161,487</td>
<td>24,108,820</td>
<td>(1,052,667)</td>
<td>-4.18</td>
</tr>
<tr>
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<td>2,028,005</td>
<td>96,364</td>
<td>4.99</td>
</tr>
<tr>
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<td>26,518,096</td>
<td>26,068,489</td>
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<td>6,320,826</td>
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<td>9,955,124</td>
<td>10,949,876</td>
<td>994,752</td>
<td>9.55</td>
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<td>26,866,202</td>
<td>(1,711,090)</td>
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<td>3,733,076</td>
<td>(236,700)</td>
<td>-6.51</td>
</tr>
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<td>11,072,827</td>
<td>14,080,837</td>
<td>3,008,010</td>
<td>27.17</td>
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<tr>
<td>South Dakota</td>
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<td>2,028,005</td>
<td>96,364</td>
<td>4.99</td>
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<td>18,374,267</td>
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<td>3,296,507</td>
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<td>(181,754)</td>
<td>-5.51</td>
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<tr>
<td>Vermont</td>
<td>1,931,641</td>
<td>2,028,005</td>
<td>96,364</td>
<td>4.99</td>
</tr>
<tr>
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<td>12,370,494</td>
<td>14,623,934</td>
<td>2,253,440</td>
<td>18.22</td>
</tr>
<tr>
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<td>14,686,344</td>
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<td>2,819,019</td>
<td>19.08</td>
</tr>
<tr>
<td>West Virginia</td>
<td>4,056,659</td>
<td>5,356,273</td>
<td>1,299,614</td>
<td>32.04</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>12,196,759</td>
<td>11,524,695</td>
<td>(672,064)</td>
<td>-5.51</td>
</tr>
<tr>
<td>Wyoming</td>
<td>1,931,641</td>
<td>2,028,005</td>
<td>96,364</td>
<td>4.99</td>
</tr>
</tbody>
</table>

State Total | 772,656,517 | 811,201,912 | 38,545,395 | 4.99 |


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TABLE B—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION WIOA ADULT ACTIVITIES STATE
ALLOTMENTS—Continued
[Comparison of PY 2016 allotments vs PY 2015 allotments]
State

PY 2015

PY 2016

Difference

% Difference

American Samoa .............................................................................
Guam ...............................................................................................
Northern Marianas ...........................................................................
Palau ................................................................................................
Virgin Islands ...................................................................................

205,921
698,958
381,883
75,000
574,721

216,608
735,231
401,702
75,000
604,547

10,687
36,273
19,819
0
29,826

5.19
5.19
5.19
0.00
5.19

Outlying Areas Total .................................................................
Evaluations set aside .......................................................................

1,936,483
2,143,000

2,033,088
2,321,000

96,605
178,000

4.99
8.31

TABLE C—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION WIOA DISLOCATED WORKER
ACTIVITIES STATE ALLOTMENTS
[Comparison of PY 2016 allotments vs PY 2015 allotments]

mstockstill on DSK4VPTVN1PROD with NOTICES

State

PY 2015

Total with Evaluations ......................................................................
Total (WIOA Dislocated Worker Activities) ......................................
Alabama ...........................................................................................
Alaska ..............................................................................................
Arizona .............................................................................................
Arkansas ..........................................................................................
California ..........................................................................................
Colorado ..........................................................................................
Connecticut ......................................................................................
Delaware ..........................................................................................
District of Columbia .........................................................................
Florida ..............................................................................................
Georgia ............................................................................................
Hawaii ..............................................................................................
Idaho ................................................................................................
Illinois ...............................................................................................
Indiana .............................................................................................
Iowa .................................................................................................
Kansas .............................................................................................
Kentucky ..........................................................................................
Louisiana ..........................................................................................
Maine ...............................................................................................
Maryland ..........................................................................................
Massachusetts .................................................................................
Michigan ...........................................................................................
Minnesota ........................................................................................
Mississippi ........................................................................................
Missouri ............................................................................................
Montana ...........................................................................................
Nebraska ..........................................................................................
Nevada .............................................................................................
New Hampshire ...............................................................................
New Jersey ......................................................................................
New Mexico .....................................................................................
New York .........................................................................................
North Carolina ..................................................................................
North Dakota ....................................................................................
Ohio .................................................................................................
Oklahoma .........................................................................................
Oregon .............................................................................................
Pennsylvania ....................................................................................
Puerto Rico ......................................................................................
Rhode Island ....................................................................................
South Carolina .................................................................................
South Dakota ...................................................................................
Tennessee .......................................................................................
Texas ...............................................................................................
Utah .................................................................................................
Vermont ...........................................................................................
Virginia .............................................................................................
Washington ......................................................................................
West Virginia ....................................................................................
Wisconsin .........................................................................................

VerDate Sep<11>2014

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PO 00000

Frm 00079

PY 2016

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2,184,119
22,511,715
8,052,059
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13,622,336
13,612,474
2,596,904
3,443,627
61,786,732
39,981,701
1,931,277
2,636,879
58,325,151
17,611,408
4,426,239
4,682,959
16,220,379
9,215,660
3,592,396
17,549,612
21,265,196
40,080,962
8,332,420
11,047,184
18,476,297
1,699,458
2,016,308
13,272,377
2,355,019
33,968,534
6,691,816
69,009,253
31,698,026
566,170
33,758,857
5,943,501
13,672,401
37,184,902
20,357,210
5,533,256
12,481,973
856,158
21,507,643
55,598,809
2,963,244
806,732
17,685,631
19,533,856
4,814,588
15,763,228

Fmt 4703

Sfmt 4703

Difference

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7,757,044
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4,499,821
65,053,785
40,521,426
1,894,161
2,385,440
52,763,567
17,062,801
4,004,176
4,609,831
14,673,688
12,042,192
3,249,844
18,580,386
19,237,457
36,259,049
7,537,884
11,826,808
17,142,075
1,537,406
1,824,043
14,417,704
2,130,457
38,809,709
7,937,300
62,428,888
31,022,721
728,444
30,539,787
5,376,760
14,140,167
36,591,154
25,824,090
5,005,633
16,310,315
1,070,734
23,146,617
50,297,194
3,143,067
890,075
16,945,520
22,462,284
6,291,269
14,260,128

E:\FR\FM\18APN1.SGM

18APN1

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$5,208,000
1,415,756
669,890
2,517,336
(295,015)
5,581,245
(1,298,955)
741,223
(247,627)
1,056,194
3,267,053
539,725
(37,116)
(251,439)
(5,561,584)
(548,607)
(422,063)
(73,128)
(1,546,691)
2,826,532
(342,552)
1,030,774
(2,027,739)
(3,821,913)
(794,536)
779,624
(1,334,222)
(162,052)
(192,265)
1,145,327
(224,562)
4,841,175
1,245,484
(6,580,365)
(675,305)
162,274
(3,219,070)
(566,741)
467,766
(593,748)
5,466,880
(527,623)
3,828,342
214,576
1,638,974
(5,301,615)
179,823
83,343
(740,111)
2,928,428
1,476,681
(1,503,100)

% Difference
0.43
0.42
9.43
30.67
11.18
¥3.66
3.40
¥9.54
5.45
¥9.54
30.67
5.29
1.35
¥1.92
¥9.54
¥9.54
¥3.12
¥9.54
¥1.56
¥9.54
30.67
¥9.54
5.87
¥9.54
¥9.54
¥9.54
7.06
¥7.22
¥9.54
¥9.54
8.63
¥9.54
14.25
18.61
¥9.54
¥2.13
28.66
¥9.54
¥9.54
3.42
¥1.60
26.85
¥9.54
30.67
25.06
7.62
¥9.54
6.07
10.33
¥4.18
14.99
30.67
¥9.54


### TABLE C—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION WIOA DISLOCATED WORKER ACTIVITIES STATE ALLOTMENTS—Continued

[Comparison of PY 2016 allotments vs PY 2015 allotments]

<table>
<thead>
<tr>
<th>State</th>
<th>PY 2015</th>
<th>PY 2016</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wyoming</td>
<td>728,014</td>
<td>740,333</td>
<td>12,319</td>
<td>1.69</td>
</tr>
<tr>
<td>State Total</td>
<td>1,012,728,000</td>
<td>1,017,955,000</td>
<td>5,227,000</td>
<td>0.52</td>
</tr>
<tr>
<td>American Samoa</td>
<td>327,780</td>
<td>329,795</td>
<td>2,015</td>
<td>0.61</td>
</tr>
<tr>
<td>Guam</td>
<td>1,112,584</td>
<td>1,119,421</td>
<td>6,837</td>
<td>0.61</td>
</tr>
<tr>
<td>Northern Marianas</td>
<td>607,872</td>
<td>611,609</td>
<td>3,737</td>
<td>0.61</td>
</tr>
<tr>
<td>Palau</td>
<td>119,383</td>
<td>114,191</td>
<td>(5,192)</td>
<td>-4.35</td>
</tr>
<tr>
<td>Virgin Islands</td>
<td>914,826</td>
<td>920,449</td>
<td>5,623</td>
<td>0.61</td>
</tr>
<tr>
<td>Outlying Areas Total</td>
<td>3,082,445</td>
<td>3,095,465</td>
<td>13,020</td>
<td>0.42</td>
</tr>
<tr>
<td>National Reserve</td>
<td>217,167,555</td>
<td>217,135,535</td>
<td>(32,020)</td>
<td>-0.01</td>
</tr>
<tr>
<td>Evaluations set aside</td>
<td>3,411,000</td>
<td>3,533,000</td>
<td>122,000</td>
<td>3.58</td>
</tr>
</tbody>
</table>

### TABLE D—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION EMPLOYMENT SERVICE (WAGNER-PYEYER)

[PY 2016 vs PY 2015 final allotments]

<table>
<thead>
<tr>
<th>State</th>
<th>Final PY 2015</th>
<th>Final PY 2016</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total with Evaluation</td>
<td>$664,184,000</td>
<td>$680,000,000</td>
<td>$15,816,000</td>
<td>2.38</td>
</tr>
<tr>
<td>Total (WIOA ES Activities)</td>
<td>$662,400,000</td>
<td>$678,155,000</td>
<td>$15,755,000</td>
<td>2.38</td>
</tr>
<tr>
<td>Alabama</td>
<td>8,491,183</td>
<td>8,970,663</td>
<td>479,480</td>
<td>5.65</td>
</tr>
<tr>
<td>Alaska</td>
<td>7,200,604</td>
<td>7,371,868</td>
<td>171,264</td>
<td>2.38</td>
</tr>
<tr>
<td>California</td>
<td>25,000,047</td>
<td>25,225,782</td>
<td>225,735</td>
<td>0.90</td>
</tr>
<tr>
<td>Colorado</td>
<td>10,626,917</td>
<td>10,789,931</td>
<td>163,014</td>
<td>1.53</td>
</tr>
<tr>
<td>Connecticut</td>
<td>7,765,360</td>
<td>7,763,324</td>
<td>199,964</td>
<td>2.64</td>
</tr>
<tr>
<td>Delaware</td>
<td>1,850,199</td>
<td>1,894,205</td>
<td>44,006</td>
<td>2.38</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>2,099,445</td>
<td>2,141,611</td>
<td>42,166</td>
<td>2.03</td>
</tr>
<tr>
<td>Florida</td>
<td>38,350,606</td>
<td>39,144,904</td>
<td>794,298</td>
<td>2.07</td>
</tr>
<tr>
<td>Georgia</td>
<td>19,841,888</td>
<td>20,216,693</td>
<td>374,805</td>
<td>1.89</td>
</tr>
<tr>
<td>Hawaii</td>
<td>2,339,563</td>
<td>2,428,629</td>
<td>89,066</td>
<td>3.81</td>
</tr>
<tr>
<td>Idaho</td>
<td>5,999,385</td>
<td>6,142,079</td>
<td>142,694</td>
<td>2.38</td>
</tr>
<tr>
<td>Indiana</td>
<td>12,751,284</td>
<td>13,000,193</td>
<td>248,909</td>
<td>1.95</td>
</tr>
<tr>
<td>Iowa</td>
<td>6,028,720</td>
<td>6,166,392</td>
<td>137,672</td>
<td>2.28</td>
</tr>
<tr>
<td>Kansas</td>
<td>5,498,111</td>
<td>5,618,970</td>
<td>120,859</td>
<td>2.20</td>
</tr>
<tr>
<td>Kentucky</td>
<td>8,456,309</td>
<td>8,515,817</td>
<td>59,508</td>
<td>0.60</td>
</tr>
<tr>
<td>Louisiana</td>
<td>8,076,868</td>
<td>9,250,226</td>
<td>1,173,358</td>
<td>14.53</td>
</tr>
<tr>
<td>Maine</td>
<td>3,567,777</td>
<td>3,662,636</td>
<td>94,859</td>
<td>2.65</td>
</tr>
<tr>
<td>Maryland</td>
<td>11,157,892</td>
<td>11,600,524</td>
<td>442,632</td>
<td>3.88</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>13,585,040</td>
<td>13,897,531</td>
<td>312,491</td>
<td>2.30</td>
</tr>
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<td>Michigan</td>
<td>21,056,725</td>
<td>21,131,809</td>
<td>75,084</td>
<td>0.36</td>
</tr>
<tr>
<td>Minnesota</td>
<td>10,920,175</td>
<td>11,125,457</td>
<td>205,282</td>
<td>1.88</td>
</tr>
<tr>
<td>Mississippi</td>
<td>5,621,814</td>
<td>5,700,269</td>
<td>78,455</td>
<td>1.40</td>
</tr>
<tr>
<td>Missouri</td>
<td>11,847,516</td>
<td>12,359,052</td>
<td>391,536</td>
<td>3.27</td>
</tr>
<tr>
<td>Montana</td>
<td>4,902,727</td>
<td>5,018,337</td>
<td>115,610</td>
<td>2.38</td>
</tr>
<tr>
<td>Nebraska</td>
<td>5,512,267</td>
<td>5,520,741</td>
<td>8,474</td>
<td>0.15</td>
</tr>
<tr>
<td>Nevada</td>
<td>6,068,982</td>
<td>6,211,983</td>
<td>143,001</td>
<td>2.36</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>2,641,511</td>
<td>2,694,892</td>
<td>53,381</td>
<td>2.02</td>
</tr>
<tr>
<td>New Jersey</td>
<td>18,973,701</td>
<td>19,315,862</td>
<td>341,161</td>
<td>1.72</td>
</tr>
<tr>
<td>New Mexico</td>
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<td>5,632,581</td>
<td>130,857</td>
<td>2.38</td>
</tr>
<tr>
<td>New York</td>
<td>38,363,357</td>
<td>39,157,376</td>
<td>794,019</td>
<td>2.07</td>
</tr>
<tr>
<td>North Carolina</td>
<td>19,378,713</td>
<td>19,761,644</td>
<td>382,931</td>
<td>1.98</td>
</tr>
<tr>
<td>North Dakota</td>
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<td>5,111,188</td>
<td>118,744</td>
<td>2.38</td>
</tr>
<tr>
<td>Ohio</td>
<td>23,445,526</td>
<td>23,704,298</td>
<td>258,772</td>
<td>1.10</td>
</tr>
<tr>
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<td>6,861,466</td>
<td>396,863</td>
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</tr>
<tr>
<td>Oregon</td>
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<td>8,237,229</td>
<td>143,395</td>
<td>1.77</td>
</tr>
<tr>
<td>Pennsylvania</td>
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<td>26,031,932</td>
<td>474,160</td>
<td>1.86</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>6,838,910</td>
<td>6,909,223</td>
<td>72,313</td>
<td>1.06</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>2,437,864</td>
<td>2,459,092</td>
<td>21,228</td>
<td>0.87</td>
</tr>
<tr>
<td>South Carolina</td>
<td>8,892,138</td>
<td>9,472,249</td>
<td>480,111</td>
<td>5.34</td>
</tr>
<tr>
<td>South Dakota</td>
<td>4,614,166</td>
<td>4,723,913</td>
<td>109,747</td>
<td>2.38</td>
</tr>
<tr>
<td>Tennessee</td>
<td>12,567,163</td>
<td>12,834,215</td>
<td>267,052</td>
<td>2.12</td>
</tr>
<tr>
<td>Texas</td>
<td>48,160,966</td>
<td>49,277,528</td>
<td>1,116,562</td>
<td>2.20</td>
</tr>
<tr>
<td>Utah</td>
<td>6,289,510</td>
<td>6,292,787</td>
<td>3,277</td>
<td>0.15</td>
</tr>
<tr>
<td>Vermont</td>
<td>2,161,537</td>
<td>2,212,949</td>
<td>51,412</td>
<td>2.38</td>
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</tbody>
</table>
### TABLE D—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION EMPLOYMENT SERVICE (WAGNER-PEYSER)—Continued

<table>
<thead>
<tr>
<th>State</th>
<th>Final PY 15</th>
<th>Final PY 16</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia</td>
<td>15,846,585</td>
<td>16,206,026</td>
<td>359,441</td>
<td>2.27</td>
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<tr>
<td>West Virginia</td>
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<td>5,406,984</td>
<td>125,616</td>
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</tr>
<tr>
<td>Wisconsin</td>
<td>11,786,589</td>
<td>12,013,389</td>
<td>226,800</td>
<td>1.92</td>
</tr>
<tr>
<td>Wyoming</td>
<td>3,579,894</td>
<td>3,665,041</td>
<td>85,147</td>
<td>2.38</td>
</tr>
<tr>
<td>State Total</td>
<td>660,785,299</td>
<td>676,501,894</td>
<td>15,716,595</td>
<td>2.38</td>
</tr>
<tr>
<td>Guam</td>
<td>309,952</td>
<td>317,324</td>
<td>7,372</td>
<td>2.38</td>
</tr>
<tr>
<td>Virgin Islands</td>
<td>1,304,749</td>
<td>1,335,782</td>
<td>31,033</td>
<td>2.38</td>
</tr>
<tr>
<td>Outlying Areas Total</td>
<td>1,614,701</td>
<td>1,653,106</td>
<td>38,405</td>
<td>2.38</td>
</tr>
<tr>
<td>Evaluations set aside</td>
<td>1,784,000</td>
<td>1,845,000</td>
<td>61,000</td>
<td>3.42</td>
</tr>
</tbody>
</table>

### TABLE E—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION WORKFORCE INFORMATION GRANTS TO STATES

<table>
<thead>
<tr>
<th>State</th>
<th>PY 2015</th>
<th>PY 2016</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$32,000,000</td>
<td>$32,000,000</td>
<td>$0</td>
<td>0.00</td>
</tr>
<tr>
<td>Alabama</td>
<td>504,328</td>
<td>503,955</td>
<td>(373)</td>
<td>−0.07</td>
</tr>
<tr>
<td>Alaska</td>
<td>289,343</td>
<td>288,924</td>
<td>(419)</td>
<td>−0.14</td>
</tr>
<tr>
<td>Arizona</td>
<td>613,057</td>
<td>624,575</td>
<td>11,518</td>
<td>1.88</td>
</tr>
<tr>
<td>Arkansas</td>
<td>405,110</td>
<td>405,098</td>
<td>(12)</td>
<td>0.00</td>
</tr>
<tr>
<td>California</td>
<td>2,512,646</td>
<td>2,535,716</td>
<td>23,070</td>
<td>0.92</td>
</tr>
<tr>
<td>Colorado</td>
<td>583,979</td>
<td>585,592</td>
<td>1,613</td>
<td>0.28</td>
</tr>
<tr>
<td>Connecticut</td>
<td>472,001</td>
<td>475,078</td>
<td>3,077</td>
<td>0.65</td>
</tr>
<tr>
<td>Delaware</td>
<td>299,203</td>
<td>300,301</td>
<td>1,098</td>
<td>0.37</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>269,948</td>
<td>291,253</td>
<td>3,265</td>
<td>0.45</td>
</tr>
<tr>
<td>Florida</td>
<td>1,406,780</td>
<td>1,409,557</td>
<td>(2,777)</td>
<td>−0.22</td>
</tr>
<tr>
<td>Georgia</td>
<td>824,471</td>
<td>818,650</td>
<td>(5,821)</td>
<td>−0.71</td>
</tr>
<tr>
<td>Hawaii</td>
<td>325,099</td>
<td>326,170</td>
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</tr>
<tr>
<td>Idaho</td>
<td>339,420</td>
<td>340,258</td>
<td>838</td>
<td>0.25</td>
</tr>
<tr>
<td>Illinois</td>
<td>1,041,040</td>
<td>1,030,239</td>
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<td>−1.04</td>
</tr>
<tr>
<td>Indiana</td>
<td>635,932</td>
<td>638,032</td>
<td>2,100</td>
<td>0.33</td>
</tr>
<tr>
<td>Iowa</td>
<td>450,811</td>
<td>451,225</td>
<td>414</td>
<td>0.09</td>
</tr>
<tr>
<td>Kansas</td>
<td>426,274</td>
<td>425,110</td>
<td>(1,164)</td>
<td>−0.27</td>
</tr>
<tr>
<td>Kentucky</td>
<td>493,479</td>
<td>482,822</td>
<td>(10,657)</td>
<td>−2.16</td>
</tr>
<tr>
<td>Louisiana</td>
<td>501,858</td>
<td>509,684</td>
<td>7,826</td>
<td>1.56</td>
</tr>
<tr>
<td>Maine</td>
<td>321,102</td>
<td>328,137</td>
<td>(2,965)</td>
<td>−0.90</td>
</tr>
<tr>
<td>Maryland</td>
<td>623,467</td>
<td>622,922</td>
<td>(545)</td>
<td>−0.09</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>671,558</td>
<td>679,830</td>
<td>8,272</td>
<td>1.23</td>
</tr>
<tr>
<td>Michigan</td>
<td>820,078</td>
<td>817,841</td>
<td>(2,237)</td>
<td>−0.27</td>
</tr>
<tr>
<td>Minnesota</td>
<td>608,644</td>
<td>607,606</td>
<td>(1,038)</td>
<td>−0.17</td>
</tr>
<tr>
<td>Mississippi</td>
<td>398,706</td>
<td>395,692</td>
<td>(3,014)</td>
<td>−0.76</td>
</tr>
<tr>
<td>Missouri</td>
<td>614,280</td>
<td>617,432</td>
<td>3,152</td>
<td>0.51</td>
</tr>
<tr>
<td>Montana</td>
<td>307,848</td>
<td>307,795</td>
<td>(53)</td>
<td>−0.02</td>
</tr>
<tr>
<td>Nebraska</td>
<td>369,401</td>
<td>367,292</td>
<td>(2,109)</td>
<td>−0.57</td>
</tr>
<tr>
<td>Nevada</td>
<td>411,778</td>
<td>415,509</td>
<td>3,731</td>
<td>0.91</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>335,286</td>
<td>334,684</td>
<td>(602)</td>
<td>−0.18</td>
</tr>
<tr>
<td>New Jersey</td>
<td>791,996</td>
<td>793,083</td>
<td>1,087</td>
<td>0.14</td>
</tr>
<tr>
<td>New Mexico</td>
<td>357,691</td>
<td>356,477</td>
<td>(2,144)</td>
<td>−0.60</td>
</tr>
<tr>
<td>New York</td>
<td>1,413,628</td>
<td>1,405,521</td>
<td>(8,107)</td>
<td>−0.57</td>
</tr>
<tr>
<td>North Carolina</td>
<td>813,419</td>
<td>814,035</td>
<td>616</td>
<td>0.08</td>
</tr>
<tr>
<td>North Dakota</td>
<td>294,439</td>
<td>295,165</td>
<td>726</td>
<td>0.25</td>
</tr>
<tr>
<td>Ohio</td>
<td>944,193</td>
<td>936,822</td>
<td>(7,371)</td>
<td>−0.78</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>464,819</td>
<td>465,408</td>
<td>589</td>
<td>0.13</td>
</tr>
<tr>
<td>Oregon</td>
<td>480,082</td>
<td>480,039</td>
<td>(43)</td>
<td>−0.01</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1,025,094</td>
<td>1,016,843</td>
<td>(8,251)</td>
<td>−0.80</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>386,665</td>
<td>385,650</td>
<td>(1,015)</td>
<td>−0.26</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>312,352</td>
<td>311,738</td>
<td>(614)</td>
<td>−0.20</td>
</tr>
<tr>
<td>South Carolina</td>
<td>509,225</td>
<td>515,528</td>
<td>6,303</td>
<td>1.24</td>
</tr>
<tr>
<td>South Dakota</td>
<td>299,749</td>
<td>299,424</td>
<td>(324)</td>
<td>−0.11</td>
</tr>
<tr>
<td>Tennessee</td>
<td>614,134</td>
<td>612,772</td>
<td>(1,362)</td>
<td>−0.22</td>
</tr>
<tr>
<td>Texas</td>
<td>1,821,458</td>
<td>1,828,910</td>
<td>7,452</td>
<td>0.41</td>
</tr>
<tr>
<td>Utah</td>
<td>420,602</td>
<td>420,937</td>
<td>335</td>
<td>0.08</td>
</tr>
<tr>
<td>Vermont</td>
<td>287,500</td>
<td>287,842</td>
<td>(342)</td>
<td>−0.23</td>
</tr>
<tr>
<td>Virginia</td>
<td>765,965</td>
<td>757,553</td>
<td>(8,412)</td>
<td>−1.10</td>
</tr>
</tbody>
</table>
TABLE E—U.S. DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION—Continued
WORKFORCE INFORMATION GRANTS TO STATES
[PY 2016 vs PY 2015 allotments]

<table>
<thead>
<tr>
<th>State</th>
<th>PY 2015</th>
<th>PY 2016</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washington</td>
<td>666,958</td>
<td>671,496</td>
<td>4,538</td>
<td>0.68</td>
</tr>
<tr>
<td>West Virginia</td>
<td>341,935</td>
<td>339,090</td>
<td>(2,845)</td>
<td>−0.83</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>619,893</td>
<td>618,500</td>
<td>(1,393)</td>
<td>−0.22</td>
</tr>
<tr>
<td>Wyoming</td>
<td>282,549</td>
<td>281,988</td>
<td>(561)</td>
<td>−0.20</td>
</tr>
<tr>
<td>State Total</td>
<td>3,182,200</td>
<td>3,182,200</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Guam</td>
<td>93,090</td>
<td>93,090</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Virgin Islands</td>
<td>83,710</td>
<td>83,710</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Outlying Areas Total</td>
<td>176,800</td>
<td>176,800</td>
<td>0</td>
<td>0.00</td>
</tr>
</tbody>
</table>

I. Background

The Aviation Safety Reporting System (ASRS) is a NASA program developed to enable the voluntary collection of aviation safety incident/situation reports from individuals to include but not limited to pilots, air traffic controllers, dispatchers, cabin crew, and maintenance technicians. The ASRS represents the continuing effort by government, industry, and individuals to maintain and improve aviation safety. The information collected is used by NASA, the Federal Aviation Administration, and the aviation community in the promotion of flight safety.

Data collected is used to identify deficiencies and discrepancies in the National Airspace System, support policy formulation and planning, and strengthen the foundation of aviation safety research. 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.

II. Method of Collection

NASA collects the information electronically, however information may also be collected via mail.

III. Data

Title: NASA Aviation Safety Reporting System.

OMB Control Number: 2700–XXXX.

Type of Review: Existing information collection in use without OMB Approval.

Affected Public: Individuals.

Estimated Number of Respondents: 92,228.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 46,114 hours.

Estimated Total Annual Cost: $311,945.

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 collection 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.

Frances Teel,
NASA PRA Clearance Officer.

[FR Doc. 2016–08851 Filed 4–15–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Account Based Disclosures in Connection With Truth in Savings; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: NCUA, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the submission for reinstatement of a previously approved collection, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). NCUA is soliciting comment on the
reinstatement of the information collection described below.

DATES: Comments should be received on or before June 17, 2016 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428; Fax No. 703–519–8579; or Email at PRAComments@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the address above.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

The Truth in Savings Act, 12 U.S.C. 4301 et seq., (TISA) requires depository institutions to disclose to consumers certain information, including interest rates, dividend rates, and fees associated with their deposit accounts and accompanying services. TISA directed the Federal Reserve Board (FRB) to issue a final regulation governing depository institution other than credit unions. FRB promulgated the TISA regulation, known as Regulation DD, 12 CFR part 230. The Dodd-Frank Wall Street Reform and Consumer Protection Act transferred FRB’s rulemaking authority for TISA to the Consumer Financial Protection Bureau (CFPB).

TISA also directed the National Credit Union Administration (NCUA) to promulgate a TISA regulation governing credit unions. Section 272(b) of TISA, 12 U.S.C. 4311(b), mandated that NCUA regulation be “substantially similar” to those issued by FRB (and now CFPB), but NCUA may take into account the unique nature of credit unions and the limitations under which they may pay dividends.

To implement TISA, NCUA published its TISA regulation, 12 CFR part 707, which applies to all credit unions whose accounts are either insured by, or eligible to be insured by, the National Credit Union Share Insurance Fund, except for any credit union that has been designated as a corporate credit union and any non-automated credit union that has $2 million or less in assets.

Credit unions are required to provide specific disclosures when an account is opened, when a disclosed term changes or a term account is close to renewal, on periodic statements of account activity, in advertisements, and upon a member’s or potential member’s request. 12 CFR 707.4, 707.5, 707.6, 707.8. Credit unions that provide periodic statements are required to include information about fees imposed, the annual percentage yield earned during those statement periods, and other account terms. The requirements for creating and disseminating account disclosures, change in terms notices, term share renewal notices, statement disclosures, and advertising disclosures are necessary to implement TISA’s purpose of providing the public with information that will permit informed comparisons of accounts at depository institutions.

The collection of information pursuant to Part 707 is triggered by specific events and disclosures and must be provided to consumers within the time periods established under the regulation. To ease the compliance cost (particularly for small credit unions), model clauses and sample forms are appended to the regulation.

Although the regulation requires depository institutions to retain evidence of compliance with the disclosure requirements, the regulation does not specify the types of records that must be retained.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (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 the information on the respondents, including the use of automated collection techniques or other forms of information technology.

II. Data

Title: Account Based Disclosures in Connection with 12 CFR part 707.
OMB Number: 3133–0134.

Type of Review: Reinstatement with change of a previously approved collection.

Description: NCUA’s TISA regulation requires credit unions to provide specific disclosures when an account is opened, when a disclosed term changes or a term account is close to renewal, on periodic statements of account activity, in advertisements, and upon a member’s or potential member’s request. 12 CFR 707.4, 707.5, 707.6, 707.8. Credit unions that provide periodic statements are required to include information about fees imposed, the annual percentage yield earned during those statement periods, and other account terms. The requirements for creating and disseminating account disclosures, change in terms notices, term share renewal notices, statement disclosures, and advertising disclosures are necessary to implement TISA’s purpose of providing the public with information that will permit informed comparisons of accounts at depository institutions.

Respondents: All credit unions whose accounts are either insured by, or eligible to be insured by, the National Credit Union Share Insurance Fund, except for any credit union that has been designated as a corporate credit union and any non-automated credit union that has $2 million or less in assets.

Estimated Number of Respondents: 6,247.

Estimated Total Annual Burden Hours: 438,852.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on April 13, 2016.

Dated: April 13, 2016

Dawn D. Wolfgang,
NCUA PRA Clearance Officer.
[FR Doc. 2016–08874 Filed 4–15–16; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities; Proposed Collections; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: NCUA, as part of its continuing effort to reduce paperwork
and respondent burden, invites the general public and other Federal agencies to comment on these reinstatements of previously approved collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments should be received on or before June 17, 2016 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Troy Hillier, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428; Fax No. 703–519–8595; or Email at PRAComments@NCUA.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the address above.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0092.

Title: Loans to Members and Lines of Credit to Members. 12 CFR 701.21 and 12 CFR 741.

Abstract: Section 107 (5) of the Federal Credit Union Act authorizes Federal Credit Unions to make loans to members and issue lines of credit (including credit cards) to members. Part 741 of NCUA’s rules and regulations established requirements for all federally insured credit unions related to loans to members and lines of credit union members. Additionally, NCUA’s rules and regulations at § 701.21 establish additional requirements related to loans to members and lines of credit to members for federal credit unions. These regulations include various information collections to ensure credit unions comply with applicable laws and operate in a safe and sound manner.

Type of Review: Reinstatement without change of a previously approved collection.

Affected Public: Private sector: not-for-profit institutions.

Estimated Number of Respondents: 1,004.

Estimated Number of Responses per Respondent: 38.

Estimated Burden Hours per Response: 0.27.

Estimated Total Annual Burden Hours: 10,540.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (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 the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on April 13, 2016.

Dated: April 13, 2016.

Dawn D. Wolfgang, NCUA PRA Clearance Officer.

[FR Doc. 2016–08876 Filed 4–15–16; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m., Thursday, April 21, 2016.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street (All visitors must use Diagonal Road Entrance), Alexandria, VA 22314–3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:


2. NCUA’s Rules and Regulations, Incentive-Based Executive Compensation.


RECESS: 11:00 a.m.

TIME AND DATE: 11:15 a.m., Thursday, April 21, 2016.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Supervisory Matter. Closed pursuant to Exemption (8).

FOR FURTHER INFORMATION CONTACT:


Gerard Poliquin, Secretary of the Board.

[FR Doc. 2016–09039 Filed 4–14–16; 4:15 pm]

BILLING CODE 7535–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of meetings.

SUMMARY: The National Endowment for the Humanities will hold three meetings of the Humanities Panel, a federal advisory committee, during May, 2016. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965.

DATES: See SUPPLEMENTARY INFORMATION section for meeting dates.
ADDITIONS: The meetings will be held at Constitution Center at 400 7th Street SW., Washington, DC 20506. See SUPPLEMENTARY INFORMATION for meeting room numbers.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW., Room, 4060, Washington, DC 20506; (202) 606–8322; evoyatzis@neh.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. Date: May 2, 2016.
   Time: 8:30 a.m. to 5:00 p.m.
   Room: P002.
   This meeting will discuss applications for the Institutes for College and University Teachers grant program, submitted to the Division of Education Programs.

2. Date: May 3, 2016.
   Time: 8:30 a.m. to 5:00 p.m.
   Room: P002.
   This meeting will discuss applications for the Institutes for College Teachers grant program, submitted to the Division of Education Programs.

3. Date: May 3, 2016.
   Time: 8:30 a.m. to 5:00 p.m.
   Room: Virtual Panel.
   This meeting will discuss applications for the Institutes for Advanced Topics in the Digital Humanities grant program, submitted to the Office of Digital Humanities.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings dated July 19, 1993.

Dated: April 12, 2016.

Elizabeth Voyatzis,
Committee Management Officer.
[FR Doc. 2016–08790 Filed 4–15–16; 8:45 am]
BILLING CODE 7555–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of RiverFront Dynamic US Dividend Advantage ETF and RiverFront Dynamic US Flex-Cap ETF under NYSE Arca Equities Rule 8.600

April 12, 2016.

I. Introduction

On February 5, 2016, NYSE Arca, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 19b–4 thereunder, a proposed rule change to list and trade shares ("Shares") of the following under NYSE Arca Equities Rule 8.600: RiverFront Dynamic US Dividend Advantage ETF and RiverFront Dynamic US Flex-Cap ETF (each a "Fund," and collectively, "Funds"). The Commission published notice of the proposed rule change in the Federal Register on February 25, 2016. On April 7, 2016, the Exchange submitted Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comment on Amendment No. 1 to the proposed rule change from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. The Exchange's Description of the Proposal

The Exchange proposes to list and trade the Shares under NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares. The Funds are each a series of 15 U.S.C. 78s(b)(1).


4 Amendment No. 1 replaced and superseded the original filing in its entirety. Amendment No. 1 is available at http://www.sec.gov/comments/sr-nysearca-2016-28/nysearca201628-1.pdf.

5 Additional information regarding the Trust and/or the Funds (as defined herein), the Funds, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings, disclosure policies, calculation of net asset value ("NAV"), distributions, and taxes, among other things, can be found in the Notice and the Registration Statement, as applicable. See Notice, supra note 3, and Registration Statement, infra note 6.

NATIONAL SCIENCE FOUNDATION

Business and Operations Advisory Committee Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Business and Operations Advisory Committee (9556).

Date/Time: May 11, 2016; 1:00 p.m. to 5:30 p.m. (EST) May 12, 2016; 9:00 a.m. to 12:00 p.m. (EST).

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230; Stafford I, Room 1235.

Type of Meeting: Open.

Contact Person: Patty Balanga, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230; (703) 292–8100.

Purpose of Meeting: To provide advice concerning issues related to the oversight, integrity, development and enhancement of NSF’s business operations.

Agenda

Wednesday, May 11, 2016; 1:00 p.m.–5:30 p.m.

Welcome/Introductions; BFA/OIRM Updates; Enterprise Risk Management; From Systems to Data and Beyond; Benchmarking: Recommendations of the National Academy of Public Administration (NAPA) Study of NSF’s Use of Cooperative Agreements to Support Large Scale Investments in Science and Technology.

Thursday, May 12, 2016; 9:00 a.m.–12:00 p.m.

Modernization of Business Processes and Workforce Structures: A Discussion of Lessons Learned; Discussion with Chief Operating Officer; Meeting Wrap-Up.

Dated: April 13, 2016.

Crystal Robinson,
Committee Management Officer.
[FR Doc. 2016–08867 Filed 4–15–16; 8:45 am]
BILLING CODE 7555–01–P
ALPS ETF Trust ("Trust"), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company. The Funds will be managed by ALPS Advisors, Inc. ("Adviser"). RiverFront Investment Group, LLC ("Sub-Adviser") is the investment sub-adviser for the Funds.7

RiverFront Dynamic US Dividend Advantage ETF: Principal Investments

The Exchange states that the investment objective of the Fund will be to seek to provide capital appreciation and dividend income. Under normal market conditions,8 the Fund will seek to achieve its investment objective by investing at least 65% of its net assets in a portfolio of exchange-traded equity securities of publicly traded U.S. companies with the potential for dividend growth. The exchange-traded equity securities the Fund may invest in as part of its principal investments are common stocks and common or preferred shares of real estate investment trusts ("REITs"). The Fund may invest in exchange-traded equity securities issued by small-, mid-, and large-capitalization companies. The Fund may also invest in other exchange-traded funds ("ETFs")9 and/or exchange-traded closed-end funds ("CEFs") which invest in equity securities.

The Exchange states that in selecting the Fund’s portfolio securities, the Sub-Adviser assembles a portfolio of eligible securities based on several core attributes such as value, quality, and momentum. The Sub-Adviser will consider multiple proprietary factors within each core attribute, such as the price-to-book value of a security when determining value, a company’s cash as a percentage of the company’s market capitalization when determining quality, and a security’s three month relative price change when determining momentum. Additionally, within a given sector, security selection will emphasize companies offering a meaningful dividend yield premium over alternative investments within that sector. This dividend yield emphasis is subject to quality screens intended to limit exposure to companies whose financial characteristics suggest the potential for dividend cuts. The Sub-Adviser then assigns each qualifying security a score based on its core attributes, including its dividend growth score, and selects the individual securities with the highest scores for investment. The Exchange states that in doing so, the Sub-Adviser will utilize its proprietary optimization process to maximize the percentage of high-scoring securities included in the portfolio. The Sub-Adviser will also consider the market capitalization of the companies in which the Fund may invest, the trading volume of a company’s shares in the secondary market.

Non-Principal Investments for Each Fund

The Exchange states that while each Fund will, under normal market conditions, principally invest at least 65% of its net assets in the securities and financial instruments as described above, each Fund may invest its remaining assets in the securities and financial instruments described below. A Fund may invest in other types of equity securities, as follows: Non-exchange traded common stock (including REITs), exchange-traded and non-exchange traded preferred stock (including REITs), exchange-traded and non-exchange traded convertible securities, exchange-traded master limited partnerships ("MLPs"), and exchange-traded business development companies ("BDCs").

According to the Exchange, a Fund may invest in exchange-traded or over-the-counter ("OTC") equity securities of...
non-U.S. companies, including issuers in emerging market countries, but investments in non-U.S. securities, including non-U.S. equity securities, may not exceed 20% of a Fund’s net assets, plus the amount of any borrowings for investment purposes, under normal market conditions.

The Exchange states that a Fund may also invest in the following short-term instruments on an ongoing basis to provide liquidity or for other reasons: Money market instruments, cash, and cash equivalents. Cash equivalents include the following: (i) Short-term obligations issued by the U.S. Government; (ii) negotiable certificates of deposit, fixed time deposits, and bankers’ acceptances of U.S. and foreign banks and similar institutions; (iii) commercial paper rated at the date of purchase “Prime-1” by Moody’s Investors Service, Inc. or “A–1+” or “A– 1” by Standard & Poor’s or, if unrated, of comparable quality as determined by the Adviser or Sub-Adviser; (iv) repurchase agreements; and (v) money market mutual funds.

In addition, the Exchange states that a Fund may use derivative instruments. Specifically, a Fund may use options, futures, swaps, and forwards, for hedging or risk management purposes or as part of its investment practices. The Exchange states that a Fund may enter into the following derivatives: Futures on securities, indices, and currencies, and options on such futures; exchange-traded and OTC options on securities, indices, and currencies; exchange-traded and OTC interest rate swaps, cross-currency swaps, total return swaps, inflation swaps, and credit default swaps; and options on such swaps (“swaptions”). The swaps in which a Fund will invest may be cleared swaps or non-cleared. A Fund may enter into derivatives traded in the U.S. or in non-U.S. countries. A Fund will collateralize its obligations with liquid assets consistent with the 1940 Act and interpretations thereunder.

The Exchange states that a Fund may invest in forward currency contracts. Currency forward contracts may be used to increase or reduce exposure to currency price movements. At the discretion of the Adviser or Sub-Adviser, the Funds may enter into forward currency exchange contracts for hedging purposes to help reduce the risks and volatility caused by changes in foreign currency exchange rates.

A Fund may gain exposure to foreign securities by purchasing U.S. exchange-listed and traded American Depositary Receipts (“ADRs”), non-exchange-listed ADRs, exchange-traded European Depositary Receipts (“EDRs”), and exchange-traded Global Depositary Receipts (“GDRs”), together with ADRs and EDRs, “Depositary Receipts.”

The Exchange states that the Funds may invest in Rule 144A restricted securities.

**Investment Restrictions for Each Fund**

Each Fund may invest up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including securities that are offered pursuant to Rule 144A under the Securities Act deemed illiquid by the Adviser or Sub-Adviser. Each Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of a Fund’s net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

Each Fund may invest up to 10% of its net assets in equity securities traded OTC.

The Funds intend to qualify for and to elect to be treated as separate regulated investment companies under Subchapter M of the Internal Revenue Code.

Each Fund’s investments will be consistent with such Fund’s investment objective and will not be used to enhance leverage. That is, while each Fund will be permitted to borrow as permitted under the 1940 Act, a Fund’s investments will not be used to seek performance that is the multiple or inverse multiple (i.e., 2Xs and 3Xs) of a Fund’s primary broad-based securities benchmark index (as defined in Form N–1A).

Not more than 10% of the net assets of each Fund in the aggregate invested in equity securities (other than non-exchange traded money market funds) shall consist of equity securities whose principal market is not a member of the Intermarket Surveillance Group (“ISG”) or party to a comprehensive surveillance sharing agreement (“CSSA”) with the Exchange. Not more than 10% of the net assets of a Fund in the aggregate invested in futures contracts or options contracts shall consist of futures contracts or exchange-traded options contracts whose principal market is not a member of the ISG or is a market with which the Exchange does not have a CSSA.

### III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange’s proposal to list and trade the Shares is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission finds that...
the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Exchange Act, which requires, among other things, that the Exchange’s rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the proposal to list and trade the Shares. U.S. exchange-traded common stocks, as well as other exchange traded equity securities, including Depositary Receipts (excluding ADRs traded OTC and GDRs), preferred securities, convertible securities, REITs, BDCs, CEFs, ETFs, and MLPs (collectively, “Exchange-Traded Equities”) will be available via the Consolidated Tape Association (“CTA”) high-speed line and from the securities exchanges on which they are listed. The Exchange represents that price information for exchange-traded derivative instruments will be available from the applicable exchange and from major market data vendors. The Exchange states that price information for instruments traded OTC (such as common stock traded OTC (including REITs), non-exchange-listed ADRs, preferred securities (including REITs), convertible securities, and cash equivalents) will be available from major market data vendors. Price information for non-U.S. exchange-traded equity securities will be readily available for exchanges trading such securities as well as automated quotation systems, published or other public sources, or on-line information services. Price information for money market instruments will be available from major market data vendors. Quotation and last sale information for GDRs will be available from the securities exchanges on which they are listed. Information relating to futures, options on futures, and exchange-traded swaps will be available from the exchange on which such instruments are traded. Price information relating to exchange-traded options will be available via the Options Price Reporting Authority. Quotation information from brokers and dealers or pricing services will be available for Rule 144A securities, ADRs traded OTC, and non-exchange-traded derivatives, including forwards, OTC swaps, and OTC options. The Exchange states that pricing information regarding each asset class in which the Funds will invest is generally available through nationally recognized data services providers through subscription agreements.

In addition, the indicative intra-day value, which is the Portfolio Indicative Value, as defined in NYSE Arca Equities Rule 8.600 (c)(3), will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, each Fund will disclose on its Web site the Disclosed Portfolio as defined in NYSE Arca Equities Rule 8.600(c)(2) that will form the basis for a Fund’s calculation of NAV at the end of the business day. The NAV per Share will be calculated by each Fund’s custodian and determined as of the close of the regular trading session on the New York Stock Exchange (“NYSE”) (ordinarily 4:00 p.m., Eastern Time) on each day that the NYSE is open. A basket composition file, which will include the security names and share quantities required to be delivered in exchange for each Fund’s Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the NYSE via the National Securities Clearing Corporation.

22 Currently, it is the Exchange’s understanding that several major market data vendors display and/or make widely available Portfolio Indicative Values taken from CTA or other data feeds. On a daily basis, the Adviser or Sub-Adviser will disclose on the Funds’ Web site the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security, commodity, index, or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value, or number of shares, contracts, or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in each Fund’s portfolio. The Web site information will be publicly available at no charge. The Funds’ disclosure of derivative positions in the Disclosed Portfolio will include information that market participants can use to value these positions intraday.

Information regarding market price and trading volume for the Shares will be continually available on a real-time basis throughout the day on brokers’ computer screens and other electronic services. Information regarding the previous day’s closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. The Web site for the Funds will include a form of the prospectus for each Fund and additional data relating to NAV and other applicable quantitative information. The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio for each Fund will be made available to all market participants at the same time.

The Exchange represents that trading in Shares of a Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of a Fund may be halted.

The Exchange represents that it has a general policy prohibiting the distribution of material, non-public information by its employees. Each of the Adviser and the Sub-Adviser is affiliated with a broker-dealer and has implemented and will maintain a firewall with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to a Fund’s portfolio. Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio of each Fund must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-

24 See NYSE Arca Equities Rule 8.600(d)(1)(B).

25 These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of a Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.

26 See note 7, supra. The Exchange represents that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940.
public information regarding the actual components of the portfolio.27

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit Holders (“ETP Holders”) in an Information Bulletin (“Bulletin”) of the special characteristics and risks associated with trading the Shares. The Exchange represents that trading in the Shares will be subject to the existing trading surveillance, administered by the Exchange or the Financial Industry Regulatory Authority (“FINRA”) on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.28

The Exchange represents that it deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange’s existing rules governing the trading of equity securities. In support of this proposal, the Exchange has also made the following representations:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600.
(2) All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange.

(3) The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Funds to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will monitor29 for compliance with the
continued listing requirements. If the Funds are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Equities Rule 5.5(m).

(4) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.
(5) Trading in the Shares will be subject to the existing trading surveillance, administered by the Exchange or FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws, and these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.
(6) The Exchange or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares, Exchange-Traded Equities, and certain exchange-traded options and futures with other markets and other entities that are members of the ISG, and the Exchange, or FINRA on behalf of the Exchange, may obtain trading information regarding trading in the Shares, Exchange-Traded Equities, and certain exchange-traded options and futures from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, Exchange-Traded Equities, and certain exchange-traded options and futures from markets and other entities that are members of ISG or with which the Exchange has in place a CSSA.

(7) Prior to the commencement of trading of the Shares, the Exchange will inform its ETP Holders in a Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (a) The procedures for purchases and redemptions of Shares in creation units (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (c) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated IV will not be calculated or publicly disseminated; (d) how information regarding the Portfolio Indicative Value and the Disclosed Portfolio is disseminated; (e) the

The Commission notes that certain other proposals for the listing and trading of managed fund shares include a representation that the exchange will monitor or surveil compliance with the continued listing requirements. See, e.g., Amendment No. 2 to SR–BATS–2016–04, available at: http://www.sec.gov/comments/sr-bats-2016-04/bats2016042-2.pdf. In the context of this representation, it is the Commission’s view that “monitor” and “surveil” both mean ongoing oversight of the Fund’s compliance with the
continued listing requirements. Therefore, the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(8) For initial and continued listing, each Fund will be in compliance with Rule 10A–3 under the Exchange Act,30 as provided by NYSE Arca Equities Rule 5.3.

(9) A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange.

(10) Under normal market conditions, the RiverFront Dynamic US Dividend Advantage ETF will seek to achieve its investment objective by investing at least 65% of its net assets in a portfolio of exchange-traded equity securities of publicly traded U.S. companies with the potential for dividend growth.

(11) Under normal market conditions, the RiverFront Dynamic US Flex-Cap ETF will seek to achieve its investment objective by investing at least 65% of its net assets in a portfolio of exchange-traded equity securities of publicly traded U.S. companies.

(12) Each Fund may invest up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including securities that are offered pursuant to Rule 144A under the Securities Act deemed illiquid by the Adviser or Sub-Adviser.

(13) Not more than 10% of the net assets of a Fund in the aggregate invested in equity securities (other than non-exchange traded money market funds) shall consist of equity securities whose principal market is not a member of the ISG or party to a CSSA with the Exchange.

(14) Not more than 10% of the net assets of a Fund in the aggregate invested in futures contracts or options contracts shall consist of futures contracts or options contracts whose principal market is not a member of the ISG or a market with which the Exchange does not have a CSSA.

(15) A Fund’s investments in non-U.S. securities, including non-U.S. equity securities, may not exceed 20% of a Fund’s net assets, plus the amount of any borrowings for investment purposes, under normal market conditions.

(16) A Fund may invest up to 10% of its net assets in equity securities traded OTC.

(17) The Funds will not invest in leveraged or leveraged inverse ETFs.

(18) A Fund’s investments will be consistent with such Fund’s investment

27 See NYSE Arca Equities Rule 8.600[d][2][iii].
28 The Exchange states that FINRA conducts cross market surveillances of trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA’s performance under this regulatory services agreement.
29 The Commission notes that certain other proposals for the listing and trading of managed fund shares include a representation that the exchange will monitor or surveil compliance with the continued listing requirements. See, e.g., Amendment No. 2 to SR–BATS–2016–04, available at: http://www.sec.gov/comments/sr-bats-2016-04/bats2016042-2.pdf. In the context of this representation, it is the Commission’s view that “monitor” and “surveil” both mean ongoing oversight of the Fund’s compliance with the continued listing requirements.

objective and will not be used to enhance leverage. That is, while a Fund will be permitted to borrow as permitted under the 1940 Act, a Fund’s investments will not be used to seek performance that is the multiple or inverse multiple (i.e., 2Xs and 3Xs) of a Fund’s primary broad-based securities benchmark index (as defined in Form N–1A).

This approval order is based on all of the Exchange’s representations, including those set forth above, in the Notice, and in Amendment No. 1. The Commission notes that the Funds and the Shares must comply with the requirements of NYSE Arca Equities Rule 8.600 to be initially and continuously listed and traded on the Exchange.

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments
- Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to rule-comments@sec.gov. Please include File Number SR–NYSEArca–2016–28 on the subject line.

Paper Comments
- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File Number SR–NYSEArca–2016–28 and should be submitted on or before May 9, 2016.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after the date of publication of notice of Amendment No. 1 in the Federal Register. Amendment No. 1 revised the proposed rule change by: (1) Clarifying the permitted investments of the Funds; (2) modifying the investment restrictions applicable to the Funds; (3) clarifying how certain investments will be valued for computing each Fund’s NAV; (4) describing where price information can be obtained for certain investments of the Funds; and (5) providing additional representations relating to the continued listing requirements for listing the Shares on the Exchange, including issuer notification requirements if a Fund fails to comply with such continued listing requirements, and Exchange surveillance obligations relating to such continued listing requirements.

Amendment No. 1 supplements the proposed rule change by, among other things, clarifying the scope of the Funds’ permitted investments and investment restrictions and providing additional information about the availability of pricing information for the Funds’ underlying assets. It also helps the Commission evaluate whether the listing and trading of the Shares of the Funds would be consistent with the protection of investors and the public interest.

Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act, to approve the proposed rule change, as modified by Amendment No. 1 on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act, that the proposed rule change (SR–NYSEArca–2016–28), as modified by Amendment No. 1 thereto, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.33

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2016–08818 Filed 4–15–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Price List To Adopt a Rebate Program for the NYSE BondsSM System

April 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ”Act”) and Rule 19b–4 thereunder, notice is hereby given that, on March 29, 2016, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List, effective April 1, 2016, to adopt a rebate program for the NYSE BondsSM system. The proposed rule change is available on the Exchange’s Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.


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II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filings with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List, effective April 1, 2016, to adopt a rebate program for the NYSE Bonds system.

The Exchange currently charges an execution fee per bond for orders that take liquidity from the NYSE Bonds Book. For executions of one to 10 bonds, the Exchange charges $0.50 per bond; for executions of 11 to 25 bonds, the Exchange charges $0.20 per bond; and for executions of 26 bonds or more, the Exchange charges $0.10 per bond. The execution fees for bonds are subject to an additional $100.00 maximum fee per execution. The Exchange currently does not provide any rebates for bond transactions, other than rebates for bond liquidity providers that meet the requirements of Rule 88. The Exchange is not proposing any change to the bond liquidity provider rebate program.

The Exchange proposes to adopt the Liquidity Provider Incentive Program, a voluntary rebate program relating to bonds pursuant to which the Exchange would pay Users of NYSE Bonds a monthly rebate provided Users who opt into the proposed rebate program meet specified quoting requirements. Under the program, the rebate payable would be based on the number of CUSIPs quoted by a User, as follows:

<table>
<thead>
<tr>
<th>Number of CUSIPs</th>
<th>Monthly rebate</th>
</tr>
</thead>
<tbody>
<tr>
<td>400–599</td>
<td>$10,000</td>
</tr>
<tr>
<td>600–799</td>
<td>20,000</td>
</tr>
<tr>
<td>800 or more</td>
<td>30,000</td>
</tr>
</tbody>
</table>

To qualify for a rebate, a User would have to provide continuous two-sided quotes for at least eighty percent (80%) of the time during the Core Bond Trading Session for an entire calendar month. The Exchange would calculate each participating User’s quoting performance beginning each month on a daily basis, up to and including the last trading day of a calendar month, to determine at the end of each month the User’s monthly average. The Exchange would provide Users a report on a daily basis with quoting statistics so that Users can determine whether or not they are meeting the Exchange’s current stated criteria. Under the program, Users must provide a two-sided quote for a minimum of hundred (100) bonds per side of the market with an average spread of half-point ($0.50) or less in CUSIPs whose average maturity is at least five (5) years as of the date the User provides a quote. Average maturity is calculated by determining the number of calendar days between the quote date and the maturity date of a bond. The resulting number (total days to maturity) is divided by 365 to derive the maturity in years.

As an incentive for Users to opt in to the Liquidity Provider Incentive Program, the Exchange proposes a lower quoting requirement of 50% that would be applicable for the first calendar month after a User opts in. After the first calendar month, the User would be required to meet the 80% quoting requirement to receive a rebate. A User who first opts in, and who therefore would be subject to the 50% quoting requirement for the first calendar month, and then opts out, would not be entitled to the 50% quoting incentive if that User decides to opt in to the program again at a later date. The 50% quoting incentive would only be available to a User once for the first calendar month after the User first opts in to the Liquidity Provider Incentive Program.

Users that opt in to the Liquidity Provider Incentive Program would be subject to a transaction fee for orders that provide liquidity to the NYSE Bonds Book of $0.50 per bond, and for orders that take liquidity from the NYSE Bonds Book, the current tiered fees would apply, i.e., $0.50 per bond for executions of one to 10 bonds, $0.20 per bond for executions of 11 to 25 bonds, and $0.10 per bond for executions of 26 bonds or more, with a maximum fee of $100 per execution. Users that do not opt in to the Liquidity Provider Incentive Program would be subject to the Exchange’s standard fees and rebates, as currently provided on the Price List.

The Liquidity Provider Incentive Program would be applicable on trading days, as determined by Securities Industry and Financial Markets Association (“SIFMA”), and not the Exchange.

As noted above, the Liquidity Provider Incentive Program would be voluntary and Users that wish to participate would be required to opt in by notifying the Exchange via electronic email. Users would be required to communicate to the Exchange their intention to opt in, or to opt out if they are already participating in the program, by the end of the Core Bond Trading Session on the first trading day of a calendar month.

The Exchange proposes that if a User meets the quoting requirements for a given month, that User would be entitled to a rebate that month. As proposed, the amount of the rebate would be based on the number of CUSIPs in which the User met the quoting requirement. For example, a User who opts in to the Liquidity Provider Incentive Program on the first trading day of the month and provides a two-sided quote for 500 CUSIPs, whose average maturity is at least five (5) years as of the quote date, for at least 50% of the time during the Core Bond Trading Session for that entire calendar month, would receive a rebate of $10,000 for that month. For subsequent months, this User would be required to provide a

4 There are currently no bond liquidity providers who meet the requirements of Rule 88 and therefore no rebates are currently provided under the program.

5 Rule 86(b)(2)(M) defines a User as any Member or Member Organization, Sponsored Participant, or Authorized Trader that is authorized to access NYSE Bonds.

6 CUSIP stands for Committee on Uniform Securities Identification Procedures. A CUSIP number identifies most financial instruments, including Stocks of all registered U.S. and Canadian companies, commercial paper, and U.S. government and municipal bonds. The CUSIP system—owned by the American Bankers Association and managed by Standard & Poor’s—facilitates the clearance and settlement process of securities. See http://www.sec.gov/answers/cusip.htm.

7 The Core Bond Trading Session commences with the Core Bond Auction at 8:00 a.m. ET and concludes at 5:00 p.m. ET. See Rule 86(b)(2).

two-sided quote for at least 80% of the time during the Core Bond Trading Session in order for the User to continue to receive the rebate.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,\(^9\) in general, and further the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,\(^10\) in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. The Exchange believes that it is reasonable and equitable to adopt the Liquidity Provider Incentive Program for the bonds trading platform, which would provide rebates for member organizations that provide liquidity and meet quoting volume requirements. The proposed rebate program would provide incentives for additional liquidity at the Exchange. The Exchange believes that the proposed quoting requirements to qualify for rebates, which would be based on the size, spread and maturity dates, are reasonable and would not unfairly discriminate between customers, issuers, and brokers or dealers because all member organizations that opt in to the Liquidity Provider Incentive Program would be subject to the same requirements. The Exchange further believes that the proposed quoting requirements are reasonable because they are designed to provide an incentive for member organizations to increase displayed liquidity at the Exchange, thereby increasing traded volume.

The Exchange also believes it is reasonable and equitable to charge a fee to Users who opt in to the proposed rebate program when they provide liquidity in bonds traded on the Exchange. The proposed maker fee is intended to offset the significant rebates proposed by the Exchange, which would increase as the number of CUSIPs quoted by a User increases. The Exchange further believes the proposed fee change is not unfairly discriminatory because all member organizations that opt in to the Liquidity Provider Incentive Program would be subject to the same fees.

Finally, recognizing the statements of Commissioners who have expressed concern about the state of the U.S. corporate and municipal bond markets as well as recommendations outlined in the Commission’s release of its Report on the Municipal Securities Market (Report), the Exchange believes that amending the Exchange’s transaction fees for the Bonds system would create an incentive for bonds traders to direct their liquidity to the Exchange, and therefore would be an important element in the democratization of the fixed income market.\(^11\) As highlighted in SEC Chair White’s statement during the SEC’s 2013 Roundtable on Fixed Income Markets, the Report makes recommendations that include (1) improving pre- and post-trade transparency; (2) promoting the use of transparent and open trading venues; and (3) requiring dealers to seek “best execution” for customers and to provide customers with relevant pricing information in connection with their transactions.\(^12\) Achieving these recommendations and applying them to both the municipal and corporate bond markets would, in the Exchange’s view, assist in lowering the systemic risk that is anticipated to increase as interest rates rise and the closed network of bond trading comes under pressure as retirement and pension managers seek to adjust their positions.

The Exchange believes the proposed fee change is consistent with these principles and the proposed Liquidity Provider Incentive Program is intended to provide additional liquidity to the market and add competition to the existing group of liquidity providers. The Exchange believes that by requiring Users to quote within the prescribed parameters for a percentage of the regular trading day, and by paying them a rebate for providing liquidity in large number of bonds, the Exchange is rewarding aggressive liquidity providers in the market, and by doing so, the Exchange will encourage the additional utilization of, and interaction with, the NYSE and provide customers with the premier venue for price discovery, liquidity, and competitive quotes.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,\(^13\) the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Debt securities typically trade on a centralized OTC dealer market that is less liquid and transparent than the equities markets. The Exchange believes that the proposed change would increase competition with these OTC venues by creating incentives to engage in bonds transactions on the Exchange and rewarding market participants for actively quoting and providing liquidity in the only transparent bond market, which the Exchange believes will enhance market quality.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues that are not transparent. In such an environment, the Exchange must continually review, and consider adjusting its fees and rebates to remain competitive with other exchanges as well as with alternative trading systems and other venues that are not required to comply with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed change will impair the ability of member organizations or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)\(^14\) of the Act and subparagraph (f)(2) of Rule 19b–4\(^15\) thereunder, because it establishes a due, fee, or other charge imposed by the Exchange. At any time within 60 days of the filing of such proposed rule change, the Commission may:

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temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments
• Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include File Number SR–NYSE–2016–26 on the subject line.

Paper Comments
• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–26, and should be submitted on or before May 9, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.17

Robert W. Errett,
Deputy Secretary.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32069; File No. 812–14557]

Nuveen Fund Advisors, LLC, et al.; Notice of Application

April 12, 2016.

AGENCY: Securities and Exchange Commission (“Commission”).

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (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) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.

SUMMARY: Applicants request an order that would permit (a) series of certain open-end management investment companies 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 (“NAV”); (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares; and (f) certain series to perform creations and redemptions of Creation Units in-kind in a master-feeder structure.

APPLICANTS: Nuveen ETF Trust (the “Trust”), Nuveen Fund Advisors, LLC (“Nuveen”), and Nuveen Securities, LLC.

FILING DATES: The application was filed on October 2, 2015, and amended on November 17, 2015 and March 4, 2016.

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 writing to the Commission’s Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 9, 2016, 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 writing to the Commission’s Secretary.

ADDRESSES: The Commission: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: 333 West Wacker Drive, Chicago, IL 60606.

FOR FURTHER INFORMATION CONTACT: James D. McGinnis, Attorney-Advisor at (202) 551–3025, or Sara Crovitz, Assistant Chief Counsel, at (202) 551–6862 (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 Web site 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’ Representations

1. The Trust is organized as a Massachusetts business trust. The Trust is, or will be prior to the commencement of operations of the initial series of the Trust (the “Initial Fund”), registered under the Act as an open-end management investment company.

2. Nuveen is registered as an investment adviser under the Investment Advisers Act of 1940 (the “Advisers Act”) and will be the investment adviser to the Initial Fund. Any other Adviser (defined below) will also be registered as an investment adviser under the Advisers Act. An Adviser may enter into sub-advisory agreements with one or more


investment advisers to act as sub-advisers to particular Funds, or their respective Master Funds (each, a “Sub-Adviser”). Any Sub-Adviser to a Fund, or its respective Master Fund, will either be registered under the Advisers Act or will not be required to register thereunder.

3. The Trust will enter into a distribution agreement with one or more distributors. Each distributor for a Fund will be a broker-dealer (a “Broker”) registered under the Securities Exchange Act of 1934 (the “Exchange Act”) and will act as distributor and principal underwriter (a “Distributor”) of one or more of the Funds. The Distributor of any Fund may be an affiliated person, as defined in section 2(a)(3) of the Act (“Affiliated Person”), or an affiliated person of an Affiliated Person (“Second-Tier Affiliate”), of that Fund’s Adviser and/or Sub-Advisers. No Distributor is or will be affiliated with any national securities exchange as defined in Section 2(a)(26) of the Act (an “Exchange”).

4. Applicants request that the order apply to the Initial Fund and any other additional series of the Trust, and any other open-end management investment company or series thereof, that may be created in the future ("Future Funds") that operate as an exchanged-traded fund (“ETF”) and track a specified index comprised of domestic or foreign equity and/or fixed income securities (each, an “Underlying Index”). Any Future Fund will (a) be advised by Nuveen or an entity controlling, controlled by, or under common control with Nuveen, an “Adviser”) and (b) comply with the terms and conditions of the application. The Initial Fund and Future Funds, together, are the “Funds.”

5. Applicants state that a Fund may operate as a feeder fund in a master-feeder structure ("Feeder Fund"). Applicants request that the order permit a Feeder Fund to acquire shares of another registered investment company in the same group of investment companies having substantially the same investment objectives as the Feeder Fund ("Master Fund") beyond the limitations in section 12(d)(1)(A) of the Act and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B) of the Act (“Master-Feeder Relief”). Applicants may structure certain Feeder Funds to generate economies of scale and incur lower overhead costs. There would be no ability by Fund shareholders to exchange Shares of Feeder Funds for shares of another feeder series of the Master Fund.

6. Each Fund, or its respective Master Fund, will hold certain securities, currencies, other assets and other investment positions (“Portfolio Holdings”) selected to correspond generally to the performance of its Underlying Index. Certain of the Funds will be based on Underlying Indexes that will be comprised solely of equity and/or fixed income securities issued by one or more of the following categories of issuers: (i) Domestic issuers and (ii) non-domestic issuers meeting the requirements for trading in U.S. markets. Other Funds will be based on Underlying Indexes that will be comprised solely of foreign and domestic, or solely foreign, equity and/or fixed income securities (“Foreign Funds”).

7. Applicants represent that each Fund, or its respective Master Fund, will invest at least 80% of its assets (excluding collateral held from securities lending) in the component securities of its respective Underlying Index ("Component Securities") and TBA Transactions, and in the case of Foreign Funds, Component Securities and Depositary Receipts representing Component Securities. Each Fund, or its respective Master Fund, may also engage in short sales in other investment companies, as well as in securities and other instruments not included in its Underlying Index but which the applicable Adviser believes will help the Fund, or its respective Master Fund, track its Underlying Index. A Fund, or its respective Master Fund, may also engage in short sales in accordance with its investment objective.

8. Future Funds may seek to track Underlying Indexes constructed using 130/30 investment strategies (“130/30 Funds”) or other long/short investment strategies (“Long/Short Funds”). Each Long/Short Fund, or its respective Master Fund, will establish (i) exposures equal to approximately 100% of the long positions specified by the Long/Short Index and (ii) exposures equal to approximately 100% of the short positions specified by the Long/Short Index. Each 130/30 Fund, or its respective Master Fund, will include strategies that: (i) Establish long positions in securities so that total long exposure represents approximately 130% of a Fund’s net assets; and (ii) simultaneously establish short positions in other securities so that total short exposure represents approximately 30% of such Fund’s net assets. Each Business Day, the Adviser for each Long/Short Fund and 130/30 Fund will provide full portfolio transparency on the Fund’s publicly available Web site ("Web site") by making available the Long/Short Fund or 130/30 Fund’s, or its respective Master Fund’s, Portfolio Holdings before the commencement of trading of Shares on the Listing Exchange (defined below). The information provided on the Web site will be formatted to be reader-friendly.

9. A Fund, or its respective Master Fund, will utilize either a replication or representative sampling strategy to track its Underlying Index. A Fund, or its respective Master Fund, using a replication strategy will invest in the Component Securities of its Underlying Index in the same approximate

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1 All existing entities that intend to rely on the requested order have been named as applicants. Any other existing or future entity that subsequently relies on the order will comply with the terms and conditions of the order. A Fund of Funds (as defined below) may rely on the order only to invest in Funds and not in any other registered investment company.

2 Operating in a master-feeder structure could also impose costs on a Feeder Fund and reduce its tax efficiency. The Feeder Fund’s Board will consider any such potential disadvantages against the benefits of economies of scale and other benefits of operating within a master-feeder structure. In a master-feeder structure, the Master Fund—rather than the Feeder Fund—would generally invest its portfolio in compliance with the requested order.

3 A “to-be-announced transaction” or “TBA Transaction” is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree upon general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to settlement date.

4 Depositary receipts representing foreign securities (“Depositary Receipts”) include American Depositary Receipts and Global Depositary Receipts. The Funds, or their respective Master Funds, may invest in Depositary Receipts representing foreign securities in which they seek to invest. Depositary Receipts are typically issued by a financial institution (a “depositary bank”) and evidence ownership interests in a security or a pool of securities that have been deposited with the depositary bank. A Fund, or its respective Master Fund, will not invest in any Depositary Receipts that the Adviser or any Sub-Adviser deems to be illiquid or for which pricing information is not readily available. No affiliated person of a Fund, the Adviser or any Sub-Adviser will serve as the depositary bank for any Depositary Receipts held by a Fund, or its respective Master Fund.
proportions as in such Underlying Index. A Fund, or its respective Master Fund, using a representative sampling strategy will hold some, but not necessarily all, of the Component Securities of its Underlying Index. Applicants state that a Fund, or its respective Master Fund, using a representative sampling strategy will not be expected to track the performance of its Underlying Index with the same degree of accuracy as would an investment vehicle that invested in every Component Security of the Underlying Index with the same weighting as the Underlying Index. Applicants expect that the returns of each Fund will have an annual tracking error relative to the performance of its Underlying Index of less than 5%.

10. The Initial Fund is, and any Future Fund will be, entitled to use its Underlying Index pursuant to either a licensing agreement with the entity that compiles, creates, sponsors or maintains the Underlying Index (each, an “Index Provider”) or a sub-licensing arrangement with the applicable Adviser, which has, or will have, a licensing agreement with such Index Provider.7 A “Self-Indexing Fund” is a Fund for which an Affiliated Person, or a Second-Tier Affiliate, of the Trust or a Fund, of the Advisers, of any Sub-Adviser to or promoter of a Fund, or of the Distributor (each, an “Affiliated Index Provider”) will serve as the Index Provider. In the case of Self-Indexing Funds, an Affiliated Index Provider will create a proprietary, rules-based methodology to create Underlying Indexes (each an “Affiliated Index”).8 Except with respect to the Self-Indexing Funds, no Index Provider is or will be an Affiliated Person, or a Second-Tier Affiliate, of the Trust or a Fund, of an Adviser, or any Sub-Adviser to or promoter of a Fund, or of a Distributor.

11. Applicants recognize that Self-Indexing Funds could raise concerns regarding the potential ability of the Affiliated Index Provider to manipulate the Underlying Index to the benefit or detriment of the Self-Indexing Fund. Applicants further recognize the potential for conflicts that may arise with respect to the personal trading activity of personnel of the Affiliated Index Provider who have knowledge of changes to an Underlying Index prior to the time that information is publicly disseminated.

12. Applicants propose that each day that a Fund is open, including any day when it satisfies redemption requests as required by Section 22(e) of the Act (a “Business Day”), each Self-Indexing Fund will post on its Web site, before commencement of trading of Shares on the Exchange on which Shares are primarily listed (the “Listing Exchange”), the identities and quantities of the Portfolio Holdings that will form the basis for the Fund’s calculation of its NAV at the end of the Business Day. Applicants believe that requiring Self-Indexing Funds, and their respective Master Funds, to maintain full portfolio transparency will provide an additional alternative mechanism for addressing any such potential conflicts of interest.

13. Applicants do not believe the potential for conflicts of interest raised by an Adviser’s use of the Underlying Indexes in connection with the management of the Self-Indexing Funds, their respective Master Funds, and the Affiliated Accounts will be substantially different from the potential conflicts presented by an adviser managing two or more registered funds. Both the Act and the Advisers Act contain various protections to address conflicts of interest where an adviser is managing two or more registered funds and these protections will also help address these conflicts with respect to the Self-Indexing Funds.9

14. Each Adviser and any Sub-Adviser has adopted or will adopt, pursuant to Rule 206(4)–7 under the Advisers Act, written policies and procedures designed to prevent violations of the Advisers Act and the rules thereunder. These include policies and procedures designed to minimize potential conflicts of interest among the Self-Indexing Funds, their respective Master Funds, and the Affiliated Accounts, such as cross trading policies, as well as those designed to ensure the equitable allocation of portfolio transactions and brokerage commissions. In addition, Nuveen has adopted policies and procedures as required under section 204A of the Advisers Act, which are reasonably designed in light of the nature of its business to prevent the misuse, in violation of the Advisers Act or the Exchange Act or the rules thereunder, of material non-public information by Nuveen or associated persons (“Inside Information Policy”). Any other Adviser and/or Sub-Adviser will be required to adopt and maintain a similar Inside Information Policy. In accordance with the Code of Ethics10 and Inside Information Policy of each Adviser and Sub-Adviser, personnel of those entities with knowledge about the composition of the Portfolio Deposit11 will be prohibited from disclosing such information to any other person, except as authorized in the course of their employment, until such information is made public. In addition, an Index Provider will not provide any information relating to changes to an Underlying Index’s methodology for the inclusion of component securities, the inclusion or exclusion of specific component securities, or methodology for the calculation or the return of component securities, in advance of a public announcement of such changes by the Index Provider. Each Adviser will also include under Item 10.C. of Part 2 of its Form ADV a discussion of its relationship to any Affiliated Index Provider and any material conflicts of interest resulting therefrom. In addition, regardless of whether the Affiliated Index Provider is a type of affiliate specified in Item 10.15. To the extent the Self-Indexing Funds, or their respective Master Funds, transact with an Affiliated Person of an Adviser or Sub-Adviser, such transactions will comply with the Act, the rules thereunder and the terms and conditions of the requested order. In this regard, each Self-Indexing Fund’s board of directors or trustees (“Board”) will periodically review the Self-Indexing Fund’s use of an Affiliated Index Provider. Subject to the approval of the Self-Indexing Fund’s Board, an Adviser, Person of the Adviser (“Adviser Affiliates”) and

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7 The licenses for the Self-Indexing Funds will specifically state that the Affiliated Index Provider (or in case of a sub-licensing agreement, the applicable Adviser) must provide the use of the Underlying Indexes and related intellectual property at no cost to the Trust and the Self-Indexing Funds.

8 The affiliated Indexes may be made available to registered investment companies, as well as separately managed accounts of institutional investors and privately offered funds that are not deemed to be “investment companies” in reliance on section 3(c)(1) or 3(c)(7) of the Act for which the Adviser acts as adviser or sub-adviser (“Affiliated Accounts”). The Affiliated Accounts and the Unaffiliated Accounts, like the Funds, would seek to track the performance of one or more Underlying Index(es) by investing in the constituence of such Underlying Index or a representative sample of such constituents of the Underlying Index. Consistent with the relief requested from section 17(a), the Affiliated Accounts will not engage in Creation Unit transactions with a Fund.

9 See, e.g., Rule 17j–1 under the Act and Section 204A under the Advisers Act and Rules 204A–1 and 206(4)–7 under the Advisers Act.

10 Each Adviser has also adopted or will adopt a code of ethics pursuant to Rule 17j–1 under the Act and Rule 204A–1 under the Advisers Act which contain provisions reasonably necessary to prevent Access Persons (as defined in Rule 17j–1) from engaging in any conduct prohibited in Rule 17j–1 (“Code of Ethics”).

11 The instruments and cash that the purchaser is required to deliver in exchange for the Creation Units it is purchasing is referred to as the “Portfolio Deposit.”
Affiliated Persons of any Sub-Adviser ("Sub-Adviser Affiliates") may be authorized to provide custody, fund accounting and administration and transfer agency services to the Self-Indexing Funds. Any services provided by an Adviser, Adviser Affiliates, Sub-Adviser and Sub-Adviser Affiliates will be performed in accordance with the provisions of the Act, the rules under the Act and any relevant guidelines from the staff of the Commission.

16. The Shares of each Fund will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified below, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments ("Deposit Instruments"), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments ("Redemption Instruments"). On any given Business Day, the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will each correspond pro rata to the positions in the Fund’s portfolio (including cash positions) except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradable round lots; (c) TBA transactions, short positions, derivatives and other positions that cannot be transferred in kind will be excluded from the Deposit Instruments and the Redemption Instruments; (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund’s portfolio; (e) for temporary periods, to effect changes in the Fund’s portfolio as a result of the rebalancing of its Underlying Index (any such change, a "Rebalancing"). If there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the "Cash Amount").

17. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Cash Amount; (b) if, on a given Business Day, the Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, the Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash; (d) if, on a given Business Day, the Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are not eligible for transfer either through

Because these instruments will be excluded from the Deposit Instruments and the Redemption Instruments, their value will be reflected in the determination of the Cash Amount (as defined below).

17. A Fund may only use sampling for this purpose if the sample: (i) is designed to generate performance that is highly correlated to the performance of the Fund’s portfolio; (ii) consists entirely of instruments that are already included in the Fund’s portfolio; and (iii) is the same for all Authorized Participants (as defined below) on a given Business Day.

In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, Nuveen may be able to obtain better execution than Share purchasers because of Nuveen’s size, experience and potentially stronger relationships in the fixed income markets. Nuveen may choose whether Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax consideration may warrant in-kind redemptions.

and the Redemption Instruments; (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund’s portfolio; (e) for temporary periods, to effect changes in the Fund’s portfolio as a result of the rebalancing of its Underlying Index (any such change, a “Rebalancing”). If there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the “Cash Amount”).

17. A Fund may only use sampling for this purpose if the sample: (i) is designed to generate performance that is highly correlated to the performance of the Fund’s portfolio; (ii) consists entirely of instruments that are already included in the Fund’s portfolio; and (iii) is the same for all Authorized Participants (as defined below) on a given Business Day.

In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, Nuveen may be able to obtain better execution than Share purchasers because of Nuveen’s size, experience and potentially stronger relationships in the fixed income markets. Nuveen may choose whether Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax consideration may warrant in-kind redemptions.

and the Redemption Instruments; (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund’s portfolio; (e) for temporary periods, to effect changes in the Fund’s portfolio as a result of the rebalancing of its Underlying Index (any such change, a “Rebalancing”). If there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the “Cash Amount”).

17. A Fund may only use sampling for this purpose if the sample: (i) is designed to generate performance that is highly correlated to the performance of the Fund’s portfolio; (ii) consists entirely of instruments that are already included in the Fund’s portfolio; and (iii) is the same for all Authorized Participants (as defined below) on a given Business Day.

In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, Nuveen may be able to obtain better execution than Share purchasers because of Nuveen’s size, experience and potentially stronger relationships in the fixed income markets. Nuveen may choose whether Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax consideration may warrant in-kind redemptions.

and the Redemption Instruments; (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund’s portfolio; (e) for temporary periods, to effect changes in the Fund’s portfolio as a result of the rebalancing of its Underlying Index (any such change, a “Rebalancing”). If there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the “Cash Amount”).

17. A Fund may only use sampling for this purpose if the sample: (i) is designed to generate performance that is highly correlated to the performance of the Fund’s portfolio; (ii) consists entirely of instruments that are already included in the Fund’s portfolio; and (iii) is the same for all Authorized Participants (as defined below) on a given Business Day.

In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, Nuveen may be able to obtain better execution than Share purchasers because of Nuveen’s size, experience and potentially stronger relationships in the fixed income markets. Nuveen may choose whether Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax consideration may warrant in-kind redemptions.
list. Each Listing Exchange or other major market data provider will disseminate, every 15 seconds during regular Exchange trading hours, through the facilities of the Consolidated Tape Association, an amount for each Fund stated on a per individual Share basis representing the sum of (i) the estimated Cash Amount and (ii) the current value of the Deposit Instruments.

20. Transaction expenses, including operational processing and brokerage costs, will be incurred by a Fund when investors purchase or redeem Creation Units in-kind and such costs have the potential to dilute the interests of the Fund’s existing shareholders. Each Fund will impose purchase or redemption transaction fees (“Transaction Fees”) in connection with effecting such purchases or redemptions of Creation Units. With respect to Feeder Funds, the Transaction Fee would be paid indirectly to the Master Fund.20 In all cases, such Transaction Fees will be limited in accordance with requirements of the Commission applicable to management investment companies offering redeemable securities. Since the Transaction Fees are intended to defray the transaction expenses as well as to prevent possible shareholder dilution resulting from the purchase or redemption of Creation Units, the Transaction Fees will be borne only by such purchasers or redeemers.21 The Distributor will be responsible for delivering the Fund’s prospectus to those persons acquiring Shares in Creation Units and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it. In addition, the Distributor will maintain a record of the instructions given to the applicable Fund to implement the delivery of its Shares.

21. Shares of each Fund will be listed and traded individually on an Exchange. It is expected that one or more member firms of an Exchange will be designated to act as a market maker (each, a “Market Maker”) and maintain a market for Shares trading on the Exchange. Prices of Shares trading on an Exchange will be based on the current bid/offer market. Transactions involving the sale of Shares on an Exchange will be subject to customary brokerage commissions and charges.

22. Applicants expect that purchasers of Creation Units will include institutional investors and arbitrages. Market Makers, acting in their roles to provide a fair and orderly secondary market for the Shares, may from time to time find it appropriate to purchase or redeem Creation Units. Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.22 The price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

23. Shares will not be individually redeemable, and owners of Shares may acquire those Shares from the Fund, or tender such Shares for redemption to the Fund, in Creation Units only. To redeem, an investor must accumulate enough Shares to constitute a Creation Unit. Redemption requests must be placed by or through an Authorized Participant. A redeeming investor will pay a Transaction Fee, calculated in the same manner as a Transaction Fee payable in connection with purchases of Creation Units.

24. Neither the Trust nor any Fund will be advertised or marketed or otherwise held out as a traditional open-end investment company or a “mutual fund.” Instead, each such Fund will be marketed as an “ETF.” All marketing materials that describe the features or method of obtaining, buying or selling Creation Units, or Shares traded on an Exchange, or refer to redeemability, will prominently disclose that Shares are not individually redeemable and will disclose that the owners of Shares may acquire those Shares from the Fund or tender such Shares for redemption to the Fund in Creation Units only. The Funds will provide copies of their annual and semi-annual shareholder reports to DTC Participants for distribution to beneficial owners of Shares.

22 Shares will be registered in book-entry form only. DTC or its nominee will be the record and registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or the DTC Participants.

Applicants’ Legal Analysis

1. Applicants request an 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 section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of 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.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision 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 proposed 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 proposed transaction is consistent with the policies of the registered investment company and the general provisions 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 provisions of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an “open-end company” as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the owner, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer’s current net assets, or the cash equivalent. Because Shares will not be individually redeemable, applicants request an order that would permit the Funds to register as open-end management investment companies and issue Shares that are redeemable in Creation Units only.23 Applicants state

23 The Master Funds will not require relief from sections 2(a)(32) and 5(a)(1) because the Master Funds will issue individually redeemable securities.
that investors may purchase Shares in Creation Units and redeem Creation Units from each Fund. Applicants further state that because Creation Units may always be purchased and redeemed at NAV, the price of Shares on the secondary market should not vary materially from NAV.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is currently being offered to the public by or through an underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, not at a current offering price described in a Fund’s prospectus, and not at a price based on NAV. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Shares. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been designed to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers, and (c) ensure an orderly distribution of investment company shares by eliminating price competition from dealers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Shares does not involve a Fund as a party and will not result in dilution of an investment in Shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in Shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

Section 22(e)

7. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants state that settlement of redemptions for Foreign Funds will be contingent not only on the settlement cycle of the United States market, but also on current delivery cycles in local markets for the underlying foreign securities held by a Foreign Fund. Applicants state that the delivery cycles currently practicable for transferring Redemption Instruments to redeeming investors, coupled with local market holiday schedules, may require a delivery process of up to fifteen (15) calendar days. Accordingly, with respect to Foreign Funds only, applicants hereby request relief under section 6(c) from the requirement imposed by section 22(e) to allow Foreign Funds to pay redemption proceeds within fifteen (15) calendar days following the tender of Creation Units for redemption.

8. Applicants believe that Congress adopted section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds. Applicants propose that allowing redemption payments for Creation Units of a Foreign Fund to be made within fifteen calendar days would not be inconsistent with the spirit and intent of section 22(e). Applicants suggest that a redemption payment occurring within fifteen calendar days following a redemption request would adequately afford investor protection.

9. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds that do not effect

24 Certain countries in which a Fund may invest have historically had settlement periods of up to fifteen (15) calendar days.

25 Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations applicants may otherwise have under rule 15c6–1 under the Exchange Act requiring that most securities transactions be settled within three business days of the trade date.

Section 12(d)(1)

10. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring securities of an investment company if such securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter and any other broker-dealer from knowingly selling the investment company’s shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company’s voting stock, or if the sale will cause more than 10% of the acquired company’s voting stock to be owned by investment companies generally.

11. Applicants request an exemption to permit registered management investment companies and unit investment trusts (“UITs”) that are not advised or sponsored by the Advisers and are not part of the same “group of investment companies,” as defined in section 12(d)(1)(C)(i) of the Act as the Funds (such management investment companies are referred to as “Investing Management Companies,” such UITs are referred to as “Investing Trusts,” and Investing Management Companies and Investing Trusts are collectively referred to as “Funds of Funds”), to acquire Shares beyond the limits of section 12(d)(1)(A) of the Act and the Funds, and any principal underwriter for the Funds, and/or any Broker-dealer registered under the Exchange Act, to sell Shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act.

12. Each Investing Management Company will be advised by an investment adviser within the meaning of section 2(a)(20)(A) of the Act (the “Fund of Funds Adviser”) and may be sub-advised by investment advisers within the meaning of section 2(a)(20)(B) of the Act (each a “Fund of Funds Sub-Adviser”). Any investment adviser to an Investing Management Company will be registered under the Advisers Act. Each Investing Trust will be sponsored by a sponsor (“Sponsor”).

26 In addition, the requested exemption from section 22(e) would only apply to in-kind redemptions by the Feeder Funds and would not apply to in-kind redemptions by other feeder funds.
13. Applicants submit that the proposed conditions to the requested relief adequately address the concerns underlying the limits in sections 12(d)(1)(A) and (B), which include concerns about undue influence by a fund of funds over underlying funds, excessive layering of fees and overly complex fund structures. Applicants believe that the requested exemption is consistent with the public interest and the protection of investors.

14. Applicants believe that neither a Fund of Funds nor a Fund of Funds Affiliate would be able to exert undue influence over a Fund.27 To limit the control that a Fund of Funds may have over a Fund, applicants propose a condition prohibiting a Fund of Funds Adviser or Sponsor, any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor, and any investment company and any issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by a Fund of Funds Adviser or Sponsor, or any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor (“Fund of Funds’ Advisory Group”) from controlling (individually or in the aggregate) a Fund, or its respective Master Fund, within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any Fund of Funds Sub-Adviser, any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Fund of Funds Sub-Adviser or any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser (“Fund of Funds’ Sub-Advisory Group”).

15. Applicants propose other conditions to limit the potential for undue influence over the Funds, including that no Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (“Affiliated Underwriting”). An “Underwriting Affiliate” is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Fund of Funds Adviser, Fund of Funds Sub-Adviser, employee or Sponsor of the Fund of Funds, or a person of which any such officer, director, member of an advisory board, Fund of Funds Adviser or Fund of Funds Sub-Adviser, employee or Sponsor is an affiliated person (except that any person whose relationship to the Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

16. Applicants do not believe that the proposed arrangement will involve excessive layering of fees. The board of directors or trustees of any Investing Management Company, including a majority of the directors or trustees who are not “interested persons” within the meaning of section 2(a)(19) of the Act (“disinterested directors or trustees”), will find that the advisory fees charged under the contract are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Fund, or its respective Master Fund, in which the Investing Management Company may invest. In addition, a Fund of Funds Adviser, or a Fund of Funds’ trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund, or its respective Master Fund, under rule 12b–1 under the Act) received from a Fund by the Fund of Funds Adviser, trustee or Sponsor or an affiliated person of the Fund of Funds Adviser, trustee or Sponsor, other than any advisory fees paid to the Fund of Funds Adviser, trustee or Sponsor or its affiliated person by a Fund, in connection with the investment by the Fund of Funds in the Fund. Applicants state that any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

17. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that no Fund, nor its respective Master Fund, will acquire securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund, or its respective Master Fund, to purchase shares of other investment companies for short-term cash management purposes or pursuant to the Master-Feeder Relief. To ensure a Fund of Funds is aware of the terms and conditions of the requested order, the Fund of Funds will enter into an agreement with the Fund (“FOF Participation Agreement”). The FOF Participation Agreement will include an acknowledgement from the Fund of Funds that it may rely on the order only to invest in the Funds and not in any other investment company.

18. Applicants also note that a Fund may choose to reject any direct purchase of Shares in Creation Units by a Fund of Funds. To the extent that a Fund of Funds purchases Shares in the secondary market, a Fund would still retain its ability to reject any initial investment by a Fund of Funds in excess of the limits of section 12(d)(1)(A) by declining to enter into a FOF Participation Agreement with the Fund of Funds.

19. Applicants also are seeking the Master-Feeder Relief to permit the Feeder Funds to perform creations and redemptions of Shares in-kind in a master-feeder structure. Applicants assert that this structure is substantially identical to traditional master-feeder structures permitted pursuant to the exception provided in section 12(d)(1)(E) of the Act. Section 12(d)(1)(E) provides that the percentage limitations of section 12(d)(1)(A) and (B) shall not apply to a security issued by an investment company (in this case, the shares of the applicable Master Fund) if, among other things, that security is the only investment security held by the investing investment company (in this case, the Feeder Fund). Applicants believe the proposed master-feeder structure complies with section 12(d)(1)(E) because each Feeder Fund will hold only investment securities issued by its corresponding Master Fund; however, the Feeder Funds may receive securities other than securities of its corresponding Master Fund if a Feeder Fund accepts an in-kind creation. To the extent that a Feeder Fund may be deemed to be holding both shares of the Master Fund and other securities, applicants request relief from section 12(d)(1)(A) and (B). The Feeder Funds would operate in compliance with all other provisions of section 12(d)(1)(E).
Sections 17(a)(1) and (2) of the Act

20. Sections 17(a)(1) and (2) of the Act generally prohibit an affiliated person of a registered investment company, or an affiliated person of such a person, from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines “affiliated person” of another person to include (a) any person directly or indirectly owning, controlling or holding with power to vote 5% or more of the outstanding voting securities of the other person, (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled or held with the power to vote by the other person, and (c) any person directly or indirectly controlling, controlled by or under common control with the other person. Section 2(a)(9) of the Act defines “control” as the power to exercise a controlling influence over the management or policies of a company, and provides that a control relationship will be presumed where one person owns more than 25% of a company’s voting securities. The Funds may be deemed to be controlled by an Adviser or an entity controlling, controlled by or under common control with an Adviser and hence affiliated persons of each other. In addition, the Funds may be deemed to be under common control with any other registered investment company (or series thereof) advised by an Adviser or an entity controlling, controlled by or under common control with an Adviser (an “Affiliated Fund”). Any investor, including Market Makers, owning 5% or holding in excess of 25% of the Trust or such Funds, may be deemed affiliated persons of the Trust or such Funds. In addition, an investor could own 5% or more, or in excess of 25% of the outstanding shares of one or more Affiliated Funds making that investor a Second-Tier Affiliate of the Funds.

21. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act pursuant to sections 6(c) and 17(b) of the Act to permit persons that are Affiliated Persons of the Funds, or Second-Tier Affiliates of the Funds, solely by virtue of one or more of the following: (a) Holding 5% or more, or in excess of 25%, of the outstanding Shares of one or more Funds; (b) an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25%, of the shares of one or more Affiliated Funds, to effectuate purchases and redemptions “in-kind” purchases or “in-kind” redemptions of Shares of a Fund in Creation Units. Both the deposit procedures for “in-kind” purchases of Creation Units and the redemption procedures for “in-kind” redemptions of Creation Units will be effected in exactly the same manner for all purchases and redemptions, regardless of size or number. There will be no discrimination between purchasers or redeemers. Deposit Instruments and Redemption Instruments for each Fund will be valued in the identical manner as those Portfolio Holdings currently held by such Fund and the valuation of the Deposit Instruments and Redemption Instruments will be made in an identical manner regardless of the identity of the purchaser or redeemer. Applicants do not believe that “in-kind” purchases and redemptions will result in abusive self-dealing or overreaching, but rather assert that such procedures will be implemented consistently with each Fund’s objectives and with the general purposes of the Act. Applicants believe that “in-kind” purchases and redemptions will be made on terms reasonable to applicants and any affiliated persons because they will be valued pursuant to verifiable objective standards. The method of valuing Portfolio Holdings held by a Fund is identical to that used for calculating “in-kind” purchase or redemption values and therefore creates no opportunity for affiliated persons or Second-Tier Affiliates of applicants to affect a transaction detrimental to the other holders of Shares of that Fund. Similarly, applicants submit that, by using the same standards for valuing Portfolio Holdings held by a Fund as are used for calculating “in-kind” redemptions or purchases, the Fund will ensure that its NAV will not be adversely affected by such securities transactions. Applicants also note that the ability to take deposits and make redemptions “in-kind” will help each Fund to track closely its Underlying Index and therefore aid in achieving the Fund’s objectives.

23. Applicants also seek relief under sections 6(c) and 17(b) from section 17(a) to permit a Fund that is an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds to sell its Shares to and redeem its Shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds. Applicants state that the terms of the transactions are fair and reasonable and do not involve overreaching. Applicants note that any consideration paid by a Fund of Funds for the purchase or redemption of Shares directly from a Fund will be based on the NAV of the Fund. Applicants believe that any proposed transactions directly between the Funds and Funds of Funds will be consistent with the policies of each Fund of Funds. The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the investment restrictions of any such Fund of Funds and will be consistent with the investment policies set forth in the Fund of Funds’ registration statement. Applicants also state that the proposed transactions are consistent with the general purposes of the Act and are appropriate in the public interest.

24. To the extent that a Fund operates in a master-feeder structure, applicants also request relief permitting the Feeder Funds to engage in in-kind creations and redemptions with the applicable Master Fund. Applicants state that the customary section 17(a)(1) and 17(a)(2) relief would not be sufficient to permit such transactions because the Feeder Funds and the applicable Master Fund could also be affiliated by virtue of having the same investment adviser. However, applicants believe that in-kind creations and redemptions between a Feeder Fund and a Master Fund advised by the same investment adviser do not involve “overreaching” by an affiliated person. Such transactions will occur only at the Feeder Fund’s proportionate share of the Master Fund’s net assets, and the distributed securities will be valued in the same manner as they are valued for the purposes of calculating the
applicable Master Fund's NAV. Further, all such transactions will be effected with respect to pre-determined securities and on the same terms with respect to all investors. Finally, such transaction would only occur as a result of, and to effectuate, a creation or redemption transaction between the Feeder Fund and a third-party investor. Applicants believe that the terms of the proposed transactions are reasonable and fair and do not involve overreaching on the part of any person concerned, the proposed transactions are consistent with the policy of each Fund and will be consistent with the investment objectives and policies of each Fund of Funds, and the proposed transactions are consistent with the general purposes of the Act.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

A. ETF Relief

1. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of index-based ETFs.

2. As long as a Fund operates in reliance on the requested order, the Shares of such Fund will be listed on an Exchange.

3. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that Shares are not individually redeemable and that owners of Shares may acquire those Shares from the Fund and tender those Shares for redemption to a Fund in Creation Units only.

4. The Web site, which is and will be publicly accessible at no charge, will contain, on a per Share basis for each Fund, the prior Business Day's NAV and the market closing price or the midpoint of the bid/ask spread at the time of the calculation of such NAV ("Bid/Ask Price"), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

5. Each Self-Indexing Fund, Long/Short Fund and 130/30 Fund will post on the Web site on each Business Day, before commencement of trading of Shares on the Exchange, the Fund's, or its respective Master Fund's, Portfolio Holdings.

6. No Adviser or any Sub-Adviser to a Self-Indexing Fund, directly or indirectly, will cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the Fund) to acquire any Deposit Instrument for a Fund, or its respective Master Fund, through a transaction in which a Fund, or its respective Master Fund, could not engage directly.

B. Section 12(d)(1) Relief

1. The members of a Fund of Funds' Advisory Group will not control (individually or in the aggregate) a Fund, or its respective Master Fund, within the meaning of section 2(a)(9) of the Act. The members of a Fund of Funds' Sub-Advisory Group will not control (individually or in the aggregate) a Fund, or its respective Master Fund, within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of a Fund, the Fund of Funds' Advisory Group or the Fund of Funds' Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25 percent of the outstanding voting securities of a Fund, it will vote its Shares of the Fund in the same proportion as the vote of all other holders of the Fund's Shares. This condition does not apply to the Fund of Funds' Sub-Advisory Group with respect to a Fund, or its respective Master Fund, for which the Fund of Funds' Sub-Adviser or a person controlling, controlled by or under common control with the Fund of Funds' Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Fund of Funds or Fund of Funds Affiliate will cause any existing or potential investment by the Fund of Funds in a Fund to influence the terms of any services or transactions between the Fund of Funds or Fund of Funds Affiliate and the Fund, its respective Master Fund, or a Fund Affiliate.

3. The board of directors or trustees of an Investing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to ensure that the Fund of Funds Adviser and Fund of Funds Sub-Adviser are conducting the investment program of the Investing Management Company without taking into account any consideration received by the Investing Management Company or a Fund of Funds Affiliate from a Fund, its respective Master Fund, or Fund Affiliate in connection with any services or transactions.

4. Any investment by a Fund of Funds in the securities of a Fund exceeds the limits in section 12(d)(1)(A)(i) of the Act, the Board of the Fund, or its respective Master Fund, including a majority of the directors or trustees who are not "interested persons" within the meaning of section 2(a)(19) of the Act ("non-interested Board members"), will determine that any consideration paid by the Fund, or its respective Master Fund, to the Fund of Funds or a Fund of Funds Affiliate in connection with any services or transactions: (i) is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund, or its respective Master Fund; (ii) is within the range of consideration that the Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned.

This condition does not apply with respect to any services or transactions between a Fund, or its respective Master Fund, and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. The Fund of Funds Adviser, or trustee or Sponsor of an Investing Trust, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund, or its respective Master Fund, under rule 12b–1 under the Act) received from a Fund, or its respective Master Fund, by the Fund of Funds Adviser, or trustee or Sponsor of the Investing Trust, or an affiliated person of the Fund of Funds Adviser, trustee or Sponsor of the Investing Trust, other than any advisory fees paid to the Fund of Funds Adviser, trustee or Sponsor of an Investing Trust, or its affiliated person by the Fund, or its respective Master Fund, in connection with the investment by the Fund of Funds in the Fund. Any Fund of Funds Sub-Adviser will waive fees otherwise payable to the Fund of Funds Sub-Adviser, directly or indirectly, by the Investing Management Company in an amount at least equal to any compensation received from a Fund, or its respective Master Fund, by the Fund of Funds Sub-Adviser, or an affiliated person of the Fund of Funds Sub-Adviser, other than any advisory fees paid to the Fund of Funds Sub-Adviser, or its affiliated person by the Fund, or its respective Master Fund, in connection with the investment by the Investing Management Company in the Fund made at the direction of the Fund of Funds Sub-Adviser. In the event that the Fund of Funds Sub-Adviser waives fees, the benefit of the waiver will be
passed through to the Investing Management Company.

6. No Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund, or its respective Master Fund, to purchase a security in any Affiliated Underwriting.

7. The Board of a Fund, or its respective Master Fund, including a majority of the non-interested Board members, will adopt procedures reasonably designed to monitor any purchases of securities by the Fund, or its respective Master Fund, in an Affiliated Underwriting, once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment of Funds in Funds of the Fund. The Board will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the Fund, or its respective Master Fund; (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the Fund, or its respective Master Fund, in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to ensure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders of the Fund.

8. Each Fund, or its respective Master Fund, will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate’s members, the terms of the purchase, and the information or materials upon which the Board’s determinations were made.

9. Before investing in a Fund in excess of the limit in section 12(d)(1)(A), a Fund of Funds and the Trust will execute a FOF Participation Agreement stating without limitation that their respective boards of directors or trustees and their investment advisers, or trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Shares of a Fund in excess of the limit in section 12(d)(1)(A)(i), a Fund of Funds will notify the Fund of the investment. At such time, the Fund of Funds will also transmit to the Fund a list of the names of each Fund of Funds Affiliate and Underwriting Affiliate. The Fund of Funds will notify the Fund of any changes to the list of the names as soon as reasonably practicable after a change occurs. The Fund and the Fund of Funds will maintain and preserve a copy of the order, the FOF Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

10. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Investing Management Company including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund, or its respective Master Fund, in which the Investing Management Company may invest. These findings and their basis will be fully recorded in the minutes of the appropriate Investing Management Company.

11. Any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

12. No Fund, or its respective Master Fund, will acquire securities of an investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent that (i) the Fund, or its respective Master Fund, acquires securities of another investment company pursuant to exemptive relief from the Commission permitting the Fund, or its respective Master Fund, to acquire securities of one or more investment companies for short-term cash management purposes or (ii) the Fund acquires securities of the Master Fund pursuant to the Master-Feeder Relief.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,
Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION


Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Proposed Amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information To Amend the Professional Subscriber Device-Based Fees Set Forth in OPRA’s Fee Schedule

April 12, 2016.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (“Act”) 1 and Rule 608 thereunder, 2 notice is hereby given that on September 22, 2015, the Options Price Reporting Authority (“OPRA”) 3 submitted to the Securities and Exchange Commission (“Commission”) an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (“OPRA Plan”). 4 Effective January 1, 2016, the OPRA Plan Amendment established a new Professional Subscriber Device-Based Fee. The

Commission is publishing this notice to provide interested persons an opportunity to submit written comments on the OPRA Plan amendment.

I. Description and Purpose of the Plan Amendment

The OPRA Plan amendment revised the OPRA Fee Schedule to establish OPRA’s Professional Subscriber Device-Based Fee and made conforming changes in OPRA’s Enterprise Rate Professional Subscriber Fee. OPRA’s Enterprise Rate Professional Subscriber Fee is available to those Professional Subscribers that elect that rate in place of the regular OPRA device-based fees.4 Specifically, effective January 1, 2016, the OPRA Plan Amendment: increased the current $28.50 monthly per device fee by $1.00; increased the Enterprise Rate, from a monthly fee of $28.50 times the number of a Professional Subscriber’s U.S.-based registered representatives, to a monthly fee of $29.50 times the number of the Subscriber’s U.S.-based registered representatives; and made conforming changes to the minimum monthly fee under the Enterprise Rate. “Professional Subscribers” are persons who subscribe to OPRA data, do not qualify for the reduced fees charged to “Nonprofessional Subscribers,” and do not redistribute the OPRA data to third parties. OPRA permits the counting of “User IDs” as a surrogate for counting “devices” for purposes of its Professional Subscriber Device-Based Fees.5

The number of devices reported to OPRA as subject to Professional Subscriber Device-Based Fees has been steadily trending downwards over many years. In 2008, OPRA received device-based fees, including enterprise fees, with respect to approximately 210,500 devices. In 2014, OPRA received device-based fees, including enterprise fees, with respect to approximately 148,400 devices. OPRA was receiving device-based fees in the third calendar quarter of 2015 with respect to approximately 134,000 devices—already a reduction of approximately 9.7% from 2014. OPRA believes that this long-term downward trend is the result of the increasing use of trading algorithms and automated trading platforms and other fundamental changes in the securities industry, and OPRA anticipates that this trend is likely to continue. The increase in the Professional Subscriber Device-Based Fees is consistent with OPRA’s past practice of making incremental $1.00 increases in its monthly Professional Subscriber Device-Based Fees.6 The increase in the Professional Subscriber Device-Based Fee—which is an increase of approximately 3.5%—will partially offset the impact on revenue of the reduction in the number of devices in 2015 as compared to 2014.7

The text of the amendment to the OPRA Plan is available at OPRA, the Commission’s Public Reference Room, the OPRA Web site at http://opradata.com, and on the Commission’s Web site at www.sec.gov.

II. Implementation of the OPRA Plan Amendment

Pursuant to paragraph (b)(3)(i) of Rule 608 of Regulation NMS under the Act, OPRA designated this amendment as establishing or changing fees or other charges collected on behalf of all of the OPRA participants in connection with access to or use of OPRA facilities. OPRA put the change in the Professional Subscriber Device-Based Fee into effect as of January 1, 2016.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the OPRA Plan amendment is consistent with the Act.8

Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or

• Send an email to rule-comments@sec.gov. Please include File No. SR–OPRA–2015–02 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OPRA–2015–02. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the OPRA Plan amendment that are filed with the Commission, and all written communications relating to the OPRA Plan amendment between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OPRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–OPRA–2015–02 and should be submitted on or before May 9, 2016.

By the Commission.

Robert W. Errett,
Deputy Secretary.

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persons may nevertheless submit written comments on the OPRA Plan amendment.
SEcurities and exchange COMMISSION


Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Proposed Amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information To Amend Certain Provisions of the OPRA’s Fee Schedule

April 12, 2016.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (“Act”) and Rule 608 thereunder, notice is hereby given that on September 22, 2015, the Options Price Reporting Authority (“OPRA”) submitted to the Securities and Exchange Commission (“Commission”) an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (“OPRA Plan”). Effective January 1, 2016, the amendment revised the structure and the amount of OPRA’s fees for “Non-Display” use of OPRA data. The Commission is publishing this notice to provide interested persons an opportunity to submit written comments on the OPRA Plan amendment.

I. Description and Purpose of the Plan Amendment

The purpose of the amendment is to amend the OPRA Fee Schedule to revise the structure and the amounts of OPRA fees for “Non-Display” use of OPRA Data. “Non-Display” use of OPRA data is use of the OPRA data for a purpose other than the display of the data to natural persons or in support of the display of the data or the internal or external redistribution of the data.

OPRA first implemented “Non-Display Application Fees” in 2012. At that time, OPRA defined the term “Non-Display Application” essentially as an application used for purposes of generating orders and/or quotations on an automated basis including any application that is used for “black box” trading, automated trading, algorithmic trading and/or program trading.” OPRA adopted those fees in response to two long-term trends in the use of OPRA market data. The first trend was the increasingly common use of OPRA market data for use in “Non-Display Applications.” The second trend was the decline, which has persisted over many years, in the number of devices and User IDs used for “Non-Display” purposes under the Securities Exchange Act of 1934 purposes under the Securities Exchange Act of 1934.

The OPRA Plan amendment comprehensively revised the structure of OPRA’s Non-Display fees so that OPRA’s fee structure parallels the Non-Display fee structures implemented by the CTA/CQ Plan Participants and the Nasdaq/UTP Plan. In addition, the OPRA Plan amendment revised the amounts of OPRA’s Non-Display fees.

A. Description of the Concepts Underlying the CTA/CQ Plan and Nasdaq/UTP Plan Non-Display Fees; Comparison to the Current OPRA Structure; Revised OPRA Structure

1. Definition of “Non-Display Use”

The CTA/CQ Plan Participants have defined the term “Non-Display Use,” with respect to the market data disseminated pursuant to the CTA/CQ Plans as referring to “accessing, processing or consuming real-time Network A or Network B quotation information or last sale price information, whether delivered via direct and/or redistributor data feeds, for a purpose other than in support of a data recipient’s display or further internal or external redistribution.”

In 2014, the Consolidated Tape Association (“CTA”) Plan and Consolidated Quotation (“CQ”) Plan participants (collectively, the “CTA/CQ Plan Participants”) proposed to amend the CTA Plan and the CQ Plan (collectively the “CTA/CQ Plans”) to implement fees for Non-Display use of the market data disseminated pursuant to the CTA/CQ Plans. At the same time, the operating committee (the “Nasdaq/UTP Plan Operating Committee”) of the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation, and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis (the “Nasdaq/UTP Plan”) proposed to amend the Nasdaq/UTP Plan to implement fees for Non-Display use of the market data disseminated pursuant to the Nasdaq/UTP Plan.

The OPRA Plan amendment comprehensively revised the structure of OPRA’s Non-Display fees so that OPRA’s fee structure parallels the Non-Display fee structures implemented by the CTA/CQ Plan Participants and the Nasdaq/UTP Plan Operating Committee. In addition, the OPRA Plan amendment revised the amounts of OPRA’s Non-Display fees.

2. Revised OPRA Structure

The Nasdaq/UTP Plan Operating Committee has implemented a parallel definition of the term: “Non-Display use refers to accessing, processing or consuming data, whether received via direct and/or redistributor Data Feeds, for a purpose other than solely facilitating the delivery of the data to

3. Comparison to the Current OPRA Structure

See supra note 4, at n.9. The decline in the number of devices and User IDs displaying OPRA data and subject to OPRA’s Professional Subscriber Device-Based Fees has continued: In 2014 an average of 136,600 devices and User IDs were reported to OPRA in each month of the year, and OPRA projects that in 2015 an average of 148,400 devices and User IDs will be reported to OPRA as receiving OPRA data in each month of the year.

See supra note 8, at 60538.
the Data Feed Recipient’s display or for the purpose of further internally or externally redistributing the data.11

These definitions are broader than OPRA’s prior definition of the term “Non-Display Application” which, as noted above, encompassed only “applications . . . used for purposes of generating orders and/or quotations on an automated basis. . . .” For example, the CTA/CQ Plan and Nasdaq/UTP definitions specifically include within their definitions of the term “Non-Display Use” use of their respective datasets for price referencing for smart order routing, operations control programs, investment analysis, order verification, surveillance programs, risk management, compliance and portfolio valuation purposes.12

The OPRA Plan amendment replaced the definition of “Non-Display Application” with a definition of the term “Non-Display Use” that parallels the definitions implemented by the CTA/CQ Plan Participants and the Nasdaq/UTP Plan Operating Committee. Specifically, the OPRA Plan amendment defined the term “Non-Display Use” as follows:

Non-Display Use refers to the accessing, processing or consuming by an OPRA data feed recipient (either an OPRA vendor or an OPRA professional subscriber) of OPRA market data received on a current basis, whether delivered via data feed directly from OPRA’s processor and/or indirect data feed from an OPRA vendor, for a purpose other than in support of the data feed recipient’s display or further internal or external redistribution. Non-Display Use includes, without limitation, trading (such as in a “black box” or a trading engine that performs automated trading, algorithmic trading or program trading, or generates arbitrage or program trading orders); automated order or quote generation and/or order pegging; price referencing for algorithmic trading; operations control programs; investment analysis; order verification; surveillance programs; risk management; compliance; and portfolio valuation.

2. Three Categories of Non-Display Use and Fee Basis for Non-Display Use in Each Category

The CTA/CQ Plan Participants and the Nasdaq/UTP Plan Operating Committee have each established three “categories” of Non-Display Use. Using the nomenclature established by the CTA/CQ Plan Participants, the three categories are as follows:

Category 1 applies when a data recipient makes non-display uses of real time market data on its own behalf.

Category 2 applies when a data recipient makes non-display uses of real time market data on behalf of its clients.

Category 3 applies when a data recipient makes non-display uses of real time market data for the purpose of internally matching buy and sell orders within the data feed recipient. Category 3 includes matching buy and sell orders on a data recipient’s own behalf and/or on behalf of its clients. Category 3 includes, but is not restricted to, use in trading platform(s), such as exchanges, alternative trading systems (“ATSs”), broker crossing networks, broker crossing systems not filed as ATSs, dark pools, multilateral trading facilities, and systematic internalization systems.13

The OPRA Plan amendment adopted the three categories of Non-Display Use that have been implemented by the CTA/CQ Plans and the Nasdaq/UTP Plan.

For the first two of these categories of Non-Display Use (“Category 1” and “Category 2” in the CTA/CQ nomenclature), the CTA/CQ Plan Participants and the Nasdaq/UTP Plan Operating Committee have established fees on a “per platform” basis. That is, a recipient of the market data pays only one “Category 1” fee if it makes any Non-Display Use of the market data in Category 1, and only one “Category 2” fee if it makes any Non-Display Use of the market data in Category 2.14 The OPRA Plan amendment adopted fees for Category 1 Non-Display Use and Category 2 Non-Display Use that are also on a “per platform” basis.15

For the third of these categories of Non-Display Use (“Category 3” in the CTA/CQ nomenclature), the CTA/CQ Plan Participants and the Nasdaq/UTP Plan Operating Committee have established fees on a “per platform” basis. That is, a recipient of the market data is required to pay a fee for Category 3 Non-Display Use on each “platform” that is used for internally matching buy and sell orders.16 The OPRA Plan amendment adopted fees for Category 3 Non-Display Use that are also on a “per platform” basis. Tracking the CTA/CQ Plan and Nasdaq/UTP Plan definitions, the OPRA Plan amendment defined the term “Platform” as follows: “A “Platform” is a platform for internally matching buy and sell orders. Matching buy and sell orders includes matching customer orders on a data recipient’s own behalf and/or on behalf of its clients. The term ‘Platform’ includes, but is not restricted to, exchanges, alternative trading systems (ATSs), broker crossing networks, broker crossing systems not filed as ATSs, dark pools, multilateral trading facilities, and systematic internalization systems.”17

As is the case with respect to the CTA/CQ Non-Display Use fees and the Nasdaq/UTP Non-Display Use fees, an OPRA data recipient may use OPRA data for one, two or all three categories and therefore be subject to non-display fees for one, two or all three categories. For example, if a broker-dealer uses OPRA data to run compliance programs for the firm (Category 1), to conduct investment analysis on behalf of its customers (Category 2), and to operate an ATS that matches buy and sell orders (Category 3), then the firm would be required to pay OPRA non-display use fees in respect of all three categories.

B. Non-Display Use Reporting Requirements

In order to minimize the administrative burden associated with their Non-Display Use fees, the CTA/CQ Plan Participants and the Nasdaq/UTP Plan Operating Committee do not impose monthly reporting requirements in respect of their Non-Display Use fees, and instead require each recipient of a real-time data feed to make an initial declaration with respect to its Non-Display Use of their respective datasets, a declaration with respect to any changes in its Non-Display Use of their respective datasets, and an annual declaration of its non-display use.17

OPRA included a note in its Fee Schedule to state that it will require reporting on the same basis. OPRA will audit data feed recipients’ Non-Display Use of market data in accordance with the terms of its applicable agreements and ordinary auditing practices, and

11 See supra note 8, at 60538 (CTA/CQ Plan). The Nasdaq/UTP Plan Operating Committee has established the same three categories, identical in substance, but using a somewhat different vocabulary: the Nasdaq/UTP Plan refers to its fee as the “Non-Display Fee for Internal Use”; for its counterpart to CTA/CQ Category 1 as the “Non-Display Fee for External Use”; and for its counterpart to CTA/CQ Category 2 as the “Non-Display Fee for Electronic Trading Systems.” See supra note 9, at 60525–26 (Nasdaq/UTP Plan).

12 See supra note 8, at 60536 (CTA/CQ Plan); and see supra note 9, at 60526 (Nasdaq/UTP Plan).

13 See supra note 9, at 60525.

14 See supra note 8, at 60538 (CTA/CQ Plan); and see supra note 9, at 60526 (Nasdaq/UTP Plan).

15 See supra note 8, at 60538 (CTA/CQ Plan); see supra note 9, at 60525–26 (Nasdaq/UTP Plan).

16 See supra note 8, at 60538 (CTA/CQ Plan); see supra note 9, at 60525 (Nasdaq/UTP Plan).

17 See supra note 8, at 60539 (CTA/CQ Plans); and see supra note 9, at 60525 (Nasdaq/UTP Plan).
will charge Non-Display Use fees in instances in which it determines that Non-Display Use has not been accurately declared.

C. Fees for Non-Display Use

The OPRA Plan amendment adopted fees for Non-Display Use as follows: A monthly fee of $2,000/Enterprise for Category 1 Non-Display Use; a monthly fee of $2,000/Enterprise for Category 2 Non-Display Use; and a monthly fee of $2,000/Platform for Category 3 Non-Display Use.

By way of comparison: The CTA/CQ Plan Participants have established separate monthly Non-Display Fees for Network A of $2,000 for last sale prices plus $2,000 for quotation information in each of the three categories of use, and Non-Display Fees for Network B of $1,000 for last sale prices plus $1,000 for quotation information in each of the three categories of use; 18 and the Nasdaq/UTP Plan Operating Committee has established a monthly fee for the data disseminated pursuant to the Nasdaq/UTP Plan of $3,500 for each of the three categories of use.19

Prior to the OPRA Plan amendment, 59 OPRA data feed recipients were paying OPRA’s “Non-Display Application Fee,” which, as described above, was applicable only to any “application used for purposes of generating orders and/or quotations on an automated basis.” 20 Because the definition of “Non-Display Use” is broader than OPRA’s prior definition of the term “Non-Display Application,” OPRA expects the number of data feed recipients that will be subject to Category 2 Non-Display fees to be greater than the number of data feed recipients paying the prior Non-Display Application Fee; OPRA’s best estimate is that approximately double the number of data feed recipients currently paying OPRA’s Non-Display Application Fee—approximately 120 data feed recipients—will be subject to Category 1 Non-Display fees. Further, OPRA’s best estimate is that approximately half of those data feed recipients—approximately 60 data feed recipients—will also be subject to “Category 2” Non-Display fees. If these estimates are accurate, then the new fee structure would generate approximately $4,300,000 in annualized revenue to OPRA, representing an increase of approximately $3,200,000 over the annualized revenues that OPRA previously received from the Non-Display Application Fee.21

If OPRA’s estimate of its annualized revenue from its revised Non-Display fees is accurate, the additional annualized revenue will represent approximately a 4.7% increase in OPRA’s total revenues for the year 2014. In terms of a perspective over a longer term, the additional annualized revenue will also represent approximately a 4.7% increase in OPRA’s total revenues for the year 2008, approximately a 0.6% increase per year for each year since 2008.

Looking at the additional annualized revenue in another way, the estimated increase in revenue will represent less than two years of revenue lost by OPRA due to decreases in the number of Devices/User IDs that are subject to OPRA’s Professional Subscriber Device-Based Fees.22 When OPRA implemented its “Non-Display Application” fee in 2012, it stated that it believed that the use of Non-Display Applications by active trading firms was resulting, and would continue to result, in a significant reduction in the number of devices and user IDs that are reported to it,23 and OPRA anticipated that the Non-Display Application fees would substantially offset the reduction in revenue from Professional Subscriber Device-Based Fees. OPRA believes that it has indeed been the case that Non-Display Use of OPRA data by active trading firms is a major reason for the reductions in the number of devices and user IDs that are reported to OPRA, and OPRA anticipates that the trend of reductions in the number of Devices/UserIDs will continue as it has for the past eight years. It has not been the case that the Non-Display Application fees have substantially offset the reduction in revenue resulting from the continuing reductions in the number of devices and user IDs that are reported to OPRA. OPRA anticipates that the “Non-Display Use” fees will offset future decreases in its revenues from Professional Subscriber Device-Based Fees to a greater extent than have OPRA’s Non-Display Application fees.

The text of the amendment to the OPRA Plan is available at OPRA, the Commission’s Public Reference Room, on OPRA’s Web site at http://opradata.com, and on the Commission’s Web site at www.sec.gov.

II. Implementation of the OPRA Plan Amendment

Pursuant to paragraph (b)(3)(i) of Rule 608 of Regulation NMS under the Act, OPRA designated this amendment as establishing or changing fees or other charges collected on behalf of all of the OPRA participants in connection with access to or use of OPRA facilities. OPRA put the revised Non-Display Application Fees into effect as of January 1, 2016.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the OPRA Plan amendment is consistent with the Act.24 Comments may be submitted by any of the following methods:

Electronic Comments
• Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include File No. SR–OPRA–2015–01 on the subject line.

Paper Comments
• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

21 OPRA is not estimating any “net” revenue derived from “Category 3” Non-Display Fees (for non-display use in connection with providing a two-sided trading platform). The OPRA Participant Exchanges are subject to Category 3 Non-Display Fees, but this revenue does not represent net revenue available to OPRA and its Participant Exchanges for collecting, consolidating, processing and disseminating OPRA data. Other than the OPRA Participant Exchanges, OPRA is aware of only one other two-sided trading platform that may be subject to “Category 3” fees. That platform would generate $24,000 in annualized Category 3 Non-Display Fees, a number that does not meaningfully change OPRA’s estimates of total revenue and increased revenue resulting from the proposed Non-Display fee structure.

22 The average number of Devices/User IDs in 2013 was 151,400. As noted above (see footnote 7), OPRA projects an average of 136,600 devices/User IDs in 2015, representing a decrease of 14,800 Devices/User IDs and a decrease in OPRA’s 2015 revenues (at a monthly rate of $28.50 per device/User ID) of approximately $5,000,000.

23 See supra note 8, at 60538.

24 Pursuant to Rule 608(b)(3)(i) of Regulation NMS, the Commission may summarily abrogate an immediately effective NMS Plan amendment within sixty days of its filing and require rolling and approval of the amendment if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934. See 17 CFR 242.608(b)(3)(i). The abrogation period for the OPRA Plan amendment has expired. Interested persons may nevertheless submit written comments on the OPRA Plan amendment.
SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

April 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act” or “Exchange Act”),1 and Rule 19b–4 thereunder,2 notice is hereby given that on April 1, 2016, the International Securities Exchange, LLC (the “Exchange” or “ISE”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change, as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

ISE proposes to amend the Schedule of Fees as described in more detail below. The text of the proposed rule change is available on the Exchange’s Internet Web site at http://www.ise.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend the Schedule of Fees to modify the Regular Order Fee for Responses to Crossing Orders in Select3 and Non-Select Symbols and Fee for Non-Select Symbols.

The Exchange proposes the following two fee changes. First, the Exchange proposes to change the Fee for Responses to Crossing Orders in Select and Non-Select Symbols for all members from $0.47 per contract to $0.50 per contract. Next, the Exchange proposes to change the Fees in Non-Select Symbols charged to Non-ISE Market Maker (“FarMM”),4 Firm Proprietary5/Broker-Dealer,6 and Professional Customer7 from $0.50 per contract to $0.72 per contract.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,8 in general, and Section 6(b)(4) of the Act,8 in particular, that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

The Exchange believes that the proposed fees increases are reasonable and equitable as the proposed fees are set at levels that the Exchange believes will continue to be attractive to market participants that trade on ISE. Moreover, the proposed fees are competitive with fees charged by other options exchanges and remain attractive to members for this reason. For example, ISE’s proposed Fee for Responses to Crossing Orders in Select Symbols is the same as ISE Mercury’s Fee for Responses to Crossing Orders (excluding Market Makers) in Penny Symbols.9 Further, ISE’s proposed Fee for Responses to Crossing Orders in Non-Select Symbols is less than ISE Mercury’s Fee for Responses to Crossing Orders (excluding Market Makers) in Non-Penny Symbols.10 Additionally, the Regular Order Non-Select Symbol Fee of $0.72 is less than the Electronic, Non-Penny Classes fee of $0.75 charged by the Chicago Board Options Exchange.11

The Exchange also notes that the proposed Fees for Responses to Crossing Orders are not unfairly discriminatory because they apply equally to all members. Additionally, the Exchange further notes that for the Non-Select Symbol Fee, Priority Customers will continue to be charged no fee, while other market participants will continue to pay a fee. The Exchange does not believe that this is unfairly discriminatory as a Priority Customer is by definition not a broker or dealer in the Act”, registered in the same options class on another options exchange.

* * *

4 A Firm Proprietary order is an order submitted by a member for its own proprietary account.
5 A Broker-Dealer order is an order submitted by a member for a non-member broker-dealer account.
6 A Professional Customer is a person who is not a broker/dealer and is not a Priority Customer.
10 Id.
11 See CBOT Fee Schedule, Equity Options Rate Table, Transaction Fee Per Contract at http://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf.
Statement on Burden on Competition

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change will impose any burden on intramarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed fees remain competitive with fees charged by other options exchanges as discussed above. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act, and subparagraph (f)(2) of Rule 19b–4 thereunder, because it establishes a due, fee, or other charge imposed by ISE.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments
- Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml);
- Send an email to rule-comments@sec.gov. Please include File No. SR–ISE–2016–09 on the subject line.

Paper Comments
- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File Number SR–ISE–2016–09. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2016–09 and should be submitted by May 9, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.  

Robert W. Errett,  
Deputy Secretary.  

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SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Rules 4702 and 4703

April 12, 2016.  

On February 10, 2016, The NASDAQ Stock Market LLC filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") 1 and Rule 19b–4 thereunder, 2 a proposed rule change to amend Rules 4702 and 4703. The proposed rule change was published for comment in the Federal Register on March 1, 2016.  

The Commission received no comment letters on the proposed rule change.  

Section 19(b)(2) of the Act 4 provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is April 15, 2016.

The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act, designates May 30, 2016, as the date by which the Commission should either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR-NASDAQ–2016–023).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.6

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2016–08823 Filed 4–15–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION


Options Price Reporting Authority;
Notice of Filing and Immediate Effectiveness of Proposed Amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information To Amend the Redistribution Fee Set Forth in OPRA’s Fee Schedule

April 12, 2016.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (“Act”) and Rule 608 thereunder, notice is hereby given that on September 22, 2015, the Options Price Reporting Authority (“OPRA”) submitted to the Securities and Exchange Commission (“Commission”) an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (“OPRA Plan”). Effective January 1, 2016, the OPRA Plan amendment revised the description of OPRA’s reduced rate Redistribution Fee. The Commission is publishing this notice to provide interested persons an opportunity to submit written comments on the OPRA Plan amendment.

I. Description and Purpose of the Plan Amendment

The purpose of the amendment is to amend the OPRA Fee Schedule to revise the description of one of OPRA’s Redistribution Fees. Specifically, the purpose of the OPRA Plan amendment is to make clear that OPRA’s “reduced rate” Redistribution Fee of $650/month is available only to Vendor Services that are intended for Subscribers that want to query specific OPRA data, and that this fee is not available for any Vendor Service that includes a data streaming capability. In effect, the OPRA Plan amendment returns the applicability of this fee to the scope that it had when it was first implemented in 1999. An OPRA Redistribution Fee is payable by every OPRA “Vendor.” An OPRA “Vendor” is a recipient of OPRA data that redistributes the data “externally”—that is, to persons outside the data recipient itself. OPRA has had a two-tier Redistribution Fee for many years: the basic OPRA Redistribution Fee has been $1,500/month for many years, and a reduced rate of $650/month has been available for many years.

OPRA has referred to this reduced rate as the “Internet Service Only” rate. The OPRA Plan amendment changed the description of the reduced rate of $650/month to specify that the reduced rate is for “Query service only,” rather than “Internet service only,” and revised the footnote that accompanies the reduced rate to state that: “A Vendor’s Service qualifies for the ‘Query service only’ rate if the Vendor’s Service provides access to OPRA Data only on a ‘query’ basis without any auto-refreshing capability. The fee does not redistribute OPRA Data via dedicated lines or to the systems of one or more other Vendors (sometimes referred to as ‘downstream Vendors’).”

When OPRA implemented the “Internet service only” Redistribution Fee, an “Internet service only” was a service that was not suitable for high-speed/high-reliability data transmission and high traffic volumes, and was a service appropriate for retail customers interested in querying specific option quotes and last sale prices.

OPRA estimates that the revised definition of the reduced rate Redistribution Fee is likely to affect between 35 and 45 of its Vendors, out of a total population of roughly 200 Vendors. Many of the remaining 155 to 165 OPRA Vendors also utilize the Internet to disseminate their data services, and pay the regular OPRA Redistribution Fee. Accordingly OPRA believes that the OPRA Plan amendment will cause all Vendors that are similarly situated in terms of the means of dissemination of their data services to be subject to the same OPRA Redistribution Fee.

For an OPRA Vendor that is required to pay the regular Redistribution Fee instead of the reduced rate as a result of the change, the change will result in an increase of $850/month or $10,200/year in its OPRA Redistribution Fees. If the maximum estimated number of 45 Vendors are affected by the change and none cease to be OPRA Vendors, OPRA’s annualized revenues would increase by $459,000 as a result of the change, representing approximately a 0.67% increase in OPRA’s annualized revenues; any lesser number of Vendors being affected by the change would result in a smaller increase in OPRA’s revenues as a result of the change. The text of the OPRA Plan amendment is available at OPRA, the Commission’s Public Reference Room, on OPRA’s Web site at http://oprdadata.com, and on the Commission’s Web site at www.sec.gov.

II. Implementation of the OPRA Plan Amendment

Pursuant to paragraph (b)(3)(i) of Rule 608 of Regulation NMS under the Act, OPRA designated this amendment as establishing or changing fees or other charges collected on behalf of all of the OPRA participants in connection with access to or use of OPRA facilities.


OPRA put the revised description of reduced rate Redistribution Fee into effect as of January 1, 2016.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the OPRA Plan amendment is consistent with the Act.6 Comments may be submitted by any of the following methods:

Electronic Comments
• Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include File No. SR–OPRA–2015–03 on the subject line.

Paper Comments
• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File Number SR–OPRA–2015–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the OPRA Plan amendment that are filed with the Commission, and all written communications relating to the OPRA Plan amendment between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and available publicly. All submissions and all written communications relating to the OPRA Plan amendment will be available for inspection and copying at the principal office of OPRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–OPRA–2015–03 and should be submitted on or before May 9, 2016.

By the Commission.
Robert W. Errett,
Deputy Secretary.

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services

April 12, 2016.

Pursuant to section 19(b)(1) 1 of the Securities Exchange Act of 1934 (the “Act”) 2 and Rule 19b–4 thereunder, 3 notice is hereby given that, on March 31, 2016, NYSE Arca, Inc. (the “Exchange” or “NYSE Arca”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services (“Fee Schedule”). The Exchange proposes to implement the fee changes effective April 1, 2016. The proposed rule change is available on the Exchange’s Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule as follows:

Routing Fees

The Exchange proposes to modify the fees that it charges for routing orders to other market centers. Currently, for the Exchange’s Tier 1 and Tier 2 customers, the Exchange charges the following routing fees:

• $0.0027 per share in Tape A

The Exchange proposes to charge the following fees for orders routed outside the Book to any away market center:

• $0.0030 per share in Tape B

Orders 4

Orders 5 and PO+ Orders routed to the primary, listing market, without sweeping the NYSE Arca book. See NYSE Arca Equities Rule 7.31P(1)(C).

5 A PO Order is a market or limit order that is to be routed to the primary, listing market (or to any away market center other than NYSE) and

6 Pursuant to Rule 608(b)(3)(iii) of Regulation NMS, the Commission may summarily abrogate an immediately effective NMS Plan amendment within sixty days of its filing and require refiling and approval of the amendment if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934. See 17 CFR 242.608(b)(3)(iii). The abrogation period for the OPRA Plan amendment has expired. Interested persons may nevertheless submit written comments on the OPRA Plan amendment.

4 A PO+ Order is a Primary Only Order (i.e., a market or limit order that is to be routed to the primary market) that is entered for participation in the primary market, other than for participation in the primary market opening or primary market reopening. See NYSE Arca Equities Rule 7.31P(1)(C).

A PO Order is a market or limit order that is routed to the primary, listing market, without sweeping the NYSE Arca book. See NYSE Arca Equities Rule 7.31P(1). See also NYSE Arca Equities Rule 7.31P(1)(C).
For Tier 3 customers, the Exchange charges the following routing fees:
- $0.0027 per share in Tape A Securities for orders routed outside the Book to the NYSE;
- $0.0030 per share in Tape B Securities for orders routed outside the Book to any away market center; and
- $0.0030 per share in Tape A and Tape C Securities for orders routed outside the Book to any away market center.

The Exchange proposes to modify the above routing fees by adopting a uniform fee of $0.0030 per share for Tier 1, Tier 2 and Tier 3 customers in Tape A, Tape B and Tape C Securities for orders that remove liquidity, including PO and PO+ Orders, that are routed outside the Book to any away market center.

Currently, for non-tier customers (i.e., Basic Rates), the Exchange charges the following routing fees:
- $0.0030 per share in Tape A Securities for orders routed outside the Book to any away market center other than NYSE;
- $0.0029 per share in Tape A Securities for orders routed outside the Book to the NYSE;
- $0.0027 per share in Tape A Securities for PO+ Orders routed to the NYSE that remove liquidity;
- $0.0035 per share in Tape B Securities for orders routed outside the Book to any away market center;
- $0.0028 per share in Tape B Securities for PO and PO+ Orders routed to NYSE MKT that remove liquidity from the NYSE MKT Book; and
- $0.0035 per share in Tape C Securities for orders routed outside the Book to any away market center.

The Exchange proposes to modify the above routing fees by adopting a uniform fee of $0.0035 per share for Basic Rates customers in Tape A, Tape B and Tape C Securities for orders that remove liquidity, including PO and PO+ Orders, that are routed outside the Book to any away market center.

MPL Orders

Currently, the Exchange provides credits under Tier 1, Tier 2 and Basic Rates for Mid-Point Passive Liquidity (“MPL”) Orders that provide liquidity. The Exchange provides different levels of credits based on the Average Daily Volume (“ADV”) of provided liquidity in MPL Orders for Tape A, Tape B and Tape C Securities combined (“MPL Adding ADV”). For ETP Holders and Market Makers that have MPL Adding ADV during the billing month of at least 3 million shares, the Exchange provides a credit of $0.0015 per share for Tape A Securities, $0.0020 per share for Tape B Securities and $0.0025 per share for Tape C Securities.7

The Exchange proposes to modify the per share credit payable under Tier 1, Tier 2 and Basic Rates from $0.0025 per share to $0.0020 per share for MPL Orders that provide liquidity in Tape C Securities for ETP Holders and Market Makers that have MPL Adding ADV during the billing month of at least 3 million shares. The Exchange does not propose to make any other change to credits for MPL Orders.

Non-Substantive Changes to the Fee Schedule

The Exchange recently amended the Fee Schedule to reflect the migration of securities to Pillar, the Exchange’s new trading technology platform. The Exchange proposes to make two non-substantive changes to the Fee Schedule that is now named Core Open Auction in Pillar. Second, in the Pillar Fee Filing, the Exchange noted that Mid-Point Passive Liquidity Order is named Mid-Point Liquidity Order on Pillar. In connection with that name change, the Exchange further noted that orders designated as retail orders for securities traded on Pillar would need to meet the requirements for the credit on Pillar. The Exchange proposes to add the reference to Rule 7.44P(a)(3) in the section for Basic Rates, under Tape C Securities.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

1. An MPL Order is a limit order priced at the midpoint of the Protected Best Bid and Offer (“PBBBO”) and not displayed. See Rule 7.31P(d)(4). An MPL Order on Pillar is a limit order that is not displayed and does not route, with a working price at the midpoint of the PBBBO. See Rule 7.31P(d)(3).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of sections 6(b)(4) and (5) of the Act, in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed change to adopt uniform routing fees for Tier 1, Tier 2, Tier 3 and Basic Rate customers in Tape A, Tape B and Tape C Securities for orders that remove liquidity, including PO and PO+ Orders, that are routed outside the Book to any away market center is equitable and not unfairly discriminatory because it will standardize the routing fee, meaning that the fee would apply uniformly within pricing tiers and all similarly situated ETP Holders and Market Makers would be subject to the same fee. This aspect of the proposed change would therefore result in a more streamlined Fee Schedule.

In addition, the Exchange believes the decrease in the per share credit payable under Tier 1, Tier 2 and Basic Rates for MPL Orders that provide liquidity in Tape C Securities for ETP Holders and Market Makers that have MPL Adding ADV during the billing month of at least 3 million shares is reasonable as it is comparable to the tiered credit available on the NASDAQ Stock Market (“NASDAQ”) for midpoint liquidity, which is currently $0.0017 per share for Tape C Securities when a firm adds greater than 3 million shares of midpoint liquidity.8 The Exchange also believes that the proposed change is equitable and not unfairly discriminatory because the proposed credit would be applicable to all market participants that use MPL Orders and meet the requirements for the credit on the Exchange and each such participant would be subject to the same credit.

The Exchange believes that the proposed non-substantive changes to the Fee Schedule are reasonable, equitable and not unfairly discriminatory because the changes are designed to make the Fee Schedule more logical and comprehensive, and therefore easier for market participants to navigate and digest, which is in the public interest.

8 ETP Holders and Market Makers with MPL Adding ADV during the billing month of at least 1.5 million shares but less than 3 million shares are provided a credit of $0.0015 per share for Tape A, Tape B and Tape C Securities. ETP Holders and Market Makers with MPL Adding ADV during the billing month of less than 1.5 million shares are provided a credit of $0.0010 per share for Tape A, Tape B and Tape C Securities. See Fee Schedule.


10 See Securities Exchange Act Release No. 74124 [sic] named Core Open Auction in Pillar. The Exchange recently amended the Fee Schedule to reflect the migration of securities to Pillar, the Exchange’s new trading technology platform. The Exchange proposes to adopt uniform fees for Tier 1, Tier 2 and Basic Rates for MPL Orders that provide liquidity in Tape C Securities for ETP Holders and Market Makers that have MPL Adding ADV during the billing month of at least 3 million shares.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange’s statement regarding the burden on competition. For these reasons, the Exchange believes that the proposal is consistent with the Act.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with section 6(b)(8) of the Act,12 the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the routing fees would not place a burden on competition because the Exchange is standardizing the fee so that each participant would pay a uniform fee. Further, the proposed change to credits applicable to MPL Orders would also not place a burden on competition because the modified credit is comparable to the level of credit for Tape C Securities provided by at least one other exchange.13

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that this proposal promotes a competitive environment.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to section 19(b)(3)(A)14 of the Act and subparagraph (i)(2) of Rule 19b–415 thereunder, because it establishes a due fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)16 of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml);
• Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca–2016–54 on the subject line.

Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File Number SR–NYSEArca–2016–54. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–54, and should be submitted on or before May 9, 2016.

The Commission will consider all comments received before the end of the comment period in determining whether to approve or disapprove the proposed rule change.

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Fees Under Rule 7018(a)

April 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),1 and Rule 19b–4 thereunder, notice is hereby given that on March 30, 2016, NASDAQ BX, Inc. ("BX" or “Exchange”) filed with the Securities and Exchange Commission ("SEC" or “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange’s transaction fees at Rule 7018(a) relating to charges assessed for providing liquidity through the NASDAQ OMX BX Equities System in securities priced at $1 or more per share that it trades to: (i) Eliminate Qualified Market Maker-based criteria and adopt new Consolidated Volume-based criteria required to receive the $0.0014 per share executed charge; and (ii) decrease the $0.0018 per share executed charge, and amend the qualification criteria currently required to receive the charge, for a displayed order entered by a member.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on April 1, 2016.
The purpose of the proposed rule change is to amend the Exchange’s transaction fees at Rule 7018(a) relating to charges assessed for providing liquidity through the NASDAQ OMX BX Equities System in securities priced at $1 or more per share that it trades to: (i) Eliminate Qualified Market Maker-based criteria and adopt new Consolidated Volume-based criteria required to receive the $0.0014 per share executed charge; and (ii) decrease the $0.0018 per share executed charge, and amend the qualification criteria currently required to receive the charge, for a displayed order entered by a member.

First Change

The purpose of the first change is to eliminate the Qualified Market Maker-based criteria required to receive the $0.0014 per share executed charge. Currently, this fee applies to all displayed orders entered by a Qualified Market Maker. A member firm may become a Qualified Market Maker by being a member firm that provides through one or more of its NASDAQ OMX BX Equities System MPIDs more than 0.20% of Consolidated Volume \(^3\).

The Exchange notes that, like the eliminated $0.0014 charge criteria discussed above, the proposed new charge criteria requires a level of Consolidated Volume in return for a reduced charge assessed for displayed orders. Although the proposed level of Consolidated Volume is 0.05% higher than the eliminated charge tier, the proposed new charge criteria does not require the member firm to also qualify as a Qualified Market Maker, which includes certain quoting requirements discussed above.

Second Change

The purpose of the second change is to decrease the $0.0018 per share executed charge, and amend the qualifications currently required to receive the charge, for a displayed order entered by a member. Under Rule 7018(a), a member firm may receive a $0.0018 per share executed charge for a displayed order if it adds liquidity equal to or exceeding 0.20% of total Consolidated Volume during a month. The Exchange is proposing to reduce the level of total Consolidated Volume required from 0.20% to 0.15% during a month, in light of the new $0.0014 per share executed charge tier discussed above that requires 0.25% Consolidated Volume.

The Exchange believes that the new $0.0014 per share executed charge criteria is reasonable because it is similar to the Qualified Market Maker charge tier criteria that the Exchange is proposing to eliminate. Under the existing Qualified Market Maker charge tier, a member firm must be a Qualified Market Maker to receive the $0.0014 per share executed charge for its displayed orders. To be a Qualified Market Maker, a member firm must: (i) Provide through one or more of its NASDAQ OMX BX Equities System MPIDs more than 0.20% of Consolidated Volume during

\(^3\) Consolidated Volume is defined as the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of a member’s trading activity, expressed as a percentage of or ratio to Consolidated Volume, the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member’s trading activity. See Rule 7018.
the month; and (ii) have at least one Qualified MPID, that is, a MPID through which, for at least 200 securities, the Qualified Market Maker quotes at the NBBO an average of at least 50% of the time during regular market hours (9:30 a.m. through 4:00 p.m.) during the month.

Under the proposed new charge tier, a member firm must provide a higher level of Consolidated Volume in contrast to the Qualified Market Maker criteria, but is not required to meet the quoting requirements of the Qualified Market Maker criteria. Accordingly, the Exchange believes that the proposed new $0.0014 per share executed charge criteria is reasonable.

The Exchange believes that assessing a $0.0014 per share executed charge and requiring a member to provide a level of Consolidated Volume to qualify for that charge is an equitable allocation and is not unfairly discriminatory because the Exchange will apply the new criteria and assess the charge to all similarly situated members. Any member firm that elects to provide the level of Consolidated Volume required by the tier will receive the charge. In this regard, the Exchange notes that all member firms that could meet the eliminated criteria will have the opportunity to qualify under the new Consolidated Volume-based criteria.

Second Change

The Exchange believes that the proposed changes to the $0.0018 per share executed charge provided for a displayed order if it is entered by a member firm that adds liquidity equal to or exceeding 0.20% of total Consolidated Volume during a month are reasonable because they better align the reduced charge with the level of Consolidated Volume required to qualify, in light of the proposed changes the Exchange is making to the $0.0014 per share executed charge criteria.

Specifically, the Exchange is reducing the level of Consolidated Volume required to qualify from 0.20%, which is close to the proposed level of Consolidated Volume required to receive the $0.0014 per share executed charge, to 0.15%, which the Exchange believes is better aligned with the charges provided and the criteria required to receive the charges. As a further incentive, the Exchange is proposing to decrease the charge assessed qualifying member firms from $0.0018 to $0.0017 per share executed.

The Exchange believes that it is reasonable to reduce the charge because it may provide the incentive to member firms to provide the level of Consolidated Volume necessary to receive the reduced charge. Moreover, the reduced charge better aligns the charge tier with the proposed new $0.0014 per share executed charge tier and its 0.25% Consolidated Volume requirement and the $0.0019 per share executed tier, which requires a member to provide 0.10% of total Consolidated Volume to receive that charge.

The Exchange believes that the proposed $0.0017 per share executed charge and changes to the Consolidated Volume requirement are an equitable allocation and are not unfairly discriminatory because the Exchange will apply the same charge to all similarly situated members. Any member firm that elects to provide the level of Consolidated Volume required by the amended tier will receive the reduced charge.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable.

In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In this instance, the proposed changes to the charges assessed member firms for execution of displayed orders do not impose a burden on competition because the Exchange’s execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues.

The proposed changes are reflective of this competition and the Exchange’s desire to offer lower fees in return for market-improving liquidity, which is ultimately limited by the Exchange’s need to cover costs and make a profit. Thus, the Exchange must carefully adjust its access fees with the understanding that if the proposed changes are unattractive to market participants, it is likely that the Exchange will lose market share to other exchanges and off-exchange venues as a result.

In this proposal, the Exchange is modifying qualification criteria and reducing the charges that it assesses its member firms for providing liquidity to the Exchange. The Exchange believes that such changes will support liquidity on the Exchange and are pro-competitive, since any other market is free to provide similar, if not better, fees should they choose to do so. For these reasons, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include File Number SR-BX—2016-020 on the subject line.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77594; File No. SR-BatsBZX–2016–01]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Under BZX Rule 14.11(c)(4) Shares of the Following Series of Market Vectors ETF Trust: Market Vectors 6–8 Year Municipal Index ETF; Market Vectors 8–12 Year Municipal Index ETF; and Market Vectors 12–17 Year Municipal Index ETF

April 12, 2016

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”), and Rule 19b–4 thereunder, notice is hereby given that on March 29, 2016, Bats BZX Exchange, Inc. (“BZX”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to list and trade under BZX Rule 14.11(c)(4) the shares of the following series of Market Vectors ETF Trust (the “Trust”): Market Vectors 6–8 Year Municipal Index ETF; Market Vectors 8–12 Year Municipal Index ETF; and Market Vectors 12–17 Year Municipal Index ETF.

The text of the proposed rule change is available at the Exchange’s Web site at www.batstrading.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade shares (“Shares”) of the following series of the Trust under BZX Rule 14.11(c)(4), which governs the listing and trading of index fund shares based on fixed income securities indexes: Market Vectors AMT-Free 6–8 Year Municipal Index ETF; Market Vectors AMT-Free 8–12 Year Municipal Index ETF; and Market Vectors AMT-Free 12–17 Year Municipal Index ETF (each a “Fund” and, collectively, the “Funds”). The Shares will be offered by the Trust, which was established as a Delaware statutory trust on March 15, 2001. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Funds on

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BZX–2016–020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written communications relating to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only comments that pertain to the proposed rule change.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 

Robert W. Errett,
Deputy Secretary.

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Form N–1A (“Registration Statement”) with the Commission.\(^5\)  
Description of the Shares and the Funds

Van Eck Associates Corporation will be the investment adviser (“Adviser”) to the Funds.\(^6\) The Adviser will serve as the administrator for the Fund (the “Administrator”). The Bank of New York Mellon will serve as the custodian (“Custodian”) and transfer agent (“Transfer Agent”) for the Funds. Van Eck Securities Corporation (the “Distributor”) will be the distributor of the Shares. Barclays Inc. will be the index provider (“Index Provider”).

Market Vectors AMT—Free 6–8 Year Municipal Index ETF

According to the Registration Statement, the Fund will seek to replicate as closely as possible, before fees and expenses, the price and yield performance of the Barclays AMT-Free 6–8 Year Intermediate Continuous Municipal Index (the “6–8 Year Index”). As of December 31, 2015, there were 2,894 issues in the 6–8 Year Index. Unless otherwise noted, all statistics related to the 6–8 Year Index presented hereafter were accurate as of December 31, 2015.

To be included in the 6–8 Year Index, a bond must be rated Baa3/BBB- or higher by at least two of the following ratings agencies if all three agencies rate the security: Moody’s, S&P and Fitch. If only two of the three agencies rate the security, the lower rating is used to determine index eligibility. If only one of the three agencies rates a security, the rating must be at least Baa3/BBB-. Potential constituents must have an outstanding par value of at least $7 million and be issued as part of a transaction of at least $75 million. The bonds must be fixed rate, have a dated date within the last five years and have an effective maturity of 6 to 8 years. The following types of bonds are excluded from the 6–8 Year Index: bonds subject to the alternative minimum tax, taxable municipal bonds, floating rate bonds and derivatives. The 6–8 Year Index is calculated using a market value weighting methodology.

The composition of the 6–8 Year Index is rebalanced monthly. Interest and principal payments earned by the component securities are held in the 6–8 Year Index without a reinvestment return until month end when they are removed from the 6–8 Year Index. Qualifying securities issued, but not necessarily settled, on or before the month end rebalancing date qualify for inclusion in the 6–8 Year Index in the following month.

The Fund normally invests at least 80% of its total assets in securities that comprise the Fund’s benchmark index. The 6–8 Year Index is comprised of publicly traded municipal bonds that cover the U.S. dollar-denominated intermediate term tax-exempt bond market with final maturities of 6–8 years. The Fund’s 80% investment policy is non-fundamental and may be changed without shareholder approval upon 60 days’ prior written notice to shareholders. To-be-announced transactions (“TBAs”) representing securities in the 6–8 Year Index may be used by the Fund in seeking performance that corresponds to the 6–8 Year Index and in such cases would count towards the Fund’s 80% policy.

Other Portfolio Holdings

While the Fund normally will invest at least 80% of its total assets in securities that compose the 6–8 Year Index, as described above, the Fund may invest its remaining assets in other financial instruments, as described below.

The Fund may invest its remaining assets in securities not included in the 6–8 Year Index including only the following instruments: municipal bonds; money market instruments, including repurchase agreements or other funds which invest exclusively in money market instruments; convertible securities; structured notes (notes on which the amount of principal repayment and interest payments are based on the movement of one or more specified factors, such as the movement of a particular stock or stock index); derivative instruments described below; and, to the extent permitted by the 1940 Act, affiliated and unaffiliated funds, such as open-end or closed-end management investment companies, including other exchange-traded funds (“ETFs”). In addition to the use described above, TBAs not included in the 6–8 Year Index may also be used by the Fund in managing cash flows.

The Fund may invest in repurchase agreements with commercial banks, brokers or dealers to generate income from its excess cash balances and to invest securities lending cash collateral. The Fund may use exchange-traded futures contracts and exchange-traded or over-the-counter (“OTC”) options thereon, together with positions in cash and money market instruments, to simulate full investment in the 6–8 Year Index. The Fund may use cleared or non-cleared index, interest rate or credit

\(^5\) See Registration Statement on Form N–1A for the Trust, dated October 29, 2015 (File Nos. 333–123257 and 811–10325). The descriptions of the Funds and the Shares contained herein are based, in part, on information in the Registration Statement. The Commission has issued an order granting certain exemptive relief to the Trust under the Investment Company Act Release No. 28021 (October 24, 2007) (File No. 812–13426).\(^\)

\(^6\) An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the “Advisers Act”). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with all applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

A TBA transaction is a method of trading mortgage-backed securities. In a TBA transaction, the buyer and seller agree upon general trade parameters such as agency, settlement date, par amount, and price. The actual pools delivered generally are determined two days prior to the settlement date.

\(^7\) Municipal bonds that are not included in the 6–8 Year Index must be publicly traded municipal bonds that cover the U.S. dollar-denominated intermediate term tax-exempt bond market with final maturities of 6–8 years. Such bonds must be rated Baa3/BBB- or higher by at least two of the following ratings agencies if all three agencies rate the security: Moody’s, S&P and Fitch. If only two of the three agencies rate the security, the lower rating is used to determine index eligibility. If only one of the three agencies rates a security, the rating must be at least Baa3/BBB-. Potential constituents must have an outstanding par value of at least $7 million and be issued as part of a transaction of at least $75 million. The bonds must be fixed rate, have a dated date within the last five years and have an effective maturity of 6 to 8 years.

\(^8\) Structured notes are derivative securities for which the amount of principal repayment and/or interest payments is based on the movement of one or more factors, including, but not limited to, currency exchange rates, interest rates (such as the prime lending rate or LIBOR), referenced bonds and stock indices.

\(^9\) Municipal bonds that are not included in the 6–8 Year Index include mortgage-backed securities, structured notes, interest rate swaps, credit default swaps, interest payment options, interest rate options, inverse derivative instruments, index-linked notes, and other derivative instruments.

\(^10\) For purposes of this filing, ETFs include Index Funds Shares (as described in Rule 14.11(i)); Portfolio Depositary Receipts (as described in Rule 14.11(b)); and Managed Fund Shares (as described in Rule 14.11(i)). The ETFs will be traded in the U.S. on registered exchanges. The Fund may invest in the securities of ETFs registered under the 1940 Act consistent with the requirements of Section 12(d)(1) of the 1940 Act, or any rule, regulation or order of the Commission or interpretation thereof. While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged [e.g., 2X, –2X, 3X or –3X] ETFs.
default swap agreements. Swap agreements are contracts between parties in which one party agrees to make payments to the other party based on the change in market value or level of a specified index or asset. The Adviser represents that currently interest rate swaps and credit default swaps on indexes are cleared. However, credit default swaps on a specific security are currently uncleared. The Fund may invest in exchange-traded warrants, which are equity securities in the form of options issued by a corporation which give the holder the right to purchase stock, usually at a price that is higher than the market price at the time the warrant is issued.

The Fund may invest in participation notes, which are issued by banks or broker-dealers and are designed to offer a return linked to the performance of a particular underlying equity security or market. The Fund will only enter into transactions in derivative instruments with counterparties that the Adviser reasonably believes are capable of performing under the contract and will post as collateral as required by the counterparty.

Index Overview

The Exchange is submitting this proposed rule change because the 6–8 Year Index for the Fund does not meet all of the "generic" listing requirements of Rule 14.11(c)(4) applicable to the listing of index fund shares based on fixed income securities indexes. The 6–8 Year Index meets all such requirements except for those set forth in Rule 14.11(c)(4)(B)(i)(b).

Specifically, as of December 31, 2015, 9.8% of the weight of the 6–8 Year Index components have a minimum original principal amount outstanding of $100 million or more. As of December 31, 2015, 95.1% of the weight of the 6–8 Year Index components was comprised of individual maturities that were part of an entire municipal bond offering with a minimum original principal amount outstanding $100 million or more. 

outstanding $100 million or more for all maturities of the offering. In addition, the total dollar amount outstanding of issues in the 6–8 Year Index was approximately $57.4 billion and the average dollar amount outstanding of issues in the 6–8 Year Index was approximately $19.8 million. Further, the most heavily weighted component represented 1.07% of the weight of the 6–8 Year Index and the five most heavily weighted components represented 3.0% of the weight of the 6–8 Year Index. Therefore, the Exchange believes that, notwithstanding that the 6–8 Year Index does not satisfy the criterion in Rule 14.11(c)(4)(B)(i)(b), the 6–8 Year Index is sufficiently broad-based to deter potential manipulation, given that it is comprised of approximately 2,894 issues. In addition, the 6–8 Year Index securities are sufficiently liquid to deter potential manipulation in that a substantial portion (95.1%) of the 6–8 Year Index weight is comprised of maturities that are part of a minimum original principal amount outstanding of $100 million or more, and in view of the substantial total dollar amount outstanding and the average dollar amount outstanding of the 6–8 Year Index issues, as referenced above. 63.8% of the 6–8 Year Index weight consisted of issues with a rating of AA/Aa2 or higher.

The 6–8 Year Index value, calculated and disseminated at least once daily, as well as the components of the 6–8 Year Index and their percentage weighting, will be available from major market data vendors. In addition, the portfolio of securities held by the Fund will be disclosed on the Fund’s Web site at www.vaneck.com/etfs.

Market Vectors AMT—Free 8–12 Year Municipal Index ETF

According to the Registration Statement, the Fund will seek to replicate as closely as possible, before fees and expenses, the price and yield performance of the Barclays AMT-Free 8–12 Year Intermediate Continuous Municipal Index (the “8–12 Year Index”). As of December 31, 2015, there were 5,662 issues in the 8–12 Year Index. Unless otherwise noted, all statistics related to the 8–12 Year Index presented hereafter were accurate as of December 31, 2015.

To be included in the 8–12 Year Index, a bond must be rated Baa3/BBB or higher by at least two of the following ratings agencies if all three agencies rate the security: Moody’s, S&P and Fitch. If only two of the three agencies rate the security, the lower rating is used to determine index eligibility. If only one of the three agencies rates a security, the rating must be at least Baa3/BBB. Potential constituents must have an outstanding par value of at least $57 million and be issued as part of a transaction of at least $75 million. The bonds must be fixed rate, have a dated date within the last five years and have an effective maturity of 8 to 12 years. The following types of bonds are excluded from the 8–12 Year Index: bonds subject to the alternative minimum tax, taxable municipal bonds, floating rate bonds and derivatives. The 8–12 Year Index is calculated using a market value weighting methodology. The composition of the 8–12 Year Index is rebalanced monthly. Interest and principal payments earned by the component securities are held in the 8–12 Year Index without a reinvestment return until month end when they are removed from the 8–12 Year Index. Qualifying securities issued, but not necessarily settled, on or before the month end rebalancing date qualify for inclusion in the 8–12 Year Index in the following month.

The Fund normally invests at least 80% of its total assets in securities that comprise the Fund’s benchmark index. The 8–12 Year Index is comprised of publicly traded municipal bonds that cover the U.S. dollar-denominated intermediate term tax-exempt bond market with final maturities of 8–12 years. The Fund’s 80% investment policy is non-fundamental and may be changed without shareholder approval upon 60 days’ prior written notice to shareholders. TBAs representing securities in the 8–12 Year Index may be used by the Fund in seeking performance that corresponds to the 8–12 Year Index and in such cases would count towards the Fund’s 80% policy.

Other Portfolio Holdings

While the Fund normally will invest at least 80% of its total assets in securities that comprise the 8–12 Year Index, as described above, the Fund may invest its remaining assets in other financial instruments, as described below.

The Fund may invest its remaining assets in securities not included in the 8–12 Year Index including only the
the right to purchase stock, usually at a price that is higher than the market price at the time the warrant is issued. The Fund may invest in participation notes, which are issued by banks or broker-dealers and are designed to offer a return linked to the performance of a particular underlying equity security or market. The Fund will only enter into transactions in derivative instruments with counterparties that the Adviser reasonably believes are capable of performing under the contract and will post as collateral as required by the counterparty.

**Index Overview**

The Exchange is submitting this proposed rule change because the 8–12 Year Index for the Fund does not meet all of the “generic” listing requirements of Rule 14.11(c)(4) applicable to the listing of index fund shares based on fixed income indexes. The 8–12 Year Index meets all such requirements except for those set forth in Rule 14.11(c)(4)(II)(b). Specifically, as of December 31, 2015, 5.7% of the weight of the 8–12 Year Index components have a minimum original principal amount outstanding of $100 million or more. As of December 31, 2015, 95.1% of the weight of the 8–12 Year Index components was comprised of individual maturities that were part of an entire municipal bond offering with a minimum original principal amount outstanding of $100 million or more for all maturities of the offering. In addition, the total dollar amount outstanding of issues in the 8–12 Year Index was approximately $108.6 billion and the average dollar amount outstanding of issues in the 8–12 Year Index was approximately $19.2 million. Further, the most heavily weighted component represented 0.26% of the weight of the 8–12 Year Index and the five most heavily weighted components represented 1.04% of the weight of the 8–12 Year Index. Therefore, the Exchange believes that, notwithstanding that the 8–12 Year Index does not satisfy the criterion in Rule 14.11(c)(4)(II)(b), the 8–12 Year Index is sufficiently broad-based to deter potential manipulation, given that it is comprised of approximately 5,662 issues. In addition, the 8–12 Year Index securities are sufficiently liquid to deter potential manipulation in that a substantial portion (95.1%) of the 8–12 Year Index weight is comprised of maturities that are part of a minimum original principal amount outstanding of $100 million or more, and in view of the substantial total dollar amount outstanding and the average dollar amount outstanding of the 8–12 Year Index issues, as referenced above, 64.7% of the 8–12 Year Index weight consisted of issues with a rating of AA/Aa2 or higher.

The 8–12 Year Index value, calculated and disseminated at least once daily, as well as the components of the 8–12 Year Index and their percentage weighting, will be available from major market data vendors. In addition, the portfolio of securities held by the Fund will be disclosed on the Fund’s Web site at www.vaneck.com/etfs.

**Market Vectors AMT-Free 12–17 Year Municipal Index ETF**

According to the Registration Statement, the Fund will seek to replicate as closely as possible, before fees and expenses, the price and yield performance of the Barclays AMT-Free 12–17 Year Intermediate Continuous Municipal Index (the “12–17 Year Index”). As of December 31, 2015, there were 6,171 issues in the 12–17 Year Index. Unless otherwise noted, all statistics related to the 12–17 Year Index presented hereafter were accurate as of December 31, 2015.

To be included in the 12–17 Year Index, a bond must be rated Baa3/BBB – or higher by at least two of the following ratings agencies if all three agencies rate the security: Moody’s, S&P and Fitch. If only two of the three agencies rate the security, the lower rating is used to determine index eligibility. If only one of the three agencies rates a security, the rating must be at least Baa3/BBB –. Potential constituents must have an outstanding par value of at least $7 million and be issued as part of a

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15 Municipal bonds that are not included in the 8–12 Year Index must be publicly traded municipal bonds that cover the U.S. dollar-denominated intermediate term tax-exempt bond market with final maturities of 8–12 years. Such bonds must be rated Baa3/BBB – or higher by at least two of the following ratings agencies if all three agencies rate the security: Moody’s, S&P and Fitch. If only two of the three agencies rate the security, the lower rating is used to determine index eligibility. If only one of the three agencies rates a security, the rating must be at least Baa3/BBB –. Such bonds must also have an outstanding par value of at least $7 million and be issued as part of a transaction of at least $75 million. The bonds must also have a fixed rate, have a dated date within the last five years and have an effective maturity of 8 to 12 years.

16 Structured notes are derivative securities for which the amount of principal repayment and interest payments are based on the movement of one or more specified factors, such as the movement of a particular stock or stock index; certain derivative instruments described below; and, to the extent permitted by the 1940 Act, affiliated and unaffiliated funds, such as open-end or closed-end management investment companies, including other ETFs. In addition to the use described above, TBAs not included in the 8–12 Year Index may also be used by the Fund in managing cash flows.

17 The Fund will seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Adviser will evaluate the creditworthiness of counterparties on a regular basis. In addition to information provided by credit agencies, the Adviser will review approved counterparties using various factors, which may include the counterparty’s reputation, the Adviser’s past experience with the counterparty and the price/market actions of debt of the counterparty.

18 Rule 14.11(c)(4)(II)(b) provides that components that in the aggregate account for at least 75% of the weight of the index or portfolio each shall have a minimum original principal amount outstanding of $100 million or more.

19 The Fund represents that currently 84.7% of the 8–12 Year Index issues, as referenced above, 64.7% of the 8–12 Year Index weight consisted of issues with a rating of AA/Aa2 or higher.

20 The Adviser represents that when bonds are close substitutes for one another, pricing vendors can use executed trade information from all similar bonds as pricing inputs for an individual security. This can make individual securities more liquid.
transaction of at least $75 million. The bonds must be fixed rate, have a dated date within the last five years and have an effective maturity of 12 to 17 years. The following types of bonds are excluded from the 12–17 Year Index: bonds subject to the alternative minimum tax, taxable municipal bonds, floating rate bonds and derivatives. The 12–17 Year Index is calculated using a market value weighting methodology.

The composition of the 12–17 Year Index is rebalanced monthly. Interest and principal payments earned by the component securities are held in the 12–17 Year Index without a reinvestment return until month end when they are removed from the 12–17 Year Index. Qualifying securities issued, but not necessarily settled, on or before the month end rebalancing date qualify for inclusion in the 12–17 Year Index in the following month. TBAs representing securities in the 12–17 Year Index may be used by the Fund in seeking performance that corresponds to the 12–17 Year Index and in such cases would count towards the Fund’s 80% policy.

The Fund normally invests at least 80% of its total assets in securities that comprise the Fund’s benchmark index. The 12–17 Year Index is comprised of publicly traded municipal bonds that cover the U.S. dollar-denominated intermediate term tax-exempt bond market with final maturities of 12–17 years. The Fund’s 80% investment policy is non-fundamental and may be changed without shareholder approval upon 60 days’ prior written notice to shareholders.

Other Portfolio Holdings

While the Fund normally will invest at least 80% of its total assets in securities that compose the 12–17 Year Index, as described above, the Fund may invest its remaining assets in other financial instruments, as described below.

The Fund may invest its remaining assets in securities not included in the 12–17 Year Index including only the following instruments: municipal bonds;21 money market instruments, including repurchase agreements or other funds which invest exclusively in money market instruments; convertible securities; structured notes (notes on which the amount of principal repayment and interest payments are based on the movement of one or more specified factors, such as the movement of a particular stock or stock index);22 certain derivative instruments described below; and, to the extent permitted by the 1940 Act, affiliated and unaffiliated funds, such as open-end or closed-end management investment companies, including other ETFs. In addition to the use described above, TBAs not included in the 12–17 Year Index may also be used by the Fund in managing cash flows.

The Fund may invest in repurchase agreements with commercial banks, brokers or dealers to generate income from its excess cash balances and to invest securities lending cash collateral. The Fund may use exchange-traded futures contracts and exchange-traded or over-the-counter (“OTC”) options thereon, together with positions in cash and money market instruments, to simulate full investment in the 12–17 Year Index.

The Fund may use cleared or non-cleared index, interest rate or credit default swap agreements. Swap agreements are contracts between parties in which one party agrees to make payments to the other party based on the change in market value or level of a specified index or asset. The Adviser represents that currently interest rate swaps and credit default swaps on indexes are cleared. However, credit default swaps on a specific security are currently uncleared. The Fund may invest in exchange-traded warrants, which are equity securities in the form of options issued by a corporation which give the holder the right to purchase stock, usually at a price that is higher than the market price at the time the warrant is issued. The Fund may invest in participation notes, which are issued by banks or broker-dealers and are designed to offer a return linked to the performance of a particular underlying equity security or market.

The Fund will only enter into transactions in derivative instruments with counterparties that the Adviser reasonably believes are capable of performing under the contract and will post as collateral as required by the counterparty.23

Index Overview

The Exchange is submitting this proposed rule change because the 12–17 Year Index for the Fund does not meet all of the “generic” listing requirements of Rule 14.11(c)(4)(B)(i) applicable to the listing of index fund shares based on fixed income securities indexes. The 12–17 Year Index meets all such requirements except for those set forth in Rule 14.11(c)(4)(B)(i)(b).24 Specifically, as of December 31, 2015, 8.3% of the weight of the 12–17 Year Index components have a minimum original principal amount outstanding of $100 million or more.

As of December 31, 2015, 95.3% of the weight of the 12–17 Year Index components was comprised of individual maturities that were part of an entire municipal bond offering with a minimum original principal amount outstanding $100 million or more for all maturities of the offering. In addition, the total dollar amount outstanding of issues in the 12–17 Year Index was approximately $123.5 billion and the average dollar amount outstanding of issues in the 12–17 Year Index was approximately $20 million. Further, the most heavily weighted component represented 0.29% of the weight of the 12–17 Year Index and the five most heavily weighted components represented 1.11% of the weight of the 12–17 Year Index.25 Therefore, the Exchange believes that, notwithstanding that the 12–17 Year Index does not satisfy the criterion in Rule 14.11(c)(4)(B)(i)(b), the 12–17 Year Index is sufficiently broad-based to deter potential manipulation, given that

21 Municipal bonds that are not included in the 12–17 Year Index must be publicly traded municipal bonds that cover the U.S. dollar-denominated intermediate term tax-exempt bond market with final maturities of 12–17 years. Such bonds must be rated Baa3/BBB – or higher by at least two of the following ratings agencies if all three agencies rate the security: Moody’s, S&P and Fitch. If only two of the three agencies rate the security, the lower rating is used to determine index eligibility. If only one of the three agencies rates a security, the rating must be at least Baa3/BBB –. Such bonds must also have an outstanding par value of at least $7 million and be issued as part of a transaction of at least $75 million. The bonds must be fixed rate, have a dated date within the last five years and have an effective maturity of 12 to 17 years.

22 Structured notes are derivative securities for which the amount of principal repayment and/or interest payments is based on the movement of one or more factors, including, but not limited to, currency exchange rates, interest rates (such as the prime lending rate or LIBOR), referenced bonds and stock indices.

23 The Fund will seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Adviser will evaluate the creditworthiness of counterparties on a regular basis. In addition to information provided by credit agencies, the Adviser will review approved counterparties using various factors, which may include the counterparty’s reputation, the Adviser’s past experience with the counterparty and the price/market actions of debt of the counterparty.

24 Rule 14.11(c)(4)(B)(i)(b) provides that components that in the aggregate account for at least 75% of the weight of the index or portfolio each shall have a minimum original principal amount outstanding of $100 million or more.

25 Rule 14.11(c)(4)(B)(i)(d) provides that no component fixed-income security (excluding Treasury Securities, as defined therein) shall represent more than 30% of the weight of the index or portfolio, and the five most heavily weighted component fixed-income securities in the index or portfolio shall not in the aggregate account for more than 85% of the weight of the index or portfolio.
it is comprised of approximately 6,171 issues. In addition, the 12–17 Year Index securities are sufficiently liquid to deter potential manipulation in that a substantial portion (95.3%) of the 12–17 Year Index weight is comprised of securities that are part of a minimum original principal amount outstanding of $100 million or more, and in view of the substantial total dollar amount outstanding and the average dollar amount outstanding of the 12–17 Year Index issues, as referenced above. 26 61.2% of the 12–17 Year Index weight consisted of issues with a rating of AA/ Aa2 or higher.

The 12–17 Year Index value, calculated and disseminated at least once daily, as well as the components of the 12–17 Year Index and their percentage weighting, will be available from major market data vendors. In addition, the portfolio of securities held by the Fund will be disclosed on the Fund’s Web site at www.vaneck.com.

The Exchange represents that: (1) Except for BZX Rule 14.11(c)(4)(B)[b], the 6–8 Year Index, the 8–12 Year Index, and the 12–17 Year Index (together, the “Indices”) currently and will continue to satisfy all of the generic listing standards under BZX Rule 14.11(c)(4); (2) the continued listing standards under BZX Rule 14.11(c) applicable to index fund shares shall apply to the Shares of each Fund; and (3) the Trust is required to comply with Rule 10A–3 27 under the Act for the initial and continued listing of the Shares of each Fund. In addition, the Exchange represents that the Shares of the Funds will comply with all other requirements applicable to index fund shares including, but not limited to, requirements relating to the dissemination of key information such as the value of the Indices and the Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance, and the information circular, as set forth in Exchange rules applicable to index fund shares and the orders approving such rules.

Correlation Among Municipal Bond Instruments With Common Characteristics

With respect to the Funds, the Adviser represents that the nature of the municipal bond market and municipal bond instruments makes it feasible to categorize individual issues represented by CUSIPs (i.e., the specific identifying number for a security) into categories according to common characteristics, specifically, rating, geographical region, purpose, and maturity. Bonds that share similar characteristics tend to trade similarly to one another; therefore, within these categories, the issues may be considered fungible from a portfolio management perspective, allowing one CUSIP to be represented by another that shares similar characteristics for purposes of developing an investment strategy. Therefore, while 9.8% of the weight of the 6–8 Year Index, 5.7% of the weight of the 8–12 Year Index, and 8.3% of the 12–17 Year Index components have a minimum original principal amount outstanding of $100 million or more, the nature of the municipal bond market makes the issues relatively fungible for investment purposes when aggregated into categories such as ratings, geographical region, purpose and maturity. In addition, within a single municipal bond issuer, there are often multiple contemporaneous or sequential issuances that have the same rating, structure and maturity, but have different CUSIPs; these separate issues by the same issuer are also likely to trade similarly to one another.

The Adviser represents that the Funds are managed utilizing the principle that municipal bond issues are generally fungible in nature when sharing common characteristics, and specifically make use of the four categories referred to above. In addition, this principle is used in, and consistent with, the portfolio construction process in order to facilitate the creation and redemption process, and to enhance liquidity (among other benefits, such as reducing transaction costs), while still allowing each Fund to closely track its reference index.

Net Asset Value

According to the Registration Statement, the net asset value (“NAV”) of each Fund will be determined each business day as of the close of trading (ordinarily 4:00 p.m. Eastern time) on the Exchange. Any assets or liabilities denominated in currencies other than the U.S. dollar are converted into U.S. dollars at the current market rates on the date of valuation as quoted by one or more sources.

The values of each Fund’s portfolio securities are based on the securities’ closing prices, when available. In the absence of a last reported sales price, or if no sales were reported, and for other assets for which market prices are not readily available, values may be based on quotes obtained from a quotation reporting system, established market makers or by an outside independent pricing service. Fixed income securities are normally valued on the basis of quotes from brokers or dealers, established market makers or an outside independent pricing service using data reflecting the earlier closing of the principal markets for those securities. Prices obtained by an outside independent pricing service may use information provided by market makers or estimates of market values obtained from yield data related to investments or securities with similar characteristics and may use a computerized grid matrix of securities and its evaluations in determining what it believes is the fair value of the portfolio securities. Debt securities and money market instruments with maturities of more than 60 days will typically be priced based on valuations provided by independent, third-party pricing agents. Such values will generally reflect the last reported sales price if the security is actively traded. Short-term investments and money market instruments having a maturity of 60 days or less are valued at amortized cost. Repurchase agreements will generally be valued at bid prices received from independent pricing services as of the announced closing time for trading in such instruments. Futures contracts will be valued at the settlement price established each day by the board or exchange on which they are traded. Exchange-traded options will be valued at the closing price in the market where such contracts are principally traded. OTC options will generally be valued on a basis of quotes obtained from established market makers or by an outside independent pricing service. Swaps, structured notes, participation notes, convertible securities, and TBAs will be valued based on valuations provided by independent, third-party pricing agents. Securities of non-exchange-traded investment companies will be valued at NAV. Exchange-traded instruments, including investment companies and warrants, will be valued at the last reported sale price on the primary exchange or market on which they are traded.

If a market quotation for a security is not readily available or the Adviser believes it does not otherwise accurately reflect the market value of the security at the time the Fund calculates its NAV, the security will be fair valued by the Adviser in accordance with the Trust’s valuation policies and procedures accepted by the Board of Trustees and in accordance with the 1940 Act. The Fund may also use fair value pricing in

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26 The Adviser represents that when bonds are close substitutes for one another, pricing vendors can use executed trade information from all similar bonds as pricing inputs for an individual security. This can make individual securities more liquid.

a variety of circumstances, including but not limited to, situations when the value of a security in the Fund’s portfolio has been materially affected by events occurring after the close of the market on which the security is principally traded (such as a corporate action or other news that may materially affect the price of a security) or trading in a security has been suspended or halted.

Creation and Redemption of Shares

The NAV of the Funds will be determined each business day as of the close of trading, (normally 4:00 p.m. Eastern time) on the exchange. The Funds currently anticipate that a “Creation Unit” will consist of 100,000 Shares, though this number may change from time to time, including prior to the listing of a Fund. The exact number of Shares that will comprise a Creation Unit will be disclosed in the Registration Statement of each Fund. The Trust will issue and sell Shares of the Funds only in Creation Units on a continuous basis through the Distributor, without an initial sales load (but subject to transaction fees), at their NAV per Share next determined after receipt, on any business day, of an order in proper form.

The consideration for purchase of a Creation Unit of a Fund generally will consist of either (i) the in-kind deposit of a designated portfolio of fixed income securities (the “Deposit Securities”) per each Creation Unit and the Cash Component (defined below), computed as described below, or (ii) as permitted or required by the Funds, of cash. The Cash Component together with the Deposit Securities, as applicable, are referred to as the “Fund Deposit,” which represents the minimum initial and subsequent investment amount for Shares. The Cash Component represents the difference between the NAV of a Creation Unit and the market value of Deposit Securities and may include a Dividend Equivalent Payment. The “Dividend Equivalent Payment” enables the Funds to make a complete distribution of dividends on the next dividend payment date, and is an amount equal, on a per Creation Unit basis, to the dividends on all the securities held by each of the Funds (“Fund Securities”) with ex-dividend dates within the accumulation period for such distribution (the “Accumulation Period”), net of expenses and liabilities for such period, as if all of the Fund Securities had been held by the Trust for the entire Accumulation Period. The Accumulation Period begins on the ex-dividend date for each Fund and ends on the next ex-dividend date.

TheAdministrator, through the National Securities Clearing Corporation (“NSCC”), makes available on each business day, immediately prior to the opening of business on the Exchange (currently 9:30 a.m. Eastern time), the list of the names and the required number of shares of each Deposit Security to be included in the current Fund Deposit (based on information at the end of the previous business day) as well as the Cash Component for each Fund. Such Fund Deposit is applicable, subject to any adjustments as described below, in order to effect creations of Creation Units of each Fund until such time as the next-announced Fund Deposit composition is made available.

Shares may be redeemed only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by the Distributor, only on a business day and only through a Participating Party or DTC Participant, if he has executed a Participation Agreement.

The Administrator, through NSCC, makes available immediately prior to the opening of business on the Exchange (currently 9:30 a.m. Eastern time) on each day that the Exchange is open for business, the Fund Securities that will be applicable (subject to possible amendment or correction) to redemption requests received in proper form (as defined below) on that day. Unless cash redemptions are permitted or required for the Fund, the redemption proceeds for a Creation Unit generally consist of Fund Securities as announced by the Administrator on the business day of the request for redemption, plus cash in an amount equal to the difference between the NAV of the Shares being redeemed, as next determined after a receipt of a request in proper form, and the value of the Fund Securities, less the redemption transaction fee and variable fees described below. Should the Fund Securities have a value greater than the NAV of the Shares being redeemed, a compensating cash payment to the Trust equal to the differential plus the applicable redemption transaction fee will be required to be arranged for by or on behalf of the redeeming shareholder. Each Fund reserves the right to honor a redemption request by delivering a basket of securities or cash that differs from the Fund Securities.29

Orders to redeem Creation Units of the Funds must be delivered through a DTC Participant that has executed the Participant Agreement with the Distributor and with the Trust. A DTC Participant who wishes to place an order for redemption of Creation Units of a Fund to be effected need not be a Participating Party, but such orders must state that redemption of Creation Units of the Fund will instead be effected through transfer of Creation Units of the Fund directly through DTC. An order to redeem Creation Units of a Fund is deemed received by the Administrator on the transmittal date if (i) such order is received by the Administrator not later than 4:00 p.m. Eastern time on such transmittal date; (ii) such order is preceded or accompanied by the requisite number of Shares of Creation Units specified in such order, which delivery must be made through DTC to the Administrator no later than 11:00 a.m. Eastern time, on such transmittal date (the “DTC Cut-Off-Time”); and (iii) all other procedures set forth in the Participant Agreement are properly followed.

After the Administrator has deemed an order for redemption received, the Administrator will initiate procedures to transfer the requisite Fund Securities (or contracts to purchase such Fund Securities) which are expected to be delivered within three business days and the cash redemption payment to the redeeming beneficial owner by the third business day following the transmittal date on which such redemption order is deemed received by the Administrator. Availability of Information

Each Fund’s Web site, which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Web site will include additional qualitative information updated on a daily basis, including, for the Fund: (1) The prior business day’s reported NAV, mid-point of the bid/ask spread at the time of calculation of such NAV (the “Bid/Ask

29 The Adviser represents that, to the extent that the Trust permits or requires a “cash in lieu” amount, such transactions will be effected in the same or equitable manner for all Authorized Participants.
Price”), daily trading volume, and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Daily trading volume information for the Funds will also be available in the financial section of newspapers, through subscription services such as Bloomberg, Thomson Reuters, and International Data Corporation, which can be accessed by authorized participants and other investors, as well as through other electronic services, including major public Web sites. On each business day, before commencement of trading in Shares during Regular Trading Hours on the Exchange, each Fund will disclose on its Web site the identities and quantities of the portfolio of securities and other assets in the daily disclosed portfolio held by the Funds that will form the basis for each Fund’s calculation of NAV at the end of the business day. The daily disclosed portfolio will include, as applicable: The ticker symbol; CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security, index or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts, or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in each Fund’s portfolio. The Web site and information will be publicly available at no charge. The value, components, and percentage weightings of each of the Indices will be calculated and disseminated at least once daily and will be available from major market data vendors.

In addition, for each Fund, an estimated value, defined in BZX Rule 14.11(c)(6)(A) as the “Intraday Indicative Value,” that reflects an estimated intraday value of each Fund’s portfolio, will be disseminated. Moreover, the Intraday Indicative Value will be based upon the current value for the components of the daily disclosed portfolio and will be updated and widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange’s Regular Trading Hours. In addition, the quotations of certain of each Fund’s holdings may not be updated during U.S. trading hours if updated prices cannot be ascertained.

The dissemination of the Intraday Indicative Value, together with the daily disclosed portfolio, will allow investors to determine the value of the underlying portfolio of the Funds on a daily basis and provide a close estimate of that value throughout the trading day.

Quotation and last sale information for the Shares of each Fund will be available via the Consolidated Tape Association (“CTA”) high speed line. Quotation information for investment company securities (excluding ETFs) may be obtained through nationally recognized pricing services through subscription agreements or from brokers and dealers who make markets in such securities. Price information regarding municipal bonds, convertible securities, and non-exchange traded assets, including investment companies, derivatives, money market instruments, repurchase agreements, structured notes, participation notes, and TBAs is available from third party pricing services and major market data vendors. For exchange-traded assets, including investment companies, futures, warrants, and options, such intraday information is available directly from the applicable listing exchange.

Initial and Continued Listing

The Shares of each Fund will conform to the initial and continued listing criteria under BZX Rule 14.11(c)(4), except for those set forth in 14.11(c)(4)(B)(i)(b). The Exchange represents that, for initial and/or continued listing, the Funds and the Trust must be in compliance with Rule 10A–3 under the Act. A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share for each Fund will be calculated daily and will be made available to all market participants at the same time.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Funds. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments composing the daily disclosed portfolio of the Funds; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(c)(1)(B)(iv), which sets forth circumstances under which Shares of a Fund may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange’s existing rules governing the trading of equity securities. The Exchange will allow trading in the Shares from 8:00 a.m. until 5:00 p.m. Eastern Time and has the appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 11.11(a), the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01, with the exception of securities that are priced less than $1.00, for which the minimum price variation for order entry is $0.0001.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange’s surveillance procedures for derivative products, including Index Fund Shares. The Exchange may obtain information regarding trading in the Shares and the underlying shares in exchange traded equity securities via the ISG, from other exchanges that are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing
agreement. In addition, the Exchange is able to access, as needed, trade information for certain fixed income instruments reported to FINRA’s Trade Reporting and Compliance Engine (“TRACE”). FINRA also can access data obtained from the Municipal Securities Rulemaking Board (“MSRB”) relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares. In addition, the Exchange may obtain information regarding trading in the Shares and the underlying shares in exchange-traded investment companies, futures, options, and warrants from markets or other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange prohibits the distribution of material non-public information by its employees.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (3) how information regarding the Intraday Indicative Value is disseminated; (4) the risks involved in trading the Shares during the Pre-Opening and After Hours Trading Sessions when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (5) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Funds. Members purchasing Shares from the Funds for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Circular will reference that each Fund is subject to various fees and expenses described in the Registration Statement. The Information Circular will also disclose the trading hours of the Shares of the Funds and the applicable NAV calculation time for the Shares. The Information Circular will disclose that information about the Shares of the Funds will be publicly available on the Funds’ Web site. In addition, the Information Circular will reference that the Trust is subject to various fees and expenses described in each Fund’s Registration Statement.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act in general and Section 6(b)(5) of the Act in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the listing criteria in BZX Rule 14.11(c). The Exchange believes that its surveillance, which generally focuses on detecting securities trading outside of their normal patterns which could be indicative of manipulative or other violative activity, and associated surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange will communicate as needed regarding trading in the Shares with other markets or other entities that are members of the Intermarket Surveillance Group (“ISG”), and may obtain trading information regarding trading in the Shares from such markets or entities. The Exchange can also access data obtained from the Municipal Securities Rulemaking Board relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares. The Exchange is able to access, as needed, trade information for certain fixed income securities held by a Fund reported to FINRA’s TRACE. FINRA also can access data obtained from the Municipal Securities Rulemaking Board (“MSRB”) relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares. In addition, the Exchange may obtain information regarding trading in the Shares and the underlying shares in exchange-traded investment companies, futures, options, and warrants from markets or other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.
outstanding and the average dollar amount outstanding of index issues.

As of December 31, 2015, the 8–12 Year Index had the following characteristics: There were 5,662 issues; 5.7% of the weight of components had a minimum original principal amount outstanding of $100 million or more; 95.1% of the weight of components was comprised of individual maturities that were part of an entire municipal bond offering with a minimum original principal amount outstanding of $100 million or more for all maturities of the offering; the total dollar amount outstanding of all issues was approximately $108.6 billion and the average dollar amount outstanding per issue was approximately $19.2 million; the most heavily weighted component represented 26.5% of the 8–12 Year Index and the five most heavily weighted components represented 1.04% of the 8–12 Year Index.

Therefore, the Exchange believes that, notwithstanding that the 8–12 Year Index does not satisfy the criterion in BZX Rule 14.11(c)(4)(B)(i), the 8–12 Year Index is sufficiently broad-based to deter potential manipulation in that a substantial portion (95.1%) of the 8–12 Year Index weight is comprised of maturities that are part of a minimum original principal amount outstanding of $100 million or more, and in view of the substantial total dollar amount outstanding and the average dollar amount outstanding of index issues.

As of December 31, 2015, the 12–17 Year Index had the following characteristics: There were 6,171 issues; 8.3% of the weight of components had a minimum original principal amount outstanding of $100 million or more; 95.3% of the weight of components was comprised of individual maturities that were part of an entire municipal bond offering with a minimum original principal amount outstanding of $100 million or more for all maturities of the offering; the total dollar amount outstanding of all issues was approximately $123.5 billion and the average dollar amount outstanding per issue was approximately $20 million; the most heavily weighted component represented 29.0% of the 12–17 Year Index and the five most heavily weighted components represented 1.11% of the 12–17 Year Index.

Therefore, the Exchange believes that, notwithstanding that the 12–17 Year Index does not satisfy the criterion in BZX Rule 14.11(c)(4)(B)(i), the 12–17 Year Index is sufficiently broad-based to deter potential manipulation in that a substantial portion (95.3%) of the 12–17 Year Index weight is comprised of maturities that are part of a minimum original principal amount outstanding of $100 million or more, and in view of the substantial total dollar amount outstanding and the average dollar amount outstanding of index issues.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that it will facilitate the listing and trading of additional types of exchange-traded funds that holds municipal bonds and that will enhance competition among market participants, to the benefit of investors and the public interest in that it will perfect the mechanism of a free and orderly market and, in general, to protect investors and the public interest in that it will promote the giving of fast, certain, current, and comprehensive quotation and market information and in that it will provide adequate facilities for dealing fairly and on an equal opportunity basis, thereby promoting market transparency. The Funds’ portfolio holdings will be disclosed on the Funds’ Web site daily after the close of trading on the Exchange and prior to the opening of trading on the Exchange the following day. Moreover, the IIV will be widely disseminated by one or more major market data vendors at least every 15 seconds during Regular Trading Hours. The current value of each of the Indices will be disseminated by one or more major market data vendors at least every 15 seconds during Regular Trading Hours. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers’ computer screens and other electronic services, and quotation and last sale information will be available via the CTA high-speed line. The Web site for the Funds will include the prospectus for the Funds and additional data relating to NAV and other applicable quantitative information.

Moreover, prior to the commencement of trading, the Exchange will inform its Members in an information circular of the special characteristics and risks associated with trading the Shares. If the Exchange becomes aware that the NAV is not being disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Funds. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments composing the daily disclosed portfolio of each Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(c)(1)(B)(iv), which sets forth circumstances under which Shares of a Fund may be halted. If the IIV of any of the Funds or value of the Indices are not being disseminated as required, the Exchange may halt trading during the day in which the interruption to the dissemination of the IIV or index value occurs.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that it will facilitate the listing and trading of additional types of exchange-traded funds that holds municipal bonds and that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information in the Shares and the underlying shares in exchange-traded investment companies, futures, options, and warrants via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, investors will have ready access to information regarding the IIV and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of additional exchange-traded products that will enhance competition among
market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization’s Statement on Comments on the
   Proposed Rule Change Received From Members, Participants, or Others

   The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the
   Proposed Rule Change and Timing for
   Commission Action

   Within 45 days of the date of publication of this notice in the Federal Register or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (a) By order approve or disapprove such proposed rule change; or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

   Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

   Electronic Comments

   • Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or
   • Send an email to rule-comments@sec.gov. Please include File No. SR–BatsBZX–2016–01 on the subject line.

   Paper Comments

   • Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, Station Place, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File No. SR–BatsBZX–2016–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BatsBZX–2016–01 and should be submitted on or before May 9, 2016.

   For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 40

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2016–08825 Filed 4–15–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77589; File No. SR–BatsEDGX–2016–04]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Rule 8.17 To Provide a Process for an Expedited Suspension Proceeding and Rule 12.15 To Prohibit Layering and Spoofing

April 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),1 and Rule 19b–4 thereunder,2 notice is hereby given that on March 30, 2016, Bats EDGX Exchange, Inc. (the “Exchange” or “EDGX”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

   The Exchange filed a proposal to adopt a new rule to clearly prohibit disruptive quoting and trading activity on the Exchange, as further described below. Further, the Exchange proposes to amend Exchange Rules to permit the Exchange to take prompt action to suspend Members or their clients that violate such rule.

   The text of the proposed rule change is available at the Exchange’s Web site at www.batstrading.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and
   Statutory Basis for, the Proposed Rule Change

   In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

   A. Self-Regulatory Organization’s Statement of the Purpose of, and
      Statutory Basis for, the Proposed Rule Change

      1. Purpose

      Introduction

      The Exchange is filing this proposal to adopt a new rule to clearly prohibit disruptive quoting and trading activity on the Exchange and to amend Exchange Rules to permit the Exchange to take prompt action to suspend Members or their clients that violate such rule. The proposal is identical to the proposal of Bats BZX Exchange, Inc., formerly known as BATS Exchange, Inc. (“BZX”),3 which was recently approved by the Commission. 4

      Background

      As a national securities exchange registered pursuant to Section 6 of the

3 The Exchange notes that the membership of the Exchange and the membership of BZX is nearly identical. BZX members and the public had the opportunity to comment—and did comment—on an identical BZX proposal to the current proposal before the Staff approved the BZX proposal. See https://www.sec.gov/comments/sr-bats-2015-101/bats2015101.shtml.


Act, the Exchange is required to be organized and to have the capacity to enforce compliance by its members and persons associated with its members, with the Act, the rules and regulations thereunder, and the Exchange’s Rules. Further, the Exchange’s Rules are required to be “designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade. . . and, in general, to protect investors and the public interest.” In fulfilling these requirements, the Exchange has developed a comprehensive regulatory program that includes automated surveillance of trading activity that is both operated directly by Exchange staff and by staff of the Financial Industry Regulatory Authority (“FINRA”) pursuant to a Regulatory Services Agreement (“RSA”). When disruptive and potentially manipulative or improper quoting and trading activity is identified, the Exchange or FINRA (acting as an agent of the Exchange) conducts an investigation into the activity, requesting additional information from the Member or Members involved. To the extent violations of the Act, the rules and regulations thereunder, or Exchange Rules have been identified and confirmed, the Exchange or FINRA as its agent will commence the enforcement process, which might result in, among other things, a censure, a requirement to take certain remedial actions, one or more restrictions on future business activities, a monetary fine, or even a temporary or permanent ban from the securities industry.

The process described above, from the identification of disruptive and potentially manipulative or improper quoting and trading activity to a final resolution of the matter, can often take several years. The Exchange believes that this time period is generally necessary and appropriate to afford the subject Member adequate due process, particularly in complex cases. However, as described below, the Exchange believes that there are certain obvious and unduplicated cases of disruptive and manipulative behavior or cases where the potential harm to investors is so large that the Exchange should have the authority to initiate an expedited suspension proceeding in order to stop the behavior from continuing on the Exchange.

In recent years, several cases have been brought and resolved by an affiliate of the Exchange and other SROs that involved allegations of wide-spread market manipulation, much of which was ultimately being conducted by foreign persons and entities using relatively rudimentary technology to access the markets and over which the Exchange and other SROs had no direct jurisdiction. In each case, the conduct involved a pattern of disruptive quoting and trading activity indicative of manipulative layering or spoofing. An affiliate of the Exchange and other SROs were able to identify the disruptive quoting and trading activity in real-time or near real-time; nonetheless, in accordance with Exchange Rules and the Act, the Members responsible for such conduct or responsible for their customers’ conduct were allowed to continue the disruptive quoting and trading activity during the entirety of the subsequent lengthy investigation and enforcement process. The Exchange believes that it should have the authority to initiate an expedited suspension proceeding in order to stop the behavior from continuing on the Exchange if a Member is engaging in or facilitating disruptive quoting and trading activity and the Member has not received sufficient notice with an opportunity to respond, but such activity has not ceased.

The following two examples are instructive on the Exchange’s rationale for the proposed rule change.

In July 2012, Biremis Corp. (formerly Swift Trade Securities USA, Inc.) (the “Firm”) and its CEO were barred from the industry for, among other things, supervisory violations related to a failure by the Firm to detect and prevent disruptive and allegedly manipulative quoting and trading activity, including layering, short sale violations, and anti-money laundering violations. The Firm’s sole business was to provide trade execution services via a proprietary day trading platform and order management system to day traders located in foreign jurisdictions. Thus, the disruptive and allegedly manipulative trading activity introduced by the Firm to U.S. markets originated directly or indirectly from foreign clients of the Firm. The pattern of disruptive and allegedly manipulative quoting and trading activity was widespread across multiple exchanges, and FINRA and other SROs identified clear patterns of the behavior in 2007 and 2008. Although the Firm and its principals were on notice of the disruptive and allegedly manipulative quoting and trading activity that was occurring, the Firm took little to no action to attempt to supervise or prevent such quoting and trading activity until at least 2009. Even when it put some controls in place, they were deficient and the pattern of disruptive and allegedly manipulative trading activity continued to occur. As noted above, the final resolution of the enforcement action to bar the Firm and its CEO from the industry was not concluded until 2012, four years after the disruptive and allegedly manipulative trading activity was first identified.

In September of 2012, Hold Brothers On-Line Investment Services, Inc. (the “Firm”) settled a regulatory action in connection with the Firm’s provision of a trading platform, trade software and trade execution, support and clearing services for day traders. Many traders using the Firm’s services were located in foreign jurisdictions. The Firm ultimately settled the action with FINRA and several exchanges for a total monetary fine of $3.4 million. In a separate action, the Firm settled with the Commission for a monetary fine of $2.5 million. Among the alleged violations in the case were disruptive and allegedly manipulative quoting and trading activity, including spoofing, layering, wash trading, and pre-arranged trading. Through its conduct and insufficient procedures and controls, the Firm also allegedly committed anti-money laundering violations by failing to detect and report manipulative and suspicious trading activity. The Firm was alleged to have not only provided foreign traders with access to the U.S. markets to engage in such activities, but that its principals also owned and funded foreign subsidiaries that engaged in the disruptive and allegedly manipulative quoting and trading activity. Although the pattern of disruptive and allegedly manipulative quoting and trading activity was identified in 2009, as noted above, the enforcement action was not concluded until 2012.

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7 Layering is a form of market manipulation in which multiple, non-bona fide limit orders are entered on one side of the market at various price levels in order to create the appearance of a change in the levels of supply and demand, thereby artificially moving the price of the security. An order is then executed on the opposite side of the market at the artificially created price, and the non-bona fide orders are cancelled.
8 “Spoofing” is a form of market manipulation that involves the market manipulator placing non-bona fide orders that are intended to trigger some type of market movement and/or response from other market participants, from which the market manipulator might benefit by trading bona fide orders.
9 See Biremis Corp. and Peter Beck, FINRA Letter of Acceptance, Waiver and Consent No. 2010021162202, July 30, 2012.


and allegedly manipulative quoting and trading was promptly detected, it continued for several years.

The Exchange also notes the current criminal proceedings that have commenced against Navinder Singh Sarao. Mr. Sarao’s allegedly manipulative trading activity, which included forms of layering and spoofing in the futures markets, has been linked as a contributing factor to the “Flash Crash” of 2010, and yet continued through 2015.

The Exchange believes that the activities described in the cases above provide justification for the proposed rule change, which is described below.

Rule 8.17—Expedited Client Suspension Proceeding

The Exchange proposes to adopt new Rule 8.17 to set forth procedures for issuing suspension orders, immediately prohibiting a Member from conducting continued disruptive quoting and trading activity on the Exchange. Importantly, these procedures would also provide the Exchange the authority to order a Member to cease and desist from providing access to the Exchange to a client of the Member that is conducting disruptive quoting and trading activity in violation of proposed Rule 12.15.

Under proposed paragraph (a) of Rule 8.17, with the prior written authorization of the Chief Regulatory Officer (“CRO”) or such other senior officers as the CRO may designate, the Office of General Counsel or Regulatory Department of the Exchange (such departments generally referred to as the “Exchange”) for purposes of proposed Rule 8.17 may initiate an expedited suspension proceeding with respect to alleged violations of Rule 12.15, which is proposed as part of this filing and described in detail below. Proposed paragraph (a) would also set forth the requirements for notice and service of such notice pursuant to the Rule, including the required method of service and the content of notice.

Proposed paragraph (b) of Rule 8.17 would govern the appointment of a Hearing Panel as well as potential disqualification or recusal of Hearing Officers. The proposed provision is consistent with existing Exchange Rule 8.6 and includes the requirement for a Hearing Officer to be recused in the event he or she has a conflict of interest or bias or other circumstances exist where his or her fairness might reasonably be questioned. In addition to recusal initiated by such a Hearing Officer, the proceeding will be permitted to file a motion to disqualify a Hearing Officer. However, due to the compressed schedule pursuant to which the process would operate under Rule 8.17, the proposed rule would require such motion to be filed no later than 5 days after the announcement of the Hearing Panel and the Exchange’s brief in opposition to such motion would be required to be filed no later than 5 days after service thereof. Pursuant to existing Rule 8.6(b), if the Hearing Panel believes the Respondent has provided satisfactory evidence in support of the motion to disqualify, the applicable Hearing Officer shall remove himself or herself and request the Chief Executive Officer to reassess the hearing to another Hearing Officer such that the Hearing Panel still meets the compositional requirements described in Rule 8.6(a). If the Hearing Panel determines that the Respondent’s grounds for disqualification are insufficient, it shall deny the Respondent’s motion for disqualification by setting forth the reasons for the denial in writing and the Hearing Panel will proceed with the hearing.

Under paragraph (c) of the proposed Rule, the hearing would be held not later than 15 days after service of the notice initiating the suspension proceeding, unless otherwise extended by the Chairman of the Hearing Panel with the consent of the Parties for good cause shown. In the event of a recusal or disqualification of a Hearing Officer the hearing shall be held not later than five days after a replacement Hearing Officer is appointed. Proposed paragraph (c) would also govern how the hearing is conducted, including the authority of Hearing Officers, witnesses, additional information that may be required by the Hearing Panel, the requirement that a transcript of the proceeding be created and details related to such transcript, and details regarding the creation and maintenance of the record of the proceeding.

Proposed paragraph (c) would also state that if a Respondent fails to appear at a hearing for which it has notice, the allegations in the notice and accompanying may be deemed admitted, and the Hearing Panel may issue a suspension order without further proceedings. Finally, as proposed, if the Exchange fails to appear at a hearing for which it has notice, the Hearing Panel may order that the suspension proceeding be dismissed.

Under paragraph (d) of the proposed Rule, the Hearing Panel would be authorized to issue a written decision stating whether a suspension order would be proposed. The Hearing Panel would be required to issue the decision not later than 10 days after receipt of the hearing transcript, unless otherwise extended by the Chairman of the Hearing Panel with the consent of the Parties for good cause shown. The Rule would state that a suspension order shall be imposed if the Hearing Panel finds by a preponderance of the evidence that the alleged violation specified in the notice has occurred and that the violative conduct or continuation thereof is likely to result in significant market disruption or other significant harm to investors.

Proposed paragraph (d) would also describe the content, scope, and form of a suspension order. As proposed, a suspension order shall be limited to ordering a Respondent to cease and desist from violating proposed Rule 12.15, and/or to ordering a Respondent to cease and desist from providing access to the Exchange to a client of the Respondent that is causing violations of Rule 12.15. Under the proposed rule, a suspension order shall also set forth the alleged violation and the significant market disruption or other significant harm to investors that is likely to result without the issuance of an order. The order shall describe in reasonable detail the act or acts the Respondent is to take or refrain from taking, and suspend such Respondent unless and until such action is taken or refrained from. Finally, the order shall include the date and hour of its issuance. As proposed, a suspension order would remain effective and enforceable unless modified, set aside, limited, or revoked pursuant to proposed paragraph (e), as described below. Finally, paragraph (d) would require service of the Hearing Panel’s decision and any suspension order consistent with other portions of the proposed rule related to service.

Proposed paragraph (e) of Rule 8.17 would state that at any time after the Office of Hearing Officers served the Respondent with a suspension order, a Party could apply to the Hearing Panel to have the order modified, set aside, limited, or revoked. If any part of a suspension order is modified, set aside, limited, or revoked, proposed paragraph (e) of Rule 8.17 provides the Hearing Panel discretion to leave the cease and desist part of the order in place. For example, if a suspension order suspends Respondent unless and until Respondent ceases and desists providing access to the Exchange to a client of Respondent, and after the order is entered the Respondent complies, the Hearing Panel is permitted to modify the order to lift the suspension portion of the order while keeping in place the cease and desist portion of the order.

With its broad modification powers, the Hearing Panel also maintains the
discretion to impose conditions upon the removal of a suspension—for example, the Hearing Panel could modify an order to lift the suspension portion of the order in the event a Respondent complies with the cease and desist portion of the order but additionally order that the suspension will be re-imposed if Respondent violates the cease and desist provisions modified order in the future. The Hearing Panel generally would be required to respond to the request in writing within 10 days after receipt of the request. An application to modify, set aside, limit or revoke a suspension order would not stay the effectiveness of the suspension order.

Finally, proposed paragraph (f) would provide that sanctions issued under the proposed Rule 8.17 would constitute final and immediately effective disciplinary sanctions imposed by the Exchange, and that the right to have any action under the Rule reviewed by the Commission would be governed by Section 19 of the Act. The filing of an application for review would not stay the effectiveness of a suspension order unless the Commission otherwise ordered.

Rule 12.15—Disruptive Quoting and Trading Activity Prohibited

The Exchange currently has authority to prohibit and take action against manipulative trading activity, including disruptive quoting and trading activity, pursuant to its general market manipulation rules, including Rule 3.1. The Exchange proposes to adopt new Rule 12.15, which would more specifically define and prohibit disruptive quoting and trading activity on the Exchange. As noted above, the Exchange also proposes to apply the proposed suspension rules to proposed Rule 12.15.

Proposed Rule 12.15 would prohibit Members from engaging in or facilitating disruptive quoting and trading activity on the Exchange, as described in proposed Interpretation and Policy .01 and .02 of the Rule, including acting in concert with other persons to effect such activity. The Exchange believes that it is necessary to extend the prohibition to situations when persons are acting in concert to avoid a potential loophole where disruptive quoting and trading activity is simply split between several brokers or customers.

To provide proper context for the situations in which the Exchange proposes to utilize its proposed authority, the Exchange believes it is necessary to review the types of disruptive quoting and trading activity that would cause the Exchange to use its authority. Accordingly, the Exchange proposes to adopt Interpretation and Policy .01 and .02, providing additional details regarding disruptive quoting and trading activity. Proposed Interpretation and Policy .01(a), which describes disruptive quoting and trading activity containing many of the elements indicative of layering, would describe disruptive quoting and trading activity as a frequent pattern in which the following facts are present: (a) A party enters multiple limit orders on one side of the market at various price levels (the “Displayed Orders”); and (b) following the entry of the Displayed Orders, the level of supply and demand for the security changes; and (c) the party enters one or more orders on the opposite side of the market of the Displayed Orders (the “Contra-Side Orders”) that are subsequently executed; and (d) following the execution of the Contra-Side Orders, the party cancels the Displayed Orders. Proposed Interpretation and Policy .01(b), which describes disruptive quoting and trading activity containing many of the elements indicative of spoofing, would describe disruptive quoting and trading activity as a frequent pattern in which the following facts are present: (a) A party narrows the spread for a security by placing an order inside the national best bid or offer; and (b) the party then submits an order on the opposite side of the market that executes against another market participant. In such a case the proposed sanction is appropriately graduated, as well as the proposed sanction. In such a case the proposed sanction would likely be to order the Member to cease and desist providing access to the Exchange to the client that is responsible for the disruptive quoting and trading activity and to suspend such Member unless and until such action is taken. The Member would have the opportunity to be heard in front of a Hearing Panel at a hearing to be conducted within 15 days of the notice. If the Hearing Panel determined that the violation alleged in the notice did not occur or that the conduct or its continuation would not have the potential to result in significant market disruption or other significant harm to investors, then the hearing Panel would dismiss the suspension order proceeding. If the Hearing Panel determined that the violation alleged in the notice did occur and that the conduct or its continuation is likely to
result in significant market disruption or other significant harm to investors, then the Hearing Panel would issue the order including the proposed sanction, ordering the Member to cease providing access to the client at issue and suspending such Member unless and until such action is taken. If such Member wished for the suspension to be lifted because the client ultimately responsible for the activity no longer would be provided access to the Exchange, then such Member could apply to the Hearing Panel to have the order modified, set aside, limited or revoked. The Exchange notes that the issuance of a suspension order would not alter the Exchange’s ability to further investigate the matter and/or later sanction the Member pursuant to the Exchange’s standard disciplinary process for supervisory violations or other violations of Exchange rules or the Act.

The Exchange reiterates that it already has broad authority to take action against a Member in the event that such Member is engaging in or facilitating disruptive or manipulative trading activity on the Exchange. For the reasons described above, and in light of recent cases like the client access cases described above, as well as other cases currently under investigation, the Exchange believes that it is equally important for the Exchange to have the authority to promptly initiate expedited suspension proceedings against any Member who has demonstrated a clear pattern or practice of disruptive quoting and trading activity, as described above, and to take action including ordering such Member to terminate access to the Exchange to one or more of such Member’s clients if such clients are responsible for the activity. The Exchange recognizes that its proposed authority to issue a suspension order is a powerful measure that should be used very cautiously. Consequently, the proposed rules have been designed to ensure that the proceedings are used to address only the most clear and serious types of disruptive quoting and trading activity and that the interests of Respondents are protected. For example, to ensure that proceedings are used appropriately and that the decision to initiate a proceeding is made only at the highest staff levels, the proposed rules require the CRO or another senior officer of the Exchange to issue written authorization before the Exchange can institute an expedited suspension proceeding. In addition, the Exchange believes that it would use this authority in limited circumstances, when necessary to protect investors, other Members and the Exchange. Further, the Exchange believes that the proposed expedited suspension provisions described above that provide the opportunity to respond as well as a Hearing Panel determination prior to taking action will ensure that the Exchange would not utilize its authority in the absence of a clear pattern or practice of disruptive quoting and trading activity.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Act and further the objectives of Section 6(b)(5) of the Act because they are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Pursuant to the proposal, the Exchange will have a mechanism to promptly initiate expedited suspension proceedings in the event the Exchange believes that it has sufficient proof that a violation of Rule 12.15 has occurred and is ongoing.

Further, the Exchange believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act, which require that the rules of an exchange “provide a fair procedure for the disciplining of members and persons associated with persons . . . and the prohibition or limitation by the exchange of any person with respect to access to services offered by the exchange or a member thereof.” Finally, the Exchange also believes the proposal is consistent with Sections 6(d)(1) and 6(d)(2) of the Act, which require that the rules of an exchange with respect to a disciplinary proceeding or proceeding that would limit or prohibit access to or membership in the exchange require the exchange to: Provide adequate and specific notice of the charges brought against a member or person associated with a member, provide an opportunity to defend against such charges, keep a record, and provide details regarding the findings and applicable sanctions. In the event a determination to impose a disciplinary sanction is made, the Exchange believes that each of these requirements is addressed by the notice and due process provisions included within proposed Rule 8.17. Importantly, as noted above, the Exchange anticipates using the authority proposed in this filing only in clear and egregious cases when necessary to protect.

12 The proposal will not supplant the Exchange’s current investigative and enforcement process. Currently, when Exchange surveillance staff identifies a pattern of potentially disruptive quoting and trading activity, the staff conducts an initial analysis and investigation of that activity. After the initial investigation, the Exchange then contacts the Member responsible for the activity to request an explanation of the activity as well as any additional relevant information, including the source of the activity. The Exchange will determine after this proposal becomes operative. The Exchange will only seek an expedited suspension when—after multiple requests to a Member for an explanation of activity—it continues to see the same pattern of manipulation from the same Member and the source of the activity is the same or has been previously identified as a frequent source of disruptive quoting and trading activity.


15 15 U.S.C. 78f(b)(1) and 78f(b)(6).

16 See supra, notes 7 and 8.


investors, other Members and the Exchange, and even in such cases, the Respondent will be afforded due process in connection with the suspension proceedings.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that each self-regulatory organization should be empowered to regulate trading occurring on their market consistent with the Act and without regard to competitive issues. The Exchange is requesting authority to take appropriate action if necessary for the protection of investors, other Members and the Exchange.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act and Rule 19b–4(f)(6) thereunder. For the Commission to determine whether the proposed rule change is consistent with the protection of investors and the public interest the Exchange is required to give the Commission written notice of the Exchange’s intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately. The Exchange asserts that the waiver of the 30-day operative delay will allow the Exchange to immediately enforce the proposed rules to protect its members and market participants from the behavior proscribed by the proposed rules. The Exchange further states that waiver of the operative delay is consistent with the protection of investors and the public interest because it is designed to protect investors and the public from disruptive quoting and trading activity. Furthermore, the Commission notes that it recently approved an identical expedited disciplinary procedure for an affiliate of the Exchange, BatsBZX, and the Exchange represents above that the membership of the Exchange and the membership of BatsBZX is nearly identical. Based on the foregoing, the Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

 Electronic Comments
• Use the Commission’s Internet comment form (http://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include File Number SR–BatsEDGX–2016–04 on the subject line.

Paper Comments
• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsEDGX–2016–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGX–2016–04, and should be submitted on or before May 9, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.26

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2016–08820 Filed 4–15–16; 8:45 am]

BILLING CODE 8011–01–P

22 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange’s intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.
25 See supra note 4.
26 See supra note 3.
27 For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2015–0077]

Requiring Electronic Access to the Electronic Folder by Certain Claimant Representatives

AGENCY: Social Security Administration.

ACTION: Notice; Implementation of requirement.

SUMMARY: This notice provides advance notification of the requirement that, for claims with certified electronic folders pending at the hearing or Appeals Council levels, an appointed representative must access and obtain a claimant’s folder through Appointed Representative Services (ARS) in matters for which the representative requests direct fee payment. Except under the limited circumstances described in this notice, we will no longer provide compact disc (CD) copies of the electronic folder to appointed representatives who request direct payment of fees. We are implementing this requirement to improve administrative efficiency, ensure that representatives can provide the best possible service to claimants by using the most up-to-date information in the claim(s) folder, and manage the unprecedented workload pending in the Office of Disability Adjudication and Review (ODAR).

DATES: Effective Date: This notice is effective August 16, 2016.

FOR FURTHER INFORMATION CONTACT: Maren Weight, Office of Disability Adjudication and Review, Social Security Administration, 5107 Leesburg Pike, Falls Church, VA 22041, (703) 605–7100, for information about this notice. 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.

For general information or inquiries about the electronic folder, please write to the Office of Electronic Services and Strategic Information, 5107 Leesburg Pike, Suite 1509, Falls Church, VA 22041.

SUPPLEMENTARY INFORMATION:

Requiring Electronic Access of the Claimant’s Certified Electronic Folder

On September 12, 2011, we published final rules that require appointed representatives to conduct business with us electronically at the times and in the manner we prescribe on matters for which the representative requests direct fee payment. At that time, we did not require representatives to use any specific electronic service. Rather, in the preamble to that final rule, we stated, “Once we determine that we should make a particular electronic service publicly available because it works well, we will publish a notice in the Federal Register. The notice will contain the new requirement(s) and a list of all established electronic service requirements.”

We implemented ARS nationally at the hearing level in November 2010, and, due to its successful application at the hearing level, expanded representative access at the Appeals Council level in June 2011. In part, ARS permits an appointed representative to examine an electronic folder online, download material from the electronic folder, and upload new evidence to the electronic folder in real time. Utilization of ARS has benefited both claimants and representatives, and has improved our efficiency and reduced our costs in associating incoming medical evidence and other information with a folder. To ensure efficient processing, it also is important that representatives use the most up-to-date claims folder. Use of ARS to access the claims folder assists the representative to prepare for a hearing and also positively affects administrative processes for both the representative and the agency. To illustrate, a representative who accesses a folder through ARS is able to determine immediately whether evidence he or she submitted is missing from the folder, and, if the evidence is not associated with a representative, can take steps immediately to address the issue, rather than later when the evidence’s absence could delay the hearing. Additionally, a representative who uses ARS can immediately access the status of cases pending at the hearing and Appeals Council levels, which saves the representative a lot of time in determining status and significantly reduces the number of inquiries received by ODAR offices. Due to the unprecedented workload currently pending in ODAR, time and resource savings such as this are vital to our operations. When a representative uses ARS for these types of tasks, hearing office staff has more time to perform other tasks needed to prepare for and schedule hearings.

Therefore, 120 days after the date of publication of this notice in the Federal Register, we will begin mandating the use of ARS at the hearings and Appeals Council levels by appointed representatives who request direct payment of the authorized fee, with a few exceptions as described below. We are providing a 120-day window to give any representative who is not currently registered for ARS, but would now like to do so, sufficient time to contact us and register for ARS. (For registration information, see Additional Information section below). After the 120-day window, we will no longer burn encrypted CD copies of the electronic folders for affected appointed representatives, as more fully described below. However, this requirement applies only to cases at the hearings and Appeals Council levels because we have not yet provided electronic folder access at the initial and reconsideration levels. Additionally, this requirement applies only to cases under Title II or Title XVI of the Social Security Act (Act) in which the official claim(s) folder is electronic.

In implementing this requirement, we acknowledge a systems limitation in providing electronic folder access through ARS when a claimant has appointed multiple representatives. Currently, in multiple representative situations, only the individual who is designated as the principal representative is able to access a claimant’s electronic folder through ARS. Under this mandate, if the principal representative requests direct payment of fees, he or she must use ARS to access the electronic folder, and SSA will not provide this representative CDs of the electronic folder upon request. Since non-principal representatives cannot currently access the electronic folder in multiples representative situations, the new mandate described in this notice does not apply to a non-principal representative. However, when the mandate applies to the principal representative, we will not provide CDs of the electronic folder to other appointed representatives who associate themselves with the principal representative by using the same Employer Identification Number (EIN) as the principal representative when requesting direct payment of fees on that case. (Representatives currently identify case-specific EINs for direct fee payment purposes via Form SSA–1695, Identifying Information for Possible Direct Payment of Authorized Fees). Instead, we expect these representatives to make arrangements with the principal representative to obtain copies of the claimant’s folder, if they need to view it. If requested, we will continue to provide CDs of the electronic folder to appointed representatives on the case who are not associated with the same


2Id.
All individuals living outside the United States receiving SVB must report to SSA any changes that may affect their benefits, such as: (1) A change in mailing address or residence; (2) an increase or decrease in a pension, annuity, or other recurring benefit; (3) a return or visit to the United States for a calendar month or longer; (4) an inability to manage benefits. SSA uses Form SSA–2010, to collect this information. Respondents are beneficiaries living outside the United States collecting SVB.

Type of Request: Revision of an OMB-approved information collection.

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II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than May 18, 2016. Individuals can obtain copies of the OMB clearance packages by writing to OR.Reports.Clearance@ssa.gov.

1. Statement for Determining Continuing Eligibility, Supplemental Security Income Payment(s)—20 CFR 416.204—0960–0416. SSA conducts disability redeterminations to determine if Supplemental Security Income (SSI) recipients (1) met and continue to meet all statutory and regulatory requirements for SSI eligibility and (2) are receiving the correct SSI payment amount. SSA makes these redeterminations through periodic use of Form SSA–8203–BK. SSA conducts
this legally mandated information collection in field offices via personal contact (face-to-face or telephone interview) using the automated Modernized SSI Claim System (MSSICS). The respondents are SSI recipients or their representative payees.

<table>
<thead>
<tr>
<th>Modality of collection</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
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</thead>
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<tr>
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<td>267,263</td>
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<td>19</td>
<td>211,036</td>
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<td>Paper</td>
<td>135,357</td>
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<td>45,119</td>
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<tr>
<td>Totals</td>
<td>1,603,577</td>
<td></td>
<td></td>
<td>523,418</td>
</tr>
</tbody>
</table>

2. Information About Joint Checking/Savings Account—20 CFR 416.1201 and 416.1208—0960–0461. SSA considers a person’s resources when evaluating eligibility for SSI. Generally, we consider funds in checking and savings accounts as resources owned by the individuals whose names appear on the account. However, individuals applying for SSI may rebut this assumption of ownership in a joint account by submitting certain evidence to establish the funds do not belong to them. SSA uses Form SSA–2574 to collect information from SSI applicants and recipients who object to the assumption that they own all or part of the funds in a joint checking or savings account bearing their names. SSA collects information about the account from both the SSI applicant or recipient and the other account holder(s). After receiving the completed form, SSA determines if we should consider the account to be a resource for the SSI applicant and recipient. The respondents are applicants and recipients of SSI, and individuals who list themselves as joint owners of financial accounts with SSI applicants or recipients.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of collection</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
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<td>Intranet version (MSSICS)</td>
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<td>Totals</td>
<td>200,000</td>
<td></td>
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</tr>
</tbody>
</table>

3. Plan for Achieving Self-Support (PASS)—20 CFR 416.110(e), 416.1180–1182, 416.1225–1227—0960–0559. The SSI program encourages recipients to return to work. One of the program objectives is to provide incentives and opportunities that help recipients toward employment. The PASS provision allows individuals to use available income or resources (such as business equipment, education, or specialized training) to enter or re-enter the workforce and become self-supporting. In turn, SSA does not count the income or resources recipients use to fund a PASS when determining an individual’s SSI eligibility or payment amount. An SSI recipient who wants to use available income and resources to obtain education or training to become self-supporting completes Form SSA–545. SSA uses the information from the SSA–545 to evaluate the recipient’s PASS, and to determine eligibility under the provisions of the SSI program. The respondents are SSI recipients who want to develop a return-to-work plan.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of collection</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSA–545</td>
<td>7,000</td>
<td>1</td>
<td>120</td>
<td>14,000</td>
</tr>
</tbody>
</table>

4. Registration for Appointed Representative Services and Direct Payment—0960–0732. SSA uses Form SSA–1699 to register appointed representatives of claimants before SSA who:

- Want to register for direct payment of fees;
- Registered for direct payment of fees prior to 10/31/09, but need to update their information;
- Registered as appointed representatives on or after 10/31/09, but need to update their information; or
- Received a notice from SSA instructing them to complete this form.

By registering these individuals, SSA:

1. Authenticates and authorizes them to do business with us;
2. Allows them to access our records for the claimants they represent;
3. Facilitates direct payment of authorized fees to appointed representatives; and,
4. Collects the information we need to meet Internal Revenue Service (IRS) requirements to issue specific IRS forms if we pay an appointed representative in excess of a specific amount ($600). The respondents are appointed representatives who want to use Form SSA–1699 for any of the purposes cited in this Notice.

Type of Request: Revision of an OMB-approved information collection.
5. Certificate of Election for Reduced Widow(er)s and Surviving Divorced Spouse’s Benefits—20 CFR 404.335—0960–0759. Section 202(q) of the Social Security Act provides SSA the authority to reduce benefits under certain conditions when elected by a Title II beneficiary. However, reduced benefits are not payable to an already entitled spouse (or divorced spouse) who:

- Is at least age 62 and under full retirement age in the month of the number holder’s death; and
- Is receiving both reduced spouse’s (or divorced spouse’s) benefits and either retirement or disability benefits in the month before the month of the number holder’s death.

To elect reduced widow(er) benefits, a recipient completes Form SSA–4111.

SSA uses the information collected to pay a qualified dually entitled widow(er) (or surviving divorced spouse) who elects to receive a reduced widow(er) benefit. The respondents are qualified dually entitled widow(er)s (or surviving divorced spouse) who elect to receive a reduced widow(er) benefit.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of collection</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
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<td>SSA–4111</td>
<td>30,000</td>
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<td>2</td>
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</tr>
</tbody>
</table>

Dated: April 13, 2016.
Naomi R. Sipple,
Reports Clearance Officer, Social Security Administration.

[FR Doc. 2016–08902 Filed 4–15–16; 8:45 am]
BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

Notice of Request To Release Airport Property

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on request to release airport property at the Hebron Municipal Airport (HJH), Hebron, Nebraska.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at the Hebron Municipal Airport (HJH), Hebron, Nebraska, under the provisions of 49 U.S.C. 47107(h)(2).

DATES: Comments must be received on or before May 18, 2016.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address:
Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust Room 364, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: William Linton, Airport Manager, Hebron Municipal Airport, Hebron Airport Authority; P.O. Box 256, Hebron, NE 68370–0256, (402) 768–6597.

FOR FURTHER INFORMATION CONTACT:
Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust Room 364, Kansas City, MO 64106, (816) 329–2644, lynn.martin@faa.gov. The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release approximately 0.21± acres of airport property at the Hebron Municipal Airport (HJH) under the provisions of 49 U.S.C. 47107(h)(2). On March 16, 2016, the City of Hebron’s Airport Manager requested from the FAA that approximately 0.21± acres of property be released for sale to the Nebraska Department of Roads for the purpose of reconstructing a bridge and road. On April 8, 2016, the FAA determined that the request to release property at Hebron Municipal Airport (HJH) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this Notice.

The following is a brief overview of the request:
Hebron Municipal Airport (HJH) is proposing the release of a parcel, totaling 0.21± acres. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at the Hebron Municipal Airport (HJH) being changed from aeronautical to nonaeronautical use and release the surface lands from the conditions of the AIP Grant Agreement Grant Assurances.

The FAA has determined that the request to release property does not and will not impact future aviation needs at the airport. The FAA will conduct a full airport need analysis. Any person may inspect, by appointment, the request in person at the FAA office listed above under FOR FURTHER INFORMATION CONTACT. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at the Hebron Municipal Airport.

Issued in Kansas City, MO, on April 11, 2016.
Jim A. Johnson,
Manager, Airports Division.

[FR Doc. 2016–08902 Filed 4–15–16; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION
Maritime Administration

Marine Highway Projects Open Season

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of open season for marine highway projects.
SUMMARY: The U.S. Department of Transportation (DOT) and Maritime Administration (MARAD) announce that the period for Marine Highway project submissions is being extended to December 31, 2018 (Open Season). The purpose of this notice is to extend the invitation to interested organizations to submit Marine Highway project applications to DOT for review and consideration.

DATES: There will be five additional project review periods during the extended Marine Highway Open Season. Table 1 contains the application due dates and review periods for each review period. Qualified projects will be announced shortly after the completion of each review period.

TABLE 1—OPEN SEASON PROJECT SUBMISSION AND REVIEW TIMELINE

<table>
<thead>
<tr>
<th>Review session</th>
<th>Project application due date (11:59 p.m. pacific)</th>
<th>Project review period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>December 31, 2016</td>
<td>January 1, 2017–April 30, 2017</td>
</tr>
<tr>
<td>2</td>
<td>June 30, 2017</td>
<td>July 1, 2017–October 31, 2017</td>
</tr>
<tr>
<td>3</td>
<td>December 31, 2017</td>
<td>January 1, 2018–April 30, 2018</td>
</tr>
<tr>
<td>4</td>
<td>June 30, 2018</td>
<td>July 1, 2017–October 31, 2018</td>
</tr>
<tr>
<td>5</td>
<td>December 31, 2018</td>
<td>January 1, 2019–April 30, 2019</td>
</tr>
</tbody>
</table>

Key Instructions/Information: The Marine Highway project application process is detailed in 46 CFR Section 393.4 Marine Highway Projects, which is accessible online at https://www.federalregister.gov search “America’s Marine Highway Program.” Full details on the Open Season were released in the Federal Register on June 2, 2014, (79 FR 31404 pp. 31404–31405).

MARAD’s Gateway Offices can respond to questions about the Marine Highway Program, Route designations and Project Open Season. Gateway Office contact information is available on the MARAD Web site at http://www.marad.dot.gov search “Office of Gateways.”


SUPPLEMENTARY INFORMATION: As originally announced in the Federal Register on June 2, 2014 (79 FR 31404), the scope of the Marine Highway Program has been expanded to include all of the United States domestic marine transportation system. Previously, the Program only included waterways that paralleled landside transportation routes, and thus, excluded routes between the mainland and non-contiguous ports. The expanded scope was specified in Section 405 of The Coast Guard and Marine Transportation Act of 2012 (Pub. L. 112–213), which reads: “[the Secretary shall designate short sea transportation routes as extensions of the surface transportation system to focus public and private efforts to use the waterways to relieve landside congestion along coastal corridors or to promote short sea transportation.”

The purpose of the open season call for projects is to seek eligible Marine Highway projects that may establish new or enhance existing Marine Highway services. Eligible projects may be designated as Marine Highway Projects by the Secretary of Transportation. Being designated a Marine Highway Project allows DOT resources to be used to assist public project sponsors, ports and other local transportation or economic development agencies in the development of Marine Highway projects.

The Department’s objective through this program is to reduce landside congestion and increase the use of domestic marine transportation by supporting the development of transportation options for shippers. These services provide economic and environmental benefits to the U.S. public at large. Marine Highway Program designated projects can improve safety and system resilience, and serve to reduce transportation-related air emissions, transportation costs for shippers, energy consumption, and costs associated with landside transportation infrastructure.

The Marine Highway Program implementation regulations at 46 CFR part 393 will be amended to reflect the new statutory changes. In the meantime, DOT/MARAD will accept and process project applications that propose to operate or expand service on Marine Highway routes, including those with no parallel landside route.

Exceptions to This Open Season

If new Marine Highway grant funds are appropriated in a fiscal year (FY), it is possible that the review period for the July 1–September 30 review session may be truncated so that projects submitted on June 30 could be made eligible to apply for Marine Highway grant funds in that FY.

Participation

Although Marine Highway Projects often involve private entities such as vessel operators, the applications must be sponsored and submitted to DOT/MARAD by a public entity, such as a State Department of Transportation, Metropolitan Planning Organization (MPO), or Port Authority. Public/private partnerships are encouraged.

To be eligible for Marine Highway Project status, the proposed project must (1) use U.S. documented vessels, (2) transport passengers, containerized freight or trailer-based freight, and (3) operate on a designated Marine Highway Route. (Refer to 46 CFR 393.4(c) for a comprehensive description of project eligibility).

However, since the number of navigable waterways eligible for designation as a Marine Highway Route was increased in the Coast Guard and Marine Transportation Act of 2012, DOT/MARAD will consider Marine Highway projects that would operate on newly eligible navigable waterways that have been recommended for, but not yet granted, a Marine Highway Route designation. For further information on recommending that a navigable waterway be designated as a Marine Highway Route, please contact your regional Gateway Office. Their contact
DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0047]

Denial of Motor Vehicle Defect Petition

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a petition submitted to NHTSA under 49 U.S.C. 30162, requesting that the agency commence a proceeding to determine the existence of a defect related to motor vehicle safety in 2015 Volvo VNL 780 vehicles. After a review of the petition and other information, NHTSA has concluded that further expenditure of the agency’s investigatory resources on the issues raised by the petition does not appear warranted. The agency accordingly has denied the petition. The petition is hereinafter identified as DP15–006.

FOR FURTHER INFORMATION CONTACT: Mr. Nate Seymour, Medium & Heavy Duty Vehicle Division, Office of Defects Investigation (ODI), NHTSA, 1200 New Jersey Ave. SE., Washington, DC 20590. Telephone: (202) 366–2069.

SUPPLEMENTARY INFORMATION: By letter dated August 7, 2015, Mr. Albert Cusson and Nancy Younger-Cusson wrote to NHTSA requesting that the agency investigate the issues they previously identified in vehicle owner questionnaires (VOQ) 10701592 and 10747593 filed with the Agency. While the Petitioner’s letter did not comply precisely with the requirements for petitions found in 49 CFR 552.4, the Agency is treating it as a petition in accordance with the regulation. ODI understands these issues to include: Cab sway, cab alignment/bottoming out, and loss of vehicle control due to false triggering of the advanced vehicle safety systems.

NHTSA has reviewed the material provided by the petitioners and other pertinent data that the agency gathered as well as test drove the petitioners’ vehicle. The results of this review and NHTSA’s analysis of the petition’s merit is set forth in the DP15–006 Evaluation Report, appearing in the public docket referenced in the heading of this notice.

For the reasons presented in the Evaluation Report, it is unlikely that an order concerning notification and remedy of a safety-related defect would be issued as a result of granting Mr. Albert Cusson and Nancy Younger-Cusson’s request. Therefore, in review of the need to allocate and prioritize NHTSA’s investigatory resources, an investigation on the issues raised by the petition does not appear to be warranted. Therefore, the petition is denied.

Authority: 49 U.S.C. 30162(d); delegations of authority at CFR 1.95 and 501.8.

Gregory K. Rea,
Associate Administrator for Enforcement.

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), the OCC, the Board, and the FDIC (the agencies) may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), have approved the publication of proposed revisions to the Regulatory Capital Reporting for Institutions Subject to the Advanced Capital Adequacy Framework (FFIEC 101) for public comment. The proposed revisions to the FFIEC 101 are consistent with the revised regulatory capital rule approved by the agencies in July 2013 (regulatory capital rule), as amended by subsequent revisions to the supplementary leverage ratio (SLR).

The proposed collection of SLR data in Tables 1 and 2 of FFIEC 101 Schedule A would apply to all banking organizations subject to the advanced approaches risk-based capital rule (generally, banking organizations with $250 billion or more in total consolidated assets or $10 billion or more in on-balance sheet foreign exposures) (advanced approaches banking organizations), unless the advanced approaches banking organization is (i) a consolidated subsidiary of a bank holding company (BHC), savings and loan holding company (SLHC), or depository institution that is subject to the disclosure requirements in Table 13 of section 173 of the advanced approaches risk-based capital rule (advanced approaches rule), or (ii) a subsidiary of a non-U.S. banking organization that is subject to comparable public disclosure requirements in its home jurisdiction. Advanced approaches banking organizations would begin reporting the proposed SLR data items in FFIEC 101 Schedule A, Tables 1 and 2, effective with the September 30, 2016, reporting date.

Separately, the proposed collection of SLR data in Tables 1 and 2 of FFIEC 101 Schedule A would apply to any U.S. intermediate holding companies (IHCs) formed or designated for purposes of compliance with the Board’s Regulation YY (12 CFR 252.153) that are advanced approaches banking organizations, effective with the March 31, 2018, reporting date. Any subsidiary BHC controlled by a foreign banking organization (FBO) that was subject to the SLR requirements prior to the formation of an IHC would complete FFIEC 101 Schedule A, Tables 1 and 2, through the December 31, 2017, reporting date. The agencies would release publicly Tables 1 and 2 of FFIEC 101 Schedule A for all covered banking organizations, including IHCs that are required to complete Schedule A.

At the end of the comment period, the comments will be analyzed to determine the extent to which the FFIEC and the agencies should modify the proposed revisions. The agencies will then submit the proposed revisions to OMB for review and final approval.

DATES: Comments must be submitted on or before June 17, 2016.
ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the OMB control number(s), will be shared among the agencies.

OCC: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible to prainfo@occ.treas.gov. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0239 (FFIEC 101), 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Board: You may submit comments, which should refer to “FFIEC 101,” by any of the following methods:


• Email: regs.comments@federalreserve.gov. Include reporting form number in the subject line of the message.

• Fax: (202) 452–3819 or (202) 452–3102.

• Mail: Robert DeV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board’s Web site at www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board’s Martin Building (20th and C Streets, NW.) between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, which should refer to “FFIEC 101,” by any of the following methods:

• Agency Web site: https://www.fdic.gov/regulations/laws/federal/. Follow the instructions for submitting comments on the FDIC Web site.

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

• Email: comments@FDIC.gov.

Include “FFIEC 101” in the subject line of the message.

• Mail: Gary A. Kuiper, Counsel, Room MB–3016, or Manuel E. Cabeza, Counsel, Room MB–3105, Attn: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

• Hand Delivery: Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

• Public Inspection: All comments received will be posted without change to https://www.fdic.gov/regulations/laws/federal/ including any personal information provided. Comments may be inspected at the FDIC Public Information Center, Room E–1002, 3501 Fairfax Drive, Arlington, VA 22226, between 9:00 a.m. and 5:00 p.m. on business days.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503; by fax to (202) 395–6974; or by email to aia_submission@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: For further information about the proposed revisions to regulatory reporting requirements discussed in this notice, please contact any of the agency clearance officers whose names appear below. In addition, copies of the proposed revised FFIEC 101 form and instructions can be obtained at the FFIEC’s Web site (http://www.ffiec.gov/ ffiec_report_forms.htm).


SUPPLEMENTARY INFORMATION: The agencies are proposing to extend for three years, with revision, the FFIEC 101, which is currently an approved collection of information for each agency.

Report Title: Risk-Based Capital Reporting for Institutions Subject to the Advanced Capital Adequacy Framework.

Form Number: FFIEC 101.

Frequency of Response: Quarterly.

Affected Public: Business or other for-profit.

OCC

OMB Number: 1557–0239.

Estimated Number of Respondents: 20 national banks and federal savings associations.

Estimated Time per Response: 674 burden hours per quarter to file.

Estimated Total Annual Burden: 53,920 burden hours to file.

Board

OMB Number: 7100–0319.

Estimated Number of Respondents: 6 state member banks; 16 bank holding companies and savings and loan holding companies; and 6 intermediate holding companies.

Estimated Time per Response: 674 burden hours per quarter for state member banks to file, 677 burden hours per quarter for bank holding companies and savings and loan holding companies to file; 3 burden hours per quarter for intermediate holding companies to file; and 300 burden hours for intermediate holding companies’ one-time implementation.

Estimated Total Annual Burden: 16,176 burden hours for state member banks to file; 43,328 burden hours for bank holding companies and savings and loan holding companies to file; 72 burden hours for intermediate holding companies to file; 1,800 burden hours for intermediate holding companies’ one-time implementation.

FDIC

OMB Number: 3064–0159.
Estimated Number of Respondents: 2 insured state nonmember banks and state savings associations.

Estimated Time per Response: 674 burden hours per quarter to file.

Estimated Total Annual Burden: 5,392 burden hours to file.

General Description of Reports


The agencies use these data to assess and monitor the levels and components of each reporting entity’s capital requirements and the adequacy of the entity’s capital under the Advanced Capital Adequacy Framework; to evaluate the impact and competitive implications of the Advanced Capital Adequacy Framework on individual reporting entities and on an industry-wide basis; and to supplement on-site examination processes. The reporting schedules also assist advanced approaches banking organizations in understanding expectations around the system; are necessary for implementation and validation of the Advanced Capital Adequacy Framework. Submitted data that are released publicly will also provide other interested parties with information about advanced approaches banking organizations’ regulatory capital.

Current Actions

I. Overview of the Proposed SLR Changes

A. Summary of Proposed SLR Changes

The agencies are inviting comment on two proposed new tables that would be added to FFIEC 101 Schedule A to collect information related to the agencies’ SLR disclosures required in Table 13 of section 173 of the advanced approaches rule. Proposed Tables 1 and 2, which will replace existing items 91 through 98 of FFIEC 101 Schedule A, would be aligned with the international leverage ratio common disclosure template that was adopted by the Basel Committee on Banking Supervision in January 2014 (international leverage ratio common disclosure template), with some minor changes to the titles of the line items and clarifications in the instructions, consistent with the revisions to the SLR in the regulatory capital rule (SLR rule) and the accounting terminology of U.S. generally accepted accounting principles. The proposal would incorporate the complete international leverage ratio common disclosure template into Schedule A in order to ensure transparency and comparability of reporting of regulatory capital elements among internationally active banking organizations. However, one item on the international leverage ratio common disclosure template is inapplicable to U.S. firms and has been excluded from proposed Schedule A by being shaded out. Specifically, “‘Adjustment for fiduciary assets recognized on the balance sheet pursuant to the operative accounting framework but excluded from the leverage ratio exposure measure’” is on the international leverage ratio common disclosure template but is not included in proposed Schedule A. The proposed revised Schedule A also would include an additional item applicable to certain advanced approaches bank holding companies only, which would collect data on an advanced approaches bank holding company’s enhanced SLR buffer, if applicable.

B. Scope, Timing, and Frequency of Proposed Reporting Changes

The proposed revisions to the FFIEC 101 would apply only to an advanced approaches banking organization as described in section 173(a)(2) of the advanced approaches rule. Generally, the SLR disclosures apply to an advanced approaches institution, unless it is (1) a consolidated subsidiary of a BHC, SLHC, or depository institution that is subject to the regulation requirements; or (2) a subsidiary of a non-U.S. banking organization that is subject to comparable public disclosure requirements in its home jurisdiction.

Completing the proposed FFIEC 101 items for the SLR would satisfy an advanced approaches banking organization’s requirement to disclose Table 13.

Separately, each advanced approaches banking organization, regardless of its parallel run status, is required to disclose its SLR, and the numerator and denominator of its SLR, under section 172(d) of the advanced approaches rule. This is a separate disclosure requirement, which the agencies have proposed to implement for banks and savings associations that are advanced approaches banking organizations through a revision to Schedule RC–R, Part I, Regulatory Capital Components and Ratios, of the Consolidated Reports of Condition and Income (Call Report) (FFIEC 031 and 041) reporting forms using the standard PRA notice and comment process.

An IHC formed or designated for purposes of compliance with the Board’s Regulation YY (12 CFR 252.153) is required to meet all applicable capital adequacy standards set forth in the Board’s Regulation Q, except for subpart E. An IHC that meets the definition of an advanced approaches banking organization under the Board’s Regulation Q (12 CFR 217.100) (advanced approaches IHC) would begin reporting the proposed SLR data items in the FFIEC 101 effective with the March 31, 2018, reporting date, and would begin calculating these proposed items starting January 1, 2018. This reporting requirement is consistent with Regulation YY, which subjects advanced approaches IHCs to the SLR beginning on January 1, 2018. Such an IHC would not be required to complete the rest of the FFIEC 101 because Regulation YY requires an IHC to calculate its risk-based capital requirements using only the standardized approach, and not the advanced approaches rule, even if it meets the advanced approaches applicability threshold. Further, any
subsidiary BHC that is controlled by an FBO that was subject to the SLR disclosures prior to the formation of an IHC would complete FFIEC 101 Schedule A, Tables 1 and 2, through the December 31, 2017, reporting date.

Depository institutions that are exempt from filing the FFIEC 101, but remain subject to the SLR, would not need to begin filing the FFIEC 101. Instead, these institutions would report a long as it remains subject to the requirements of section 173(a)(2) of the advanced approaches rule.

The agencies propose to collect the SLR information in Tables 1 and 2 of FFIEC 101 Schedule A quarterly. Each reporting entity would continue to submit the applicable quarterly reports on the same due dates as are currently in effect for the reporting entity for as long as it remains subject to the requirements of section 173(a)(2) of the advanced approaches rule.

C. Confidentiality

To ensure transparency of regulatory capital data reported by internationally active banking organizations, the agencies propose to make public the SLR information collected in proposed SLR Tables 1 and 2 of FFIEC 101 Schedule A, regardless of an advanced approaches banking organization’s parallel run status.

D. Initial Reporting

For the September 30, 2016, and March 31, 2018, initial report dates, as applicable, banking organizations may provide reasonable estimates for any new or revised items in SLR Tables 1 and 2 of FFIEC 101 Schedule A initially required to be reported as of that date for which the requested information is not readily available. The specific wording of the captions for the new or revised SLR items discussed in this proposal and the numbering of these data items should be regarded as preliminary.

II. Detail of the Proposed FFIEC 101 SLR Data Changes

Schedule A: Advanced Approaches Regulatory Capital

As described in section I.A of this proposal, the proposed SLR items in entirety of the FFIEC 101. See 12 CFR 22705 Federal Register

FFIEC 101 Schedule A, Tables 1 and 2, are aligned with the international leverage ratio common disclosure template to ensure consistency and comparability of reporting of regulatory capital elements by internationally active banking organizations. While the SLR calculated under the SLR rule and this reporting proposal would be the same, the proposed SLR Items in Tables 1 and 2 may require different calculation steps than those described in the SLR rule because Tables 1 and 2 have been designed to be consistent with the calculation steps in the international template.

The proposed items are divided into two tables: (1) Summary comparison of accounting assets and total leverage exposure (Table 1) and (2) Supplementary leverage ratio (Table 2).

A. Table 1, Items 1.1–1.8: Summary Comparison of Accounting Assets and Total Leverage Exposure

Proposed Table 1, items 1.1 through 1.8, would collect summary information on accounting assets for purposes of reconciling balance sheet assets reported in published financial statements and total leverage exposure. The proposed items align with those included in Table 1 of the international leverage ratio common disclosure template. Item 1.1 would collect total consolidated assets as of quarter end as reported in published financial statements. Item 1.2 would collect the adjustment for investments in banking, financial, insurance, and commercial entities that are consolidated for accounting purposes but are outside the scope of regulatory consolidation. Item 1.3, adjustment for fiduciary assets recognized on-balance sheet but excluded from total leverage exposure, would be shaded out and not collected, as it is not applicable to U.S. banking organizations. Item 1.4 would collect the accounting and regulatory adjustments required to reconcile what an institution reports on its published financial statements with the amount an institution includes for exposures to repo-style transactions in total leverage exposure (calculated on a quarter end basis), in addition to any off-balance sheet and related regulatory adjustments (calculated using the mean of the amount calculated as of the last day of each of the three months of the reporting quarter). Similarly, item 1.5 would collect the accounting and regulatory adjustments required to reconcile what an institution reports on its published financial statements with the amount an institution includes for exposures to repo-style transactions in its total leverage exposure (calculated on a quarter end basis), in addition to any off-balance sheet and related regulatory adjustments (calculated using the mean of the amount calculated as of the last day of each of the three months of the reporting quarter). Item 1.6 would collect the adjustment for off-balance sheet exposures. Item 1.7 would include two subcomponents where item 1.7a would collect adjustments for deductions from tier 1 capital and item 1.7b would collect adjustments due to the difference in the frequency of certain calculations required for accounting purposes compared to the measurement required for purposes of total leverage exposure. Specifically, 1.7b would adjust an institution’s calculations in Table 1, items 1.1, 1.4 and 1.5 that are reported on a quarter end basis to a daily average as required in the calculation of an institution’s total leverage exposure as reported in Table 2, item 2.21. Item 1.8 would collect total leverage exposure by subtracting items 1.1 through 1.6 and subtracting items 1.7a and 1.7b. This item should equal Table 2, item 2.21.

The agencies request comment on whether Table 1 should include an additional reporting item for any other adjustments necessary to reconcile an institution’s balance sheet assets reported in published financial statement with total leverage exposure as reported in Table 2, item 2.21.

Commenters should also provide a description of the additional adjustments.

B. Table 2, Items 2.1–2.23: Supplementary Leverage Ratio

Proposed Table 2, items 2.1 through 2.23, would collect detailed information for the calculation of total leverage exposure and the SLR, consistent with the international leverage ratio common disclosure template. Items 2.1 through 2.23 would collect information about an institution’s on-balance sheet exposures. Item 2.1 would collect the balance sheet carrying value of all on-balance sheet assets, net of the allowance for loan and lease losses as defined in the regulatory capital rule (excluding on-balance sheet assets for derivative transactions and repo-style transactions, but including on-balance sheet collateral received in derivative transactions). Item 2.2 would collect deductions from common equity tier 1 capital and additional tier 1 capital, calculated as the sum of existing items 1.8 and 43 on Schedule A of the FFIEC 101, net of Schedule A, items 11, 14, and certain amounts reported in item...
Items 2.2 through 2.11 would collect information about an institution’s derivative exposures. Item 2.4 would collect the replacement cost for cleared and non-cleared derivative transactions. Item 2.5 would collect the add-on amounts for potential future exposure (PFE) for all derivative transactions included in item 2.4 (regardless of whether the transaction or the transaction’s netting set has a positive or negative fair value). Item 2.6 would collect the gross-up amount for collateral posted in derivative transactions if the collateral is deducted from on-balance sheet assets. Item 2.7 would collect the deduction of receivable assets for qualifying cash variation margin posted in derivative transactions. Item 2.8 would collect exempted exposures to central counterparties in cleared transactions. Item 2.9 would collect the adjusted effective notional principal amount of sold credit protection. Item 2.10 would collect the adjusted effective notional principal amount offsets and PFE deductions for sold credit protection. Item 2.11 would collect total derivative exposures, calculated as the sum of items 2.4, 2.5, 2.6, and 2.9, minus items 2.7, 2.8, and 2.10.

Items 2.12 through 2.16 would collect information about an institution’s repo-style transactions. Item 2.12 would collect gross assets for repo-style transactions with no recognition of netting. Item 2.13 would collect the reduction of the gross value of receivables in reverse repurchase transactions by cash payables in repurchase transactions with the same counterparty. Item 2.14 would collect the counterparty credit risk for all repo-style transactions. Item 2.15 would collect the exposure amount for repo-style transactions, calculated as the sum of items 2.12, 2.14, and 2.15, minus item 2.13.

Items 2.17 through 2.19 would collect information about an institution’s off-balance sheet exposures. Item 2.17 would collect off-balance sheet exposures at gross notional amounts. Item 2.18 would collect adjustments for conversion to credit equivalent amounts. Item 2.19 would collect total off-balance sheet exposures, calculated as the difference between items 2.17 and 2.18.

Items 2.20 through 2.22 would collect information about an institution’s capital, total leverage exposure, and the SLR. Item 2.20 would collect tier 1 capital as reported in existing item 45 on Schedule A of the FFIEC 101. Item 2.21 would collect total leverage exposure, calculated as the sum of items 2.3, 2.11, 2.16, and 2.19. Item 2.22 would collect the SLR, calculated by dividing item 2.20 by item 2.21. Item 2.23, the enhanced SLR buffer, is an additional line item that is not included on the international leverage ratio common disclosure template. This item would apply only to advanced approaches BHCs that are subject to the enhanced SLR standard and it would help determine whether the bank holding company is subject to limitations on capital distributions and discretionary bonus payments.

III. Reporting the Legal Entity Identifier

The Legal Entity Identifier (LEI) is a 20-digit alpha-numeric code that uniquely identifies entities that engage in financial transactions. The recent financial crisis spurred the development of a Global LEI System (GLEIS). Internationally, regulators and market participants have recognized the importance of the LEI as a key improvement in financial data systems. The Group of Twenty (G–20) nations directed the Financial Stability Board (FSB) to lead the coordination of international regulatory work and deliver concrete recommendations on the GLEIS by mid-2012, which in turn were endorsed by the G–20 later that same year. In January 2013, the LEI Regulatory Oversight Committee (ROC), including participation by regulators from around the world, was established to oversee the GLEIS on an interim basis. With the establishment of the full Global LEI Foundation in 2014, the ROC continues to review and develop broad policy standards for LEIs. The OCC, the Board, and the FDIC are all members of the ROC.

The LEI system is designed to facilitate several financial stability objectives, including the provision of higher quality and more accurate financial data. In the United States, the Financial Stability Oversight Council (FSOC) has recommended that regulators and market participants continue to work together to improve the quality and comprehensiveness of financial data both nationally and globally. In this regard, the FSOC also has recommended that its member agencies promote the use of the LEI in reporting requirements and rulemakings, where appropriate. Effective beginning October 31, 2014, the Board started requiring holding companies to provide their LEI on the cover pages of the FR Y–6, FR Y–7, and FR Y–10 reports only if a holding company already has an LEI. Thus, if a reporting holding company does not have an LEI, it is not required to obtain one for purposes of these Board reports. Additionally, effective December 31, 2015, the Board expanded the collection of the LEI to all holding company subsidiary banking and nonbanking legal entities reportable on certain schedules of the FR Y–10 and in one section of the FR Y–6 and FR Y–7 if an LEI has already been issued for the reportable entity. With respect to the FFIEC 101, the agencies are proposing to have advanced approaches banking organizations provide their LEI on the cover page of the report beginning March 31, 2016, only if an organization already has an LEI. As with the Board reports, an advanced approaches banking organization that does not have an LEI would not be required to obtain one for purposes of reporting it on the FFIEC 101.

IV. Request for Comment

Public comment is requested on all aspects of this joint notice. Comments are invited on:
(a) Whether the collections of information that are the subject of this notice are necessary for the proper performance of the agencies’ functions, including whether the information has practical utility;
(b) The accuracy of the agencies’ estimates of the burden of the information collections as they are proposed to be revised, including the validity of the methodology and assumptions used;
(c) Ways to enhance the quality, utility, and clarity of the information to be collected;
(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and
(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this joint notice will be shared among the agencies and will be summarized or included in the agencies’ requests for OMB approval. All comments will become a matter of public record.

Dated: April 7, 2016.

Stuart Feldstein,
Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, April 13, 2016. 

Robert deV. Frierson,
Secretary of the Board.

Dated at Washington, DC, this 6th day of April, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman, 
Executive Secretary.

DEPARTMENT OF VETERANS AFFAIRS

Special Medical Advisory Group, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Special Medical Advisory Group will meet on May 25, 2016, room 230 at the Department of Veterans Affairs Central Office, 810 Vermont Ave. NW., Washington, DC 20420 from 8:00 a.m. to 3:30 p.m. ET. The meeting is open to the public.

The purpose of the Group is to advise the Secretary of Veterans Affairs and the Under Secretary for Health on the care and treatment of Veterans, and other matters pertinent to the Department’s Veterans Health Administration (VHA).

The agenda for the meeting will include review the potential policy requiring physicians provide a 90 day notification when they leave the VA, Pay for Performance and review best practice dissemination project.

Thirty (30) minutes will be allocated for receiving oral presentations from the public. Members of the public may submit written statements for review by the Committee to Brigid McCarthy, Department of Veterans Affairs, Office of Speciality Care Services (10P4E), Veterans Health Administration, 810 Vermont Avenue NW., Washington, DC 20420, or by email at brigid.mccarthy@va.gov.

Because the meeting is being held in a VA Central Office, a photo I.D. is required at the entrance as a part of the clearance process. Therefore, you should plan to arrive 15 minutes before the meeting begins to allow time for the clearance process. Any member of the public wishing to attend the meeting or seeking additional information should contact Ms. McCarthy at (202) 461-5129 or by email.

Dated: April 13, 2016.

By Direction of the Secretary.

Jeffrey M. Martin,
Program Manager, Regulation Policy and Management, Office of the General Counsel.

DEPARTMENT OF VETERANS AFFAIRS

Veterans Rural Health Advisory Committee Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Veterans Rural Health Advisory Committee will meet on May 3–4, 2016, at 2815 N. Assembly Street, Building 40, Room 225, Spokane, Washington, from 8:30 a.m. to 5:00 p.m. on both days. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on health care issues affecting enrolled Veterans residing in rural areas. The Committee examines programs and policies that impact the provision of VA health care to enrolled Veterans residing in rural areas, and discusses ways to improve and enhance VA services for these Veterans.

The agenda will include updates from the Committee Chairman and the Director of the Veterans Health Administration Office of Rural Health, as well as presentations on general health care access and quality topics.

Public comments will be received at 4:30 p.m. on May 4, 2016. Interested parties should contact Mr. Elmer D. Clark, by mail at 810 Vermont Avenue, Mail Code 10P1R, Washington, DC 20420, or via email at VRHHAC@ova.gov, or by fax at (202) 632–8609. Individuals scheduled to speak are invited to submit a 1–2 page summary of their comments for inclusion in the official meeting record.

Dated: April 13, 2016.

By Direction of the Secretary

Jeffrey M. Martin,
Program Manager, Regulation Policy and Management, Office of the General Counsel.

Subcommittee | Date | Location
--- | --- | ---
Research Career Scientists & Promotions | May 9, 2016 | American College of Surgeons.
Nephrology | May 19, 2016 | Hilton Crystal City—Reagan National Airport.
Infectious Diseases-B | May 19, 2016 | Hilton Crystal City—Reagan National Airport.
Hematology | May 20, 2016 | American College of Surgeons.
Cellular & Molecular Medicine | May 23, 2016 | Hilton Garden Inn—DC/US Capitol.
Oncology-C | May 26, 2016 | Hilton Garden Inn—DC/US Capitol.
Immunology-A | June 1, 2016 | American College of Surgeons.
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<tr>
<th>Subcommittee</th>
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<tr>
<td>Neurobiology-F</td>
<td>June 1, 2016</td>
<td>* VA Central Office.</td>
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<tr>
<td>Neurobiology-B</td>
<td>June 1, 2016</td>
<td>Hilton Garden Inn—DC/US Capitol.</td>
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<tr>
<td>Oncology-E</td>
<td>June 1, 2016</td>
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<tr>
<td>Pulmonary Medicine</td>
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<td>Special Emphasis on Genomics</td>
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<td>Neurobiology-A</td>
<td>June 3, 2016</td>
<td>American College of Surgeons.</td>
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<td>Neurobiology-D</td>
<td>June 3, 2016</td>
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<td>Endocrinology-A</td>
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<td>Mental Health and Behavioral Sciences-A</td>
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<td>Neurobiology-E</td>
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<td>Eligibility</td>
<td>July 18, 2016</td>
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The purpose of the subcommittees is to provide advice on the scientific quality, budget, safety, and mission relevance of investigator-initiated research proposals submitted for VA merit review evaluation. Proposals submitted for review include diverse medical specialties within the general areas of biomedical, behavioral, and clinical science research. These subcommittee meetings will be closed to the public for the review, discussion, and evaluation of initial and renewal research proposals, which involve reference to staff and consultant critiques of research proposals. Discussions will deal with scientific merit of each proposal and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly frustrate implementation of proposed agency action regarding the research proposals. As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the subcommittee meetings is in accordance with Title 5 U.S.C. 552b(c)(6) and (9)(B).

Those who would like to obtain a copy of the minutes from the closed subcommittee meetings and rosters of the subcommittee members should contact Holly Krull, Ph.D., Manager, Merit Review Program (10P9B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at (202) 632–8522 or by email at holly.krull@va.gov.

By Direction of the Secretary.
Dated: April 13, 2016.

Jeffrey M. Martin,
Program Manager, Regulation Policy and Management, Office of the General Counsel.

[FR Doc. 2016–08855 Filed 4–15–16; 8:45 am]

BILLING CODE 8320–01–P
Endangered and Threatened Wildlife and Plants; Withdrawal of the Proposed Rule To List the West Coast Distinct Population Segment of Fisher; Proposed Rule
DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

50 CFR Part 17


RIN 1018–BA05

Endangered and Threatened Wildlife and Plants; Withdrawal of the Proposed Rule To List the West Coast Distinct Population Segment of Fisher

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; withdrawal.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), withdraw the proposed rule to list the West Coast Distinct Population Segment of fisher (Pekania pennanti), a mustelid species from California, Oregon, and Washington, as a threatened species under the Endangered Species Act of 1973, as amended (Act). This withdrawal is based on our evaluation of the best scientific and commercial information available. Our evaluation took into consideration an extensive amount of information and comments regarding the proposed West Coast DPS of fisher received during multiple comment periods. Our evaluation of all this information leads us to conclude that the stressors acting upon the proposed West Coast DPS of fisher are not of sufficient imminence, intensity, or magnitude to indicate that they are singly or cumulatively resulting in significant impacts at either the population or rangewide scales. We find the best scientific and commercial data available indicate that the proposed West Coast DPS of fisher does not meet the statutory definition of an endangered or threatened species because the stressors potentially impacting the proposed DPS and its habitat are not of sufficient magnitude, scope, or imminence to indicate that the DPS is in danger of extinction, or likely to become so within the foreseeable future. Consequently, we are withdrawing our proposal to list the West Coast DPS of fisher as a threatened species.

ADDRESSES: The withdrawal of our proposed rule, comments, and supplementary documents are available on the Internet at http://www.regulations.gov at Docket No. FWS–R8–ES–2014–0041. Comments and materials received, as well as supporting documentation used in the preparation of this withdrawal, are also available for public inspection, by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Yreka Fish and Wildlife Office, 1829 South Oregon Street, Yreka, CA 96097; telephone 530–842–5763; or facsimile 530–842–4517.

DATES: The October 7, 2014, proposed rule (79 FR 60419) to list the West Coast DPS of fisher as a threatened species is withdrawn as of April 18, 2016.

FOR FURTHER INFORMATION CONTACT: Jenny Ericson, Deputy Field Supervisor, Yreka Fish and Wildlife Office (see ADDRESSES). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish this document. Under the Endangered Species Act, a species may warrant protection through listing if it is endangered or threatened throughout all or a significant portion of its range. Listing a species as an endangered or threatened species can only be completed by issuing a rule. We issued a proposed rule to list a distinct population segment (DPS) of fisher in California, Oregon, and Washington (identified herein as the “proposed West Coast DPS of fisher,” “proposed DPS,” or “fishers in the west coast States”) in 2014. This document withdraws that proposed rule because we now determine that the threats identified in the proposed rule are not as significant as previously thought based on our evaluation of the best scientific and commercial information available at this time. Our evaluation took into consideration an extensive amount of information and comments submitted during the two public comment periods regarding the proposed West Coast DPS of fisher. At this time, we do not find any indication that fishers or their habitat in the west coast States are responding negatively to the stressors to which they are exposed to a significant degree at either the population or rangewide scales, nor are they likely to do so in the foreseeable future. The best available scientific and commercial data lead us to conclude that the proposed West Coast DPS of fishers is not in danger of extinction now or in the foreseeable future. Therefore, we cannot conclude that the proposed DPS meets the definition of an endangered or threatened species under the Act, and we are withdrawing the proposed rule.

The basis for our action. Under the Endangered Species Act, we can determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We now determine that although stressors to one or more populations of fishers in the west coast States exist, they are not causing significant impacts at either the population or rangewide scales that would indicate that the magnitude, imminence, or severity of these threats are such that the proposed West Coast fisher DPS is in danger of extinction, or likely to become so within the foreseeable future.

Peer review and public comment. We sought comments from independent specialists to ensure that our consideration of the status of the species is based on scientifically sound data, assumptions, and analyses. We invited these peer reviewers to comment on our listing proposal and our draft Species Report. We also considered all comments and information received during the comment periods. Public comments and peer reviewer comments are addressed at the end of this Federal Register document.

Acronyms and Abbreviations Used in This Document

We use many acronyms and abbreviations throughout this document. To assist the reader, we provide a list of these here for easy reference:

Act = Endangered Species Act of 1973, as amended
AR = anticoagulant rodenticides
BLM = Bureau of Land Management
CAL FIRE = California Department of Forestry and Fire Protection
CCAA = Candidate Conservation Agreement with Assurances
CDFG = California Department of Fish and Game (see below)
CDFW = California Department of Fish and Wildlife (formerly CDFG)
CEQA = California Environmental Quality Act
CESA = California Endangered Species Act
CFR = Code of Federal Regulations
DPS = Distinct Population Segment
EIS = Environmental Impact Statement
EPA = U.S. Environmental Protection Agency
ESU = evolutionarily significant unit
FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act
FPA = Forest Practices Act
FPR = Forest Practice Rules
FR = Federal Register
GNN = gradient nearest neighbor data/maps
KFA = Klamath Falls Resource Area
LRMP = Land Resource Management Plan
LSR = late-successional and old-growth forest reserve (under the NWFP)
MDL = Multi-District Litigation
MOU = Memorandum of Understanding
MTBS = Monitoring Trends in Burn Severity (mapping data)
NCSO = northern California-southern Oregon native population of fishers
NEPA = National Environmental Policy Act
NFMA = National Forest Management Act
NSN = northern Sierra Nevada reintroduced population of fishers
NWFP = Northwest Forest Plan
OAR = Oregon Administrative Rules
ODF = Oregon Department of Forestry
ODFW = Oregon Department of Fish and Wildlife
OGSI–80 = old-growth structural index of 80 or more, per Davis et al. (20XX, entire)
ONP = Olympic Peninsula reintroduced population of fishers (Olympic National Park)
RCW = the Forest Practices Act, Revised Code of Washington
RMP = Resource Management Plan
Service = U.S. Fish and Wildlife Service
SNFPA = Sierra Nevada Forest Plan Amendment
SOC = southern Oregon Cascades (Crater Lake) reintroduced population of fishers
SPR = Significant Portion of its [species] Range
SSN = southern Sierra Nevada native population of fishers
THP = timber harvest plan
USDA = U.S. Department of Agriculture
USDI = U.S. Department of the Interior
WDNR = Washington Department of Natural Resources

Previous Federal Actions
Please refer to the proposed listing rule for the West Coast DPS (79 FR 60419; October 7, 2014) of fisher for a detailed description of the Federal actions concerning this proposed DPS that occurred prior to publication of the proposed listing rule. The proposed listing rule established a 90-day comment period, during which we held one public hearing and seven public information meetings. We received requests to extend this comment period on the proposed rule beyond the January 5, 2015, due date. In order to ensure that the public had an adequate opportunity to review and comment on the proposed rule, we extended the comment period for an additional 30 days to February 4, 2015 (79 FR 76950; December 23, 2014).

On April 14, 2015, we reopened the comment period on our October 7, 2014, proposed rule to list the West Coast DPS of fisher for another 30 days (80 FR 19953). We also announced a 6-month extension of the final listing determination for the proposed West Coast DPS of fisher as a threatened species to acquire new information and comments regarding toxicants and rodenticides and survey information in order to help assess distribution and population trends, due to disagreement regarding the sufficiency or accuracy of the available data related to those issues. The comment period was reopened until May 14, 2015, and we announced that we would publish a listing determination on or before April 7, 2016.

Background
In our October 7, 2014, proposed rule (79 FR 60419), we proposed to list the West Coast DPS of fisher; this DPS included both extant populations of fisher and much of the fisher’s historical range from the southern Sierra Nevada of California north through the States of Oregon and Washington. In that proposed rule, we also presented two possible alternative DPS configurations for consideration and comment, and solicited additional possible DPS alternatives from both peer reviewers and the public. Although this presentation of alternative DPS delineations is unusual, it reflects, in part, the high level of uncertainty and wide range of opinions within the Service regarding the appropriate status of the DPS. In our proposed rule, we specifically referenced the complexity of the issues under review in our request for public comment, and throughout the document we noted the tremendous regional variability in the degree to which stressors may be affecting fishers or their habitat. Following thorough consideration of all information available to us, our decision is that the original DPS configuration as presented in the proposed listing rule is most appropriate to serve as the focus of our analysis here (see Figure 1). Thus throughout this document, when we refer to the “analysis area,” we are referring to the area within that DPS boundary.
Although much of the proposed West Coast DPS of fisher is a genetically unique (i.e., native NCSO and SSN populations, and reintroduced NSN population) and markedly separate population segment from the rest of the fisher’s range in North America, fishers in the west coast States have similar life-history and habitat requirements across their entire range. In the proposed rule and this document, we use information specific to fishers in the west coast States where available. Where fisher-specific data and studies from the west coast States were not available, we used information from fisher studies from elsewhere in North America. 

1 – This figure has not been updated from the 2014 proposed listing rule. We received many new fisher detection data, and this information is currently being reviewed for redundancy against the survey records we had obtained previously. This new information does not include new locations beyond the current population boundaries with the exception of detections in the southern Oregon Cascades and the southern Cascades of California. We are currently reviewing information for redundancy and will make an updated map available when we have completed this quality control process.
America. This approach follows the scientific management principles and practices followed by the wildlife and land management agencies that have responsibility for management of both fishers and their habitat within the west coast States.

A detailed discussion of the proposed West Coast DPS of fisher's description, taxonomy, habitat, life-history characteristics (e.g., reproduction), habitat description, habitat use (e.g., dispersal and food habits), and distribution and abundance is available in the final Species Report (Service 2016, entire), prepared by a team of Service biologists. The team included biologists from the Service's Yreka, Sacramento, Arcata, and Klamath Falls Fish and Wildlife Offices within the Pacific Southwest Region, the Western Washington and Oregon Fish and Wildlife Offices within the Pacific Region, staff from both the Pacific Southwest and Pacific Regions of the Fish and Wildlife Service, and staff from our national Headquarters Office. The final Species Report (Service 2016, entire) represents a compilation of the best scientific and commercial data available concerning the biological status of the proposed West Coast DPS of fisher, including present and potential future stressors to fishers in this DPS.

We consider a stressor to be any activity or process that may have some negative effect on fishers or their habitat—for example, timber harvest activities or wildfire that results in the removal of denning structures required by fishers for successful reproduction, or mortality of individuals from vehicle collisions, disease, or predation. Stressors are primarily related to human activities, but can be natural events and act on fishers at various scales and intensities throughout the analysis area. All species experience stressors; however, we consider a stressor to rise to the level of a threat to the species (or in this case the proposed West Coast DPS of fishers) if the magnitude of the stressor is such that it is resulting in significant impacts at either the population or rangewide scales to fishers or their habitat. As described in our proposed rule (79 FR 60419, p. 60427), in considering what stressors might constitute threats, we must look beyond the mere exposure of the DPS to the stressor to determine whether the DPS responds to the stressor in a way that causes actual negative impacts to the DPS. In our draft Species Report, we attempted to evaluate the magnitude of the effects of identified stressors to the proposed West Coast DPS of fisher and its habitat by quantifying the severity and scope of those stressors. That analysis required us to make assumptions or extrapolate impacts in an effort to quantify stressors in areas where stressor-specific information was not available. Our presentation of the scope and severity of stressors in quantitative terms may have created a false sense of precision with regard to the level of scientific accuracy underlying these estimates. To avoid this perception, in our final Species Report we use a qualitative approach to describe stressors (i.e., stressors are categorized as low, moderate, or high, as defined in that Report). We use quantitative data wherever available, but if specific data are lacking, we rely on qualitative evidence to derive a qualitative descriptor of each stressor, based on the best scientific and commercial information available, rather than extrapolating. The quantitative measures from the draft Species Report are preserved and provided in Appendix C in the final Species Report. A key point for our determination regarding the proposed West Coast DPS of fisher, however, is that our ultimate conclusion regarding the status of the DPS remains the same regardless of whether we consider the stressors to the DPS in quantitative or qualitative form: Fishers within the west coast States have been exposed to multiple stressors, in some cases over many decades, and per surveys over the past decade or more, the best available data do not indicate significant impacts at either the population or rangewide scales. In other words, stressors may be impacting some individual fishers or habitat in one or more populations, but the best available information does not show that the stressors are functioning as operative threats on the fisher’s habitat, populations, or the proposed DPS as a whole to the degree we considered to be the case at the time of the proposed listing. Thus, we no longer find that the stressors are functioning as operative threats on the proposed DPS to the extent that listing is warranted (see Summary of Basis for This Withdrawal, below).

The final Species Report and other materials relating to this final agency action can be found at http://www.regulations.gov under Docket No. FWS–R8–ES–2014–0041. [Note: In the draft Species Report and the proposed listing rule we identified “threats” to the proposed DPS. However, in this withdrawal and based on our evaluation of the best scientific and commercial information available, as described above, we now refer to the threats identified in the proposed rule as “stressors,” because the best available data do not indicate significant impacts across the proposed DPS at either the population or rangewide scales, as described above].

Summary of Basis for This Withdrawal

At the time of our October 7, 2014, proposed rule, we had concluded that fishers are still absent from much of their historical range (the two original extant populations have not expanded), threats to the DPS at the time of the 2004 Finding are still in place, and some threats since the time of the 2004 Finding have increased or are new. We additionally concluded that it is too early to determine if the reintroduced populations will persist (79 FR 60419, p. 60436). Threats identified in the 2014 proposed rule included habitat loss from wildfire and vegetation management, toxicants, and the cumulative impact and synergistic effects of these and other stressors in small populations.

We have reviewed and considered the best scientific and commercial data available to us, including public comments, Federal and State agency comments, peer review comments, issues articulated at the public hearing and public meetings, and all new information brought to our attention during the public comment periods, relevant to the conservation status of the proposed West Coast DPS of fisher. There was a significant amount of varied scientific, Service, other agency, and public opinion regarding the status of fisher both prior to, and following, the October 7, 2014 (79 FR 60419), proposed listing of the West Coast DPS of fisher. The equivocal nature of the information regarding potential threats and status of the proposed West Coast DPS of fisher at the time of our proposed rule led us to ask the public for input on many questions we posed in the proposed listing rule to help us better understand the degree of threats faced by the proposed DPS and its status. By reconsidering the information available to us prior to the proposed listing as well as all new information received after the proposed rule was published, we have considered all best scientific and commercial information available at this time.

Upon careful consideration and evaluation of all of the information before us, we have arrived at a different conclusion regarding the status of the proposed West Coast DPS of fishers. In our proposed determination, we identified stressors that could impact the fishers in the west coast States negatively and identified some of those stressors (wildfire and fire suppression,
vegetation management, and small population size and isolation) as threats. We also identified exposure to toxics (specifically ARs) and cumulative effects from multiple stressors as threats, although there were uncertainties at that time. We applied the standards we had laid out in our proposed rule: “This determination does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of stressors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these stressors are operative threats that act on the species to the point that the species meets the definition of an endangered or threatened species under the Act.” (October 7, 2014; 79 FR 60419, p. 60427).

We now conclude that the threats we identified are not of such immedience, intensity, or magnitude that they are manifesting in terms of significant impacts at either the population or rangewise scales. Further, we conclude that in the foreseeable future it is likely that fishers in the west coast States will continue to maintain their populations in the face of these stressors just as they have demonstrated the capacity to do so in recent times. We relied on an evaluation of the foreseeability of those stressors and the foreseeability of the effect of the stressors on the proposed DPS, only so far as we can rely on the data to formulate reliable predictions about the status of the proposed DPS, and not extending so far as to venture into the realm of speculation. In this case, many of the stressors fell into a foreseeable future timeframe within which we concluded the effects of stressors on the proposed DPS could be reliably projected out over a time period of approximately 40 years. Therefore, we conclude that the stressors acting on the proposed West Coast DPS are not so great that fishers in the DPS are currently in danger of extinction (endangered), or likely to become so within the foreseeable future. Our evaluation of all of the best scientific and commercial data available does not allow us to draw this conclusion at this time. As we cannot conclude that the proposed West Coast DPS of fisher meets the definition of an endangered or threatened species under the Act, we must withdraw our proposed rule. Our complete rationale for withdrawing our proposal is outlined in the Summary of Factors Affecting the Species and Determination sections of this document.

Species Information

A thorough review of the taxonomy, life history, and ecology of the fishers in the west coast States is presented in the final Species Report (Service 2016, entire; Docket No. FWS–R8–ES–2014–0041). The fisher is a medium-sized, light-brown to dark blackish-brown mammal, with the face, neck, and shoulders sometimes being slightly gray; the chest and underside often has irregular white patches. The fisher is classified in the order Carnivora, family Mustelidae, a family that also includes weasels, mink, martens, and otters (Service 2016, p. 8). The occurrence of fishers at regional scales is consistently associated with low- to mid-elevation coniferous and mixed conifer and hardwood forests with characteristics of late-successional forests (large-diameter trees, coarse downed wood, and singular features of large snags, tree cavities, or deformed trees). Historically, fishers were well-distributed throughout the analysis area in the habitats described above. In Washington and Oregon, outside of the existing known reintroduced populations, fishers are considered likely extirpated (although on occasion individual fishers may be detected; specific to the Oregon Cascades, ODFW commented that the absence of fishers cannot be determined without dedicated surveys following a peer-reviewed protocol, and it is possible that fishers occur at low population levels). In California, recent survey efforts have not detected fishers in the northern Sierra Nevada, outside of the reintroduced population. Key fisher habitat includes forests with diverse successional stages containing a high proportion of mid- and late-successional characteristics. Throughout their range, fishers are obligate users of tree or snag cavities for denning, and they select resting sites with characteristics of late-successional forests. Late-successional forest characteristics are maintained and recruited through natural and ecological processes such as fire, insect-related tree mortality, disease, and decay (e.g., Service 2016, pp. 64, 123–124).

Fishers are found only in North America. Fishers on the west coast are found in British Columbia, Washington, Oregon, and California. The proposed West Coast DPS of fishers encompasses the area where fishers historically occurred throughout western Washington, western Oregon, and California to the Sierra Nevada (Service 2016, pp. 25–29). Currently, the fishers in the west coast States include two original native fisher populations (Northern California–Southwestern Oregon Population (NCSO) and the Southern Sierra Nevada Population (SSN)). There are three reintroduced populations—Olympic Peninsula Reintroduced Population (ONP) in Washington, Southern Oregon Cascades (SOC) Reintroduced Population in Oregon, and the Northern Sierra Nevada Reintroduced Population (NSN) in California. Based on survey data and genetic information submitted during the two public comment periods, the SOC and NSN reintroduced populations are now considered to be within the boundary of the NCSO population area (Service 2016, pp. 38–41). An additional reintroduction site in the South Washington Cascades was established in December 2015. Following are brief accounts of the populations and the new reintroduction site in the South Washington Cascades. Primary stressors and conservation activities are introduced in these summaries and described in more detail in the Summary of Factors Affecting the Species section below, and fully evaluated and described in the “Review of Stressors” section of the final Species Report (Service 2016, pp. 53–162). Conservation efforts resulting from the plans and strategies being implemented within each of the population areas are described in detail in the final Species Report in either the “Conservation measures to reduce the stressors related to habitat or range of the species” section (Service 2016, pp. 115–122), or, when applicable, within specific stressor discussions of the final Species Report.

Here we describe (from north to south) the known native and reintroduced populations of fisher within the west coast States, as well as one recent reintroduction:

1. Reintroduced Population—Olympic Peninsula (ONP)

The Washington Department of Fish and Wildlife (WDFW), in cooperation with Olympic National Park, United States Geological Survey, and others, began to reintroduce fishers onto Park
Service lands on the Olympic Peninsula in Washington in January 2008 (Lewis and Happe 2008, p. 7). These reintroductions were complete at the end of 2010 with a total of 90 fishers (40 males and 50 females) relocated from British Columbia to Olympic National Park (Lewis et al. 2011, p. 4). WDFW monitored translocated fishers for several years with radio-telemetry and were able to evaluate post-release survival, home-range establishment, reproduction, and resource selection of founding individuals. Initial findings indicate that survival was highly variable among release years (Lewis et al. 2012, pp. 5–8), but project researchers confirmed reproduction seven times from 2009 to 2011 (Lewis et al. 2012, pp. 9–10). A second monitoring phase consisting of noninvasive surveys of fisher distribution and relative abundance started during summer 2013, which was designed to determine whether a self-sustaining population of fishers has been established in the Olympic Peninsula. In 2013 and 2014 the monitoring team detected fishers in 14 of the 132 areas sampled, including 6 of the founding fishers and 7 new recruits of the 132 areas sampled, including 6 of the founding fishers and 7 new recruits.

The most significant stressors on this reintroduced population are predation and collisions with vehicles. Conservation efforts being implemented for this population are associated with the State of Washington Fisher Recovery Plan (Hayes and Lewis 2006), which is focused on reintroduction efforts, and NPS management in accordance with the Organic Act of 1916, as amended (54 U.S.C. 100100) and the National Park Service General Authorities Act of 1970 (54 U.S.C. 100101(b)) (see Existing Regulatory Mechanisms, below). In addition, in January 2016, the Service received an application for a Section 10(a)(1)(A) Enhancement of Survival Permit from the WDFW to implement a draft Candidate Conservation Agreement with Assurances (CCAA) for fisher. The Service announced the availability of the draft CCAA and EA, and a 30-day open comment period on February 29, 2016 (81 FR 10269). If the Enhancement of Survival Permit is issued, WDFW would hold the permit and be responsible for enrolling non-Federal Washington landowners in the CCAA and issuing certificates of inclusion; see the final Species Report for further details (Service 2016, p. 118).

(2) New Reintroduction Site—South Washington Cascades

The WDFW began a fisher reintroduction project in the South Cascades of Washington State on December 3, 2015. Between December 3, 2015, and February 10, 2016, project employees released 23 fishers from the Cispus Learning Center along the Cispus River, just south of Mount Rainier National Park. This project is the second phase of WDFW’s efforts to recover fishers in Washington according to the Washington State Recovery Plan for the Fisher (Hayes and Lewis 2006). The reintroduction plan (Lewis 2013) calls for a total of 160 fishers to be released into the Cascade Mountains at a rate of 40 per year for 4 years (2 years in the South Cascades, 2 years in the North Cascades). The source population for the fishers (British Columbia) is the same as for the Olympic National Park reintroduction. The Washington fisher recovery plan has the goal of establishing multiple self-sustaining populations of fishers in Washington (Hayes and Lewis 2006). We are not referring to this group of fisher individuals in the South Cascades as a population at this time because they have not yet had the opportunity to successfully reproduce. These animals are not physically or demographically connected to any other populations of fishers. Population size and trend information are not known at this time. The most significant stressors on this reintroduced population are predation and collisions with vehicles. Conservation efforts being implemented for this population are associated with the State of Washington Fisher Recovery Plan (Hayes and Lewis 2006), which is focused on reintroduction efforts, and NPS management in accordance with the Organic Act of 1916, as amended (54 U.S.C. 100100) and the National Park Service General Authorities Act of 1970 (54 U.S.C. 100101(b)) (see Existing Regulatory Mechanisms, below). In addition, in January 2016, the Service received an application for a Section 10(a)(1)(A) Enhancement of Survival Permit from the WDFW to implement a draft Candidate Conservation Agreement with Assurances (CCAA) for fisher. The Service announced the availability of the draft CCAA and EA, and a 30-day open comment period on February 29, 2016 (81 FR 10269). If the Enhancement of Survival Permit is issued, WDFW would hold the permit and be responsible for enrolling non-Federal Washington landowners in the CCAA and issuing certificates of inclusion; see the final Species Report for further details (Service 2016, p. 118).

Fishers in the SOC portion of the NCSO population stem from a translocation of 24 fishers from British Columbia and Minnesota to the area west of Crater Lake between 1977 and 1981 (Aubry and Lewis 2003, p. 84). Based on survey and research efforts starting in 1995 genetic evidence shows these fishers continue to persist (Drew et al. 2003, p. 57; Aubry et al. 2004, pp. 211–215; Wisely et al. 2004, p. 646; Pilgrim and Schwartz 2014–2015, entire). Little survey work has occurred north of this population, although a radio-collared juvenile male dispersed 34 mi (55 km) northeast of this population to the Big Marsh area on the Deschutes National Forest (Aubry and Raley 2006, p. 5). West of Big Marsh, over the Cascade crest, the first verifiable contemporary detection of a fisher on the Willamette National Forest occurred in 2014 (Wolfer 2014, pers. comm.); however, genetic evidence was not obtained to determine whether or not this individual was from fishers reintroduced from British Columbia and Minnesota.

Information is not available on population size for the SOC portion of NCSO population. Recent detections of fisher in areas where they were not previously recorded (e.g., north and eastern portions of Crater Lake National Park and portions of the Lakeview and Medford BLM study area) may or may not represent an expansion of this population. However, based on the current survey efforts along with multiple unsolicited sightings of fishers in the past few years on the Lakeview District BLM Klamath Falls Resource Area (KFRA) where fishers were previously not detected (based on protocol surveys conducted from 1998 to 2001), fishers are now being detected in the KFRA (Hayner 2016, pers. comm.).

Fishers in the NSN portion of the NCSO population stem from a 2009 to 2012 translocation of 40 fishers from Humboldt, Siskiyou, and Trinity counties, California, to the SPI Stirling Management Unit in Butte, Plumas, and Tehama counties, California. Ongoing monitoring of fishers that were reintroduced have confirmed that some fishers born and raised in established home ranges and have successfully reproduced. Trapping efforts in the fall...
of 2015 as part of ongoing monitoring of the reintroduced population indicate a minimum of 49 fishers (34 females, 15 males), 9 more individuals than were originally introduced.

Population size estimates for the approximately 17,375 mi² (45,000 km²) NCSO population (excluding the SOC and NSN reintroduced populations) using various methodologies range from a low of 258–2,850 individuals, based on genetic data (Tucker et al. 2012, pp. 7, 9–10), to a high of 4,018 individuals based on extrapolation of data from two small study areas within the NCSO population to the entire NCSO population (Sel et al. 2008, pp. 3–5). A recent 2015 estimate of 632–1,165 fishers was based on data collected by CDFW as part of a meso-carnivore monitoring program in northern California (Furnas et al. 2015, pers. comm.). It is important to note that the sampling area for the CDFW study excluded southwest Oregon and the coastal redwood of California; thus, this estimate is not representative of the entire area within the NCSO population.

Population trend information for the NCSO population is based on two long-term studies. The NCSO population includes the area in both the SOC and NSN reintroduced fisher populations. (1) The Hoopa study area is approximately 145 mi² (370 km²) in size and represents the more mesic portion of the NCSO population area. Fisher studies have been ongoing since 1996. The population trend from 2005–2012 indicates a lambda (population growth rate) of 0.992 (C.I. 0.883–1.100) with a higher lambda rate for females 1.038 (0.881–1.196) than males 0.912 (0.777–1.047) (Hipley et al. 2014, p. 102, Hipley 2015, pers. comm.). Demographic parameters are showing a decrease in overall male fisher survival. A lambda of approximately 1.0 indicates a stable overall population trend.

(2) The Eastern Klamath Study Area (EKSA) is approximately 200 mi² (510 km²) in size and represents the more xeric portion of the NCSO population area. Monitoring has been conducted since 2006. Estimates for lambda from 2006–2013 are 1.06 (C.I. 0.97–1.15) (Powell et al. 2014, p. 23). This lambda of approximately 1.0 indicates a current stable population within the study area.

The major stressors experienced by the NCSO population are wildfire and fire suppression activities, vegetation management, ARs, and, in some areas, predation. Within the Oregon portion of the NCSO population two fishers were tested for the presence of ARs; exposure to ARs has been tested for in both Conservation measures that benefit fishers include those being implemented within the portion of the range covered by the NWF, including potential measures associated with section 7 consultations in overlapping northern spotted owl (Strix occidentalis caurina) designated critical habitat. The principal conservation efforts currently in progress in Oregon include the recently signed intergovernmental Memorandum of Understanding (MOU) for fisher conservation, and, upon finalization, the western Oregon fisher CCAA (81 FR 15737). A strong desire to implement the western Oregon fisher CCAA is exhibited by us receiving, as of mid-March 2016, letters of intent from nine different landowners (private and ODF) covering nearly 2 million ac (809,371 ha); most of these letters also commit to financial or in-kind support of a coordinated program of work to increase our understanding of fisher populations and potentially reintroduce fishers in Oregon. In addition, ODF has committed, via a separate letter of intent, to submit a budget request of $1,000,000 to the Oregon legislature to fund and administer the CCAA and other fisher conservation actions in Oregon. The portion of the NCSO population in California, ongoing monitoring efforts for the SPI Stirling Management Area CCAA indicate the reintroduction efforts may result in establishment of an additional fisher population in the northern Sierra Nevada. The NEPA process will soon be initiated for the approximately 1.6 million-ac (647 thousand-ha) CCAA for fishers on SPI ownership in the Klamath, Cascade, and Sierra Nevada mountains. If implemented, this proposed CCAA could secure habitat for the fishers for the 10-year time period of the permit and likely retain important fisher habitat components into the future.

(4) Original Native Population—Southern Sierra Nevada (SSN)

The SSN native population of fisher is small and is geographically separated from the remainder of the fishers in the west coast States. The SSN population is found in Mariposa, Madera, Fresno, Tulare, and Kern counties in California. While historically the population extended farther north, today the northern limit is the Merced River in Yosemite National Park in Mariposa County. The southern limit is the forested lands abutting the Kern River Canyon, while the eastern limit is the high-elevation, granite-dominated mountains, and the western limit is the low-elevation extent of mixed-conifer forest. Much of the evidence suggests that the isolation of the SSN population from other populations of fisher within the west coast States is longstanding and predates European settlement (Knaus et al. 2011, entire; Tucker et al. 2012, entire; Tucker 2015, pers. comm., pp. 1–2).

No census of the SSN fisher population has been conducted. Estimates for the SSN population range from a low of 100 to a high of 500 individuals (Lamberson et al. 2000, entire). A recent estimate of 256 female fishers was based on available habitat (Spencer et al. 2016, p. 44). Other population estimates are: (1) 125–250 adult fishers (Spencer et al. 2011, p. 788); (2) fewer than 300 adult fishers (Spencer et al. 2011, p. 801); and 276–359 fishers, including juveniles and subadults (Spencer et al. 2011, p. 802). The latter estimate was based on extrapolation from portions of the population where fishers have been intensely studied to the range of the entire population.

An 8-year monitoring study that sampled 139.5 units (i.e., sample sites)/year showed no decline and an occupancy. However, this study had been designed to be run for 10 years while sampling 288 units/year and was intended to have an 80 percent probability of detecting a 20 percent decline over 10 years (Zielinski et al. 2013, p. 11; Tucker 2013, p. 82). As a result of the smaller sample size and shorter duration, the results of this study must be considered inconclusive. Another study of radio-collared fishers monitored from 2007 through 2014 in the SSN population showed the survival rate (calculated using demographic parameters) of adult males, but not females, is lower than other populations in the west coast States, and estimates a lambda of 0.97 (C.I. 0.79–1.16) (Sweitzer et al. 2015a, pp. 781–783; Sweitzer et al. 2015b, p. 10). Population growth in the SSN population area is thus estimated to trend less than 1.0; the authors suggest the population is not in persistent decline, however, but is offset by periods of stability or growth (Sweitzer et al. 2015a, p. 784). Although the authors express concern for the population and the need for continued monitoring, their research suggests a basically stable trend when considered together with information on population size and density (Sweitzer et al. 2015b, p. 10).

The major stressors on this population are wildfire and fire suppression activities, vegetation management, high mortality rates from predation, and small population size. Potential conservation measures include the development of the Southern Sierra Nevada Fisher Conservation Strategy (Spencer et al. 2016, entire).
Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Each of these factors is discussed below.

A thorough analysis and discussion of the stressors that may impact the proposed West Coast DPS of fisher is included in the final Species Report (Service 2016, entire) associated with this document (and available at http://www.regulations.gov under Docket No. FWS–R8–ES–2014–0041). All potential threats of which we are aware that are acting upon fishers or their habitat within the proposed West Coast DPS currently or in the foreseeable future were evaluated and addressed in the final Species Report, and are summarized in the following paragraphs.

Many of the stressors on fisher populations and their habitat are present throughout the proposed DPS’s range, although their effects vary across the range. For example, the population and habitat in the SSN population area likely will continue to be more susceptible to the various stressors than will the NCSO population area given SSN’s smaller population size and more limited amount of unoccupied, suitable habitat available. Nevertheless, at this point in time, our review and consideration of the best available information does not indicate that loss of or declines in these populations, or a contraction of their ranges, is either ongoing or is likely to occur in the foreseeable future (see “Review of Stressors” section of the final species report (Service 2016, pp. 53–162) and Determination section of this document). As discussed in the stressor summaries and Determination sections, below, our evaluation of the best available information leads us to conclude that the native populations will persist into the future (which is also likely for the reintroduced populations, although more time is needed to confirm their persistence with certainty), and that as a whole the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act. Although our finding that the proposed West Coast DPS of fisher is not endangered or threatened does not depend on it, we anticipate that the fishers in the new reintroduction in the South Washington Cascades will likely survive and reproduce (Lewis 2013, pp. 4–5), based on our past experience with other fisher reintroductions. If successful, the South Washington Cascades fisher reintroduction will provide an additional population in the future that would provide even greater insurance against the fisher’s risk of extinction in the west coast States caused by possible catastrophic events (see redundancy discussion under the Small Population Size and Isolation, below). Finally, the best available information indicates that these populations will continue to receive direct or indirect management that we reasonably can predict will contribute to the conservation of fishers in the west coast States as a whole, although these future conservation activities (and the anticipated future population in the South Washington Cascades), are not relied upon as part of the basis for this decision.

The stressors that are of highest current or future scope and magnitude within the range of the proposed DPS (i.e., the most significant stressors overall across the range of the proposed DPS) include those that may result in current or future habitat destruction or modification and natural or human-induced stressors affecting fishers in the west coast States (i.e., wildfire and fire suppression, and vegetation management) and exposure to toxicants (specifically ARs). These impacts, along with those that are currently considered less significant or minor (i.e., rural or suburban development, forest insect and tree diseases, climate change, trapping and incidental capture, research activities, disease or predation, collisions with vehicles, and small population size), also have the potential to act cumulatively or synergistically to negatively affect the populations of fishers in the west coast States.

Forest insects and tree diseases were discussed as stressors in the draft Species Report with respect to their influence on habitat loss and fragmentation and the potential synergistic effects associated with climate change (Service 2014, pp. 72, 146, 170–172). However, this stressor was not summarized in the proposed listing rule. We have included a summary of forest insects and diseases in this document.

We recognize that multiple stressors have impacted individuals of the proposed West Coast DPS of fisher and their habitat, as well as populations in some cases, and that these stressors may be considered ongoing (and expected to continue into the future) in certain areas within the proposed DPS’s range. Given these ongoing impacts, and the various recommendations or concerns expressed from partners, species experts, and the public, we intend to continue monitoring the biological status of the populations of fisher within California, Oregon, and Washington through active Service-directed science efforts and through the efforts of cooperating Federal, State, and private entities. If at any time in the future the stressors appear to be rising to the level such that listing may be warranted, we will initiate a status review as appropriate.

Following are summary evaluations of stressors assessed for the proposed West Coast DPS of fisher: (1) Wildfire and fire suppression; (2) forest insects and tree diseases; (3) effects of climate change; (4) vegetation management; (5) development (including linear infrastructure); (6) trapping and incidental capture; (7) research activities; (8) disease or predation; (9) collision with vehicles; (10) exposure to toxicants; (11) small population size and isolation; and (12) cumulative or synergistic effects. The inadequacy of existing regulatory mechanisms is also evaluated. We have evaluated these stressors consistent with the five statutory factors set forth in section 4(a)(1) of the Act, although the factors are not set forth in this document.

The final Species Report (found at http://www.regulations.gov under Docket No. FWS–R8–ES–2014–0041) presents the best available information currently known: We note that the final Species Report now describes the magnitude (scope and severity) of various stressors using the terms low, medium, and high. While we have also included as Appendix C the more quantitative evaluation we employed for the draft Species Report, that quantitative analysis implied a greater level of certainty or precision in assessing effects than is supported by the underlying information. The final Species Report includes: (1) A discussion of the stressors that may be impacting the proposed West Coast DPS of fishers, based on our evaluation of the best scientific and commercial information available at the time of the withdrawal; (2) inclusion of corrections
or clarifications, where applicable, such as those identified by peer reviewers or other public commenters; (3) inclusion of significant new information since the proposed listing rule, where applicable; and (4) summary conclusions of our assessment of the best scientific and commercial information currently available.

The following sections provide a summary of the past, current, and potential future impacts to the proposed West Coast DPS of fisher and its habitat. Please see the final Species Report (Service 2016, pp. 33–162) for a full evaluation of the stressors evaluated for the proposed West Coast DPS of fisher.

**Wildfire and Fire Suppression**

Our evaluation of the effects of wildfire on fisher habitat included those activities associated with fire suppression that may result in removal of fisher habitat (for example, backburning, fuel breaks, and snag removal). In the proposed listing rule, we stated that the naturally occurring fire regimes vary widely across the analysis area, and, therefore, the effects of wildfire are also likely to vary geographically (Service 2014, p. 58, 62, Figure 13). In general, high-severity fire has the potential to permanently remove suitable fisher habitat, and is very likely to remove habitat for a period of many decades while the forest regrows. Moderate-severity fire may also remove habitat, but likely in smaller patches and for a shorter length of time. Low-severity fire may reduce some elements of fisher habitat temporarily, but in general is unlikely to remove habitat.

Fishers’ behavioral and population responses to fires are unknown within the West Coast range. Based on fisher information outside of the West Coast range and other related species, it is possible that large fires, particularly those of higher severity and larger scale, could cause shifts in home ranges and movement patterns of fishers in the west coast states, lower the fitness of fishers remaining in the burned area, and create barriers to dispersal. We also: (1) Considered fire and fire suppression to be particularly problematic in the SSN because of the narrow band of habitat that comprises SSN and the small population size; (2) Stated that the degree to which fire-related effects impact NCSO was lower than SSN because the NCSO does not exist in a narrow band of habitat and covers a larger area; (3) Indicated that fire and fire suppression will likely have some negative effect on NCSO because fire will further decrease connectivity in the fragmented habitat of NCSO (noting that it was difficult to fully determine the impact at NCSO because the locations and severities of future fires relative to important habitat components were not known at [that] time); and (4) Indicated that scope and severity of fire are lower in Washington and Oregon given that much of this area is considered to be unoccupied but that fire could have a negative impact on existing fisher populations if fires occur within or in proximity to occupied areas (again, similar to NCSO, noting that the locations and severities of future fires relative to important habitat components were not known at [that] time).

In conducting our updated analysis of the best scientific and commercial information available, we reviewed information provided by commenters and peer reviewers, and made corrections and clarifications of wildfire information in the final Species Report as necessary, and have clarified the discussion of the effects of wildfire on ecosystems. This approach contributed to our goal of describing as accurately as possible whether the best available information indicates if this stressor is causing impacts to fishers or their habitat in the west coast states, and if so, whether those impacts are resulting in significant impacts to individuals, populations, or the proposed DPS range wide. For example, in the final Species Report: (1) We clarified the fire severity categories, particularly as they relate to “mixed-severity” fires (Halofsky et al. 2011, entire). (2) We included and described the significant beneficial aspects of wildfire on the landscape, such as creation or maintenance of some structural elements used by fishers, or how some areas of high-severity fire may contribute to the regeneration of the hardwood component of mixed-conifer forest used by fisher (Cocking et al. 2012, 2014, entire, for example). (3) We noted how low-severity fires can be critical in the creation or maintenance of reproductive habitat for fishers by creating fire scars that enhance the formation of cavities that serve as denning sites (Weir et al. 2012, pp. 237–238). (4) We described how fishers in areas that experience mixed-severity fires could benefit from associated increases in mammalian prey species, including how fishers may use burned forests for foraging (e.g., Hanson 2013, p. 27). (5) We noted how fragmentation due to fire can increase risk of predation due to the lack of cover and higher abundance of predators in fragmented landscapes (Naney et al. 2012, pp. 7–8). (6) We included discussion of studies (Shatford et al. 2007, pp. 144–145; Donato et al. 2009, p. 142; Halofsky et al. 2011, p. 14; Baker 2014, p. 26; Cocking et al. 2014, pp. 94, 102–104) that suggest that systems characterized by highly variable natural disturbances, such as mixed-severity fire regimes, are relatively resilient to recurrent severe fire, and that severe, short-interval fires do not result in loss of species richness, including hardwood and conifer species (suggesting that such fires promote vigorous regeneration of mixed-conifer forest).

In sum, these corrections, clarifications, and revised discussions in the final Species Report provide a clearer picture of the degree to which fisher may be able to use burned...
landscapes and potential effects of wildfire to fisher habitat across the landscape.

When considering all scientific and commercial information available regarding wildfire and fire suppression activities (including new information since the time of the proposed listing rule), we maintain that wildfire is a natural ecological process that occurs throughout the range of the proposed West Coast DPS of fisher. As stated above, there are some indications that wildfire may be increasing in terms of frequency, severity, and magnitude, although these projected increases are greater in California and southern Oregon than areas further north. Whether fires may be increasing in severity is subject to continuing debate; thus, it is necessary for us to use our best professional judgment based on the best fire effects information available. Studies on the effects of wildfire on fisher habitat, although limited, demonstrate a variety of both positive and negative consequences, depending on the specific circumstances (see “Effects of fire on fisher habitat elements” in the final Species Report (Service 2016, pp. 63–65)). If the severity and extent of the fire is such that substantial areas of canopy and large trees are lost, it may take decades for the area to support fisher reproduction. If the fire severity is low or mixed, important habitat elements to fisher can be both created and removed within a home range, such that the burned habitat may continue to support both fisher foraging and reproduction. The degree to which fire may affect fisher populations is unknown, but all indications are that the population response would be specific to the forest type, landscape location, size, and intensity of the fire.

Another factor to consider regarding wildfires is the potential for overlay of future fires with fisher-occupied habitat, and the subsequent potential likelihood of wildfire-displaced fishers moving successfully into nearby suitable unoccupied habitat. Although fishers are not abundant throughout their known current range, their distribution where found covers very large geographic areas of habitat. Because of this broad distribution, even in the event that wildfire frequency and severity increases rather than decreases, it is extremely unlikely that any wildfires would be of such magnitude that they would cover an entire fisher population area. Therefore, while future wildfires may impact individual fishers, with the potential of displacement rather than injury or death, there will likely also be unaffected fishers outside the wildfire zones.

Coupled with this likelihood is the fact that throughout the analysis area, there are numerous areas of suitable but currently unoccupied habitat. While some of these areas may be inaccessible to extant fisher populations, due to being far removed from the known current fisher distribution or to existing landscape patterns that are not conducive to dispersal, there are other areas of suitable unoccupied habitat that are adjacent to occupied habitats or connected to them via dispersal-conducive landscapes. This combination of available and accessible suitable habitat with the likelihood that any future wildfires would be extremely unlikely to affect entire fisher population areas, suggests as it relates to wildfires that habitat is not limiting for fishers across the west coast States. We also note that there are active hazardous fuels reduction plans and projects being actively implemented throughout the analysis area (such as those on Federal lands described in the National Fire Plan, or on private lands in California via California Fire Safe Council or CALFIRE wildfire prevention grants (see “Conservation measures that may reduce impacts of fire effects” in the final Species Report (Service 2016, pp. 76–77)), which should help reduce the future frequency, size, and severity of wildfires.

Our updated analysis of the best information now available leads us to change our previous conclusion that wildfire and fire suppression rise to the level of a threat, particularly given that the best available data do not indicate habitat impacts are significant at either the population or rangewide scales. In other words, following wildfire events and subsequent salvage operations, no surveys or other information have shown this stressor to be functioning as an operative threat on the fisher’s habitat to the degree we considered to be the case at the time of the proposed listing. We have reached this conclusion given:

(1) Our evaluation of past and continued predicted impacts of wildfire in the future across the landscape within the range of the proposed West Coast DPS of fisher;

(2) The beneficial as well as negative aspects of wildfire to fisher habitat;

(3) The beneficial aspects of current and continued management activities into the future to help reduce wildfire impacts (e.g., fuels reduction projects that reduce the risk of high-severity wildfires while retaining appropriate habitat structures, composition, and configuration for fishers); and

(4) The presence of suitable but unoccupied habitat available to the fisher throughout the west coast States (although to a greater extent in the northern portion of the proposed DPS’s range), coupled with the extremely low likelihood that future wildfires would impact entire fisher population areas, and the lack of data to demonstrate that this stressor is manifesting itself to a significant degree across the proposed DPS such that the fisher populations in the west coast States are in decline across its range due to significant wildfire impacts to their habitat.

We acknowledge that individual fishers in the proposed West Coast DPS (or potentially portions of one or more populations) likely are impacted as a result of the level of impact this stressor is having on fisher habitat, particularly to a greater extent in the California portions of the proposed DPS’s range, and that these impacts to fisher habitat could increase in magnitude in the future within portions of the proposed DPS’s range. However, the best available information does not suggest that fisher habitat will experience significant impacts at either the population or rangewide scales in the future as a result of wildfire fire and suppression activities given:

(1) Future wildfires are expected to continue at a similar rate and severity across the landscape as has been occurring in the recent past;

(2) wildfires are not expected to be high severity in all cases such that they destroy habitat for entire populations;

(3) forest ingrowth is expected to continue to provide suitable habitat across the proposed DPS’s range to help offset some future wildfire impacts;

(4) future low- or mixed-severity wildfires are expected to continue to provide some benefits to fisher habitat to help offset some future wildfire impacts.

Climate Change

At the time of the proposed rule, we stated that, overall, fisher habitat is likely to be affected by climate change, but the severity will vary, potentially greatly, among different regions, with effects to fishers ranging from negative, neutral, or potentially beneficial. Climate change is likely to alter the structure and tree species composition of fisher habitat, and also result in changes to habitat of prey communities and ultimately prey availability. However, studies of climate change present a range of effects including some that indicate conditions could remain suitable for fisher, Climate throughout the analysis area is projected to become warmer over the next century, and in particular, summers will
be hotter and drier, with more frequent heat waves. In the northern portion of the analysis area, winters will likely become wetter, but even these areas will likely experience increased water deficits during the growing season.

Climate modeling projections are done at a large scale, and effects to species can be complex, unpredictable, and highly influenced by local-level biotic and abiotic factors. Although many climate models generally agree about the changes in temperature and precipitation, the consequent effects on vegetation are more uncertain. Therefore, it is not clear how changes in forest type, species composition, or growth rate will affect the availability of fisher habitat and its ability to support fisher populations (Service 2014, pp. 71–84). Consequently, we concluded that climate change was not viewed as a threat to fisher habitat at that time or in the foreseeable future.

Based on our evaluation of the best available information known at this time, we reaffirm our previous conclusion that climate change does not rise to the level of a threat now nor do we anticipate it as a threat in the foreseeable future. Most predictions of future conditions are relatively general in nature, and provide little specificity with regard to timeframes or geographic region of occurrence that would be informative in terms of our consideration of future habitat conditions for fishers within the analysis area. This same viewpoint applies even after taking into consideration new information available since the time of the proposed listing rule. Overall, we place relatively greater weight on studies or models that are more narrowly focused on fisher habitat needs, specifically, or are downscaled to our geographic region of interest. Studies specific to predicting the effects of climate change on suitable fisher habitat have produced a wide range of results. Ecotype conversion to woodland, shrubland, or grassland would result in the loss of suitable fisher habitat. This type of shift is predicted, for example, in the southern Sierra Nevada (Gonzalez et al. 2010, Fig. 3; Lawler et al. 2012, p. 388). On the other hand, shifts from conifer forest to hardwood-dominated mixed forest in the southern Sierra Nevada or Klamath region are unlikely to have negative effects on fishers, and the species’ response may be relatively neutral to such a change (Lawler et al. 2012, pp. 385–386; Loharie et al. 2008, p. 4 and Fig. 4). Some studies have suggested that fishers may experience an overall net gain of suitable habitat in response to climate change, for example due to reduced snowpack, or that areas inhabited by fishers will remain in climate refugia (Burns et al. 2003, p. 11476; Olson et al. 2014, pp. 93, 94, 97). Others predict that fisher distribution will remain largely stable (Spencer et al. 2015, p. 143 and Table 9.6, Figures 9.3–9.5). All of these predictions are accompanied by a wide range of assumptions and caveats. In sum, predictions regarding future habitat suitability for fishers in response to climate change are not consistent, and the likely specific response of the species to these predicted changes remains highly uncertain. Moreover, we find that the best available information does not indicate that this stressor is causing or contributing to significant habitat loss or range contraction at either the population or rangewide scales, nor do we anticipate that it will do so in the future. Finally, there is also suitable but unoccupied habitat available for fishers throughout the analysis area where fisher populations occur, although to a greater extent in the northern portion of the proposed DPS’s range. These areas likely would help offset any potential foreseeable future impacts to fisher habitat from climate change (i.e., we do not have information to suggest that fishers are habitat limited currently or expected to become so in the future).

With regard to direct impacts to fishers in the west coast States, fishers may be sensitive, physiologically, to warming summer temperatures (Zielinski et al. 2004, p. 488; Slauzon et al. 2009, p. 27; Facka 2013, pers. comm.; Powell 2013, pers. comm.). If so, fishers likely will either alter their use of microhabitats or shift their range northward and upslope, in order to avoid thermal stress associated with increased summer temperatures, as demonstrated by fishers in California that choose rest sites in areas of cooler microclimate (Zielinski et al. 2004, p. 488), and based on studies that have made projections for future range shifts specifically for fishers (Lawler et al. 2012, entire; Burns et al. 2003, entire; Olson et al. 2014). However, there is no information to suggest that such changes will result in significant, negative impacts to fishers or their habitat at either the population or rangewide scales. Thus, the best scientific and commercial information currently available does not indicate that significant impacts at either the population or rangewide scales as a result of direct effects of climate change are occurring, nor is there any indication that these scales of impacts are likely to occur in the foreseeable future.

Vegetation Management

Vegetation management techniques of the past (primarily timber harvest) have been implicated as one of the two primary causes for fisher declines across the United States. Many fisher researchers have suggested that the magnitude and intensity of past timber harvest is one of the main reasons fishers have not recovered in Washington, Oregon, and portions of California, as compared to the northeastern United States (Service 2014, pp. 54–56). At the time of the proposed rule, we stated that vegetation management techniques have, and can, substantially modify the overstory canopy, the numbers and distribution of structural elements, and the ecological processes that create them. There are also areas where habitat may not be the limiting factor for current or potential fisher populations and where habitat is being managed intentionally or incidentally in ways that benefit fisher. For example, the Northwest Forest Plan (NWFP), which was adopted by the U.S. Forest Service and the BLM in 1994 to guide the management of more than 24 million ac (9.7 million ha) of Federal lands in Washington, Oregon, and northwestern California within the range of the northern spotted owl, provides the basis for conservation of the spotted owl and other late-successional and old-growth forest associated species, such as fisher, on Federal lands (USDA Forest Service and USDI BLM 1994, entire). The NWFP incorporates seven land allocations—Congressionally Resered Areas, Late-Successional Reserves (LSRs), Adaptive Management Areas, Managed Late-Successional Areas, Administratively Withdrawn Areas, Riparian Reserves, and Matrix. Much of the NWFP area currently provides fisher habitat, which is expected to increase over time. The Matrix, which represents only 16 percent of the Federal land within the NWFP area, is the Federal land outside the other six NWFP land allocations and is the area in which most timber harvest and other silvicultural activities are conducted. LSRs, which cover 30 percent of the NWFP area, are expected, in combination with the other allocations and standards and guidelines, to maintain a functional, interactive, late-successional and old-growth forest ecosystem and are designed to serve as habitat for late-successional and old-growth related species including fisher. Management is limited in LSRs, is subject to review, and does not

At the time of the proposed rule, we concluded that data limitations in most sub-regions across the analysis area prevented us from quantifying what proportion of the treatments in the data sets we used may be outside the scope of habitat loss or downgrade (e.g., areas subject to vegetation management activities that may still function as fisher habitat post-treatment). Thus, at that time, the severity scores presented in the draft Species Report and summarized in the proposed listing rule represented our best estimate and constituted a relatively broad range to incorporate this uncertainty. Our previous quantitative analysis of stressors resulting in habitat loss also did not account for ingrowth of fisher habitat over our 40-year analysis timeframe and, therefore, provided no values for net habitat loss (or gain); although we acknowledged that ingrowth occurs, primarily on Federal lands, we lacked the data at that time to quantitatively estimate that ingrowth (Service 2014, pp. 84–92). Although we recognized data limitations in most subregions across the analysis area and we did not account for ingrowth, we found that vegetation management was a threat because activities that remove or substantially degrade fisher habitat through the removal of large structures and overstory vegetation are projected to take place within the analysis area over the next 40 years. Based on information and comments received from peer reviewers and the public, we reevaluated our analysis (as stated previously) and changed our approach to rely on qualitative evidence to derive a qualitative descriptor of each stressor, rather than extrapolating.

Several sources of data currently available provide information on past changes in vegetation in different areas of the proposed West Coast DPS of fisher’s range. Because of the large area encompassed by the fisher, these different sources are not directly comparable and do not easily combine to paint a complete picture of the vegetation trends within the west coast States. The limitations of this information were acknowledged in our proposed rule, and we explicitly requested information from the public to better inform our analysis of this stressor and to help us make a final determination. Specifically, we requested information related to the scope and severity of vegetation management on Federal land within the range of the fisher, and scientific or commercial information on the type, scope, and severity of vegetation management (timber harvest, restoration thinning, fuels reduction, etc.) on non-Federal land in Oregon and Washington. We also requested scientific evaluation of our use of the northern spotted owl habitat data as a surrogate for fisher habitat data, and its use in our draft Species Report as the best available data to determine the scope and severity of vegetation management effects on Federal lands.

Currently, there is no analysis that explicitly tracks changes in fisher habitat in recent decades where loss specifically attributable to vegetation management specifically can be determined. Therefore, we used other available information, as described below, and our best professional judgment to analyze the potential effects of this stressor on the proposed West Coast DPS of fisher. After considering the best available data, including comments received from peer reviewers and the public regarding the vegetation management stressor analysis presented in the draft Species Report (Service 2014, pp. 85–96) and summarized in the proposed listing rule, we updated and reconsidered our analysis. Our updated analysis included use of several different sources of information to depict net forest vegetation changes caused by vegetation management activities within the west coast States. With the exception of the non-Federal timber harvest database in California (CAL FIRE THP 2013), all of these sources are either new or updated since the time of the proposed listing rule (Davis et al. 20XX, entire; USDA Forest Service 2016, entire; Spencer et al. 2016, entire; gradient nearest neighbor (GNN) data/maps). Because we were able to utilize these sources of data, we did not need to rely on northern spotted owl habitat data as a surrogate for fisher habitat data in our final evaluation. Our analysis is described in detail in the final Species Report (Service 2016, pp. 98–111) and summarized as follows.

While historical loss of older forests via timber harvest through much of the 1990s resulted in a substantial loss of fisher habitat in the west coast States, harvest volume has sharply declined throughout this area since 1990, primarily on Federal lands, but also on non-Federal lands. Although timber harvest is still ongoing throughout the west coast States, habitat ingrowth is also occurring, offsetting some of those losses. For example, modeling in the southern Sierra Nevada region indicates that ingrowth of fisher habitat has even replaced losses due todisturbances in the southern Sierra Nevada region since 1990, resulting in a net gain of habitat since that time in that area (see below in this section).

Within the NWFP region, we used information from the draft late-successional and old-growth forest monitoring report (Davis et al. 20XX, entire) to assess changes in fisher habitat as a result of vegetation management. Over a 20-year period (1993–2012), Davis et al. (20XX, pp. 5–6, 13–16) tracked changes in forests classified as OSGI–80, which represents forests that begin to show stand structures associated with older forests (e.g., large live trees, snags, down wood, and diverse tree sizes). Though OSGI–80 forests are not a comprehensive representation of fisher habitat, we considered this report the best available scientific and commercial information to assess changes in fisher habitat within the NWFP area. This information was the only data set available that identified the amount of acres lost to specific disturbance types (e.g., timber harvest or vegetation management, fire) and calculated specific acres of forest ingrowth. In these areas, where available, we had to look separately at timber harvest data to assess loss to vegetation management.

Although loss of older-forest habitat due to timber harvest on non-Federal lands (21.8 percent since 1993) was substantially greater than on Federal lands (1.2 percent since 1993), in combining all ownerships, the percent loss due to timber harvest over the past 20 years was low (8.2) (Service 2016, Table 6). This translates to a 4.1 percent loss per decade (see Table 6 in the final Species Report). The net loss of habitat, however, is somewhat less because 4.1 percent per decade does not include ingrowth of OSGI–80 stands, which were recruited at a rate of 6 percent per decade during the 20-year period, or 3 percent per decade (Service 2016, Table 6). However, it is not an entirely accurate representation to subtract total ingrowth from total loss to vegetation management without also considering all other disturbances that may be offset by ingrowth. We evaluate net vegetation changes as a result of all disturbance types separately below. The projection of vegetation loss may also be an overestimate given that projections in the NWFP showed older forest recruitment on Federal lands would replace losses to the degree that within
50 to 100 years, older forests would be within the range of amounts occurring prior to logging and extensive fire suppression (Davis et al. 20XX, p. 6). Thus, older forest recruitment rates on Federal lands would result in a future increase in ingrowth, offsetting losses more than what is currently projected based on ingrowth rates over the first 20 years of the NWFP.

Elsewhere in the west coast States, where we could track vegetation changes over time, the available data did not indicate the amount or types of disturbances affecting the specific vegetation types; that is, we could only determine net vegetation change of a particular vegetation type, not the specific amount of that type that was lost to a specific disturbance type, unlike in the NWFP area. Timber harvest records were available for the Sierra Nevada region, but idiosyncrasies in the Forest Service FACTS database (see Spencer et al. (2016, p. A–30) and the fact that the available private lands database (CAL FIRE timber harvest plans) did not indicate types of treatment or what portion of the plans may have actually been implemented, led to concerns in translating acres of “treatment” as depicted in these databases into on-the-ground changes in forest vegetation types that could represent fisher habitat. Instead, we relied on net vegetation change data to display actual changes in forests that represent fisher habitat, realizing that net changes include other disturbances and that vegetation management will be some unknown portion of that change.

In the Sierra Nevada region, we approximated fisher habitat change using a GNN vegetation trend analysis to track changes in forests with large structural conditions thought to be associated with fisher habitat. Note that the vegetation category tracked in this analysis is not equivalent to the OGSI–80 forests used by Davis et al. (20XX, entire), where the net change in OGSI–80 stands was 5.9 percent over a 20-year period, or almost 3 percent per decade. Instead, we used defined GNN structure conditions describing forests with larger trees (greater than 20 in (50 cm)), realizing this may not include all vegetation types used by fishers. This analysis showed that net loss of forests with larger structural conditions was 6.2 percent across all ownerships over the past 20 years, which equates to a loss of 3.1 percent per decade. Outside of the NWFP area, in the eastern Washington Cascades and eastern Oregon Cascades regions, net losses were 3.2 and 9.5 percent, respectively, translating to 1.6 and 4.8 percent per decade. These losses, while incorporating ingrowth, included all disturbances (e.g., fire) across all ownerships, so the loss due to timber harvest is actually less. In the single analysis where fisher habitat was actually modeled and tracked through time (southern Sierra Nevada region), ingrowth of fisher habitat actually replaced habitat lost by all disturbances between 1990 and 2012, equivalent to an increase of 151 mi² (390 km²) of fisher habitat at the female home range scale, or a 7.8 percent increase in suitable cells during the 22-year analysis window (Spencer et al. 2016, p. A–21). The authors note that their analysis window did not include the large fires of 2013 and 2014, but that even with those losses, a net increase in fisher habitat still results (Spencer et al. 2016, p. 44).

Vegetation Management Summary

In the southern Sierra Nevada, fisher habitat appears to be increasing despite losses to vegetation management and recent large wildfires. Within the NWFP area, where we were able to explicitly track loss of older forest structural condition due to vegetation management activities, the scale of loss was at a low level (4.1 percent per decade) and was partly compensated by ingrowth. We incorporated ingrowth by looking at net forest change over time, although we could not quantify amounts lost to specific disturbance types throughout the west coast States; outside of the NWFP area, net loss of forests with larger structural conditions ranged from 1.6 to 4.8 percent per decade, depending on the region, for all disturbance types. Although the habitat types tracked in the GNN analysis for the non-NWFP area is not the same as the OGSI–80 vegetation type tracked in the NWFP area, the net change in the OGSI–80 type (almost 3 percent per decade) is relatively similar to that observed in forests with larger structural condition outside the NWFP area.

Based on our analysis of the best scientific and commercial information available, we find that forest losses were less than 5 percent per decade, either when looking at just total vegetation management loss within the NWFP area, or looking at net loss (i.e., incorporating ingrowth) that included all disturbances, knowing vegetation management comprises some proportion of that loss. Given the large home range of fishers and the geographic extent of forest management activities throughout the analysis area, some fisher individuals are likely affected as a result of habitat impacts. While these individuals are affected to some degree as a result of loss of cover and structural features associated with various vegetation management activities, we have not found evidence of a population-level response directly from vegetation management activities to fisher habitat. Fishers occur in landscapes and stands where timber harvest has occurred (e.g., Slauson et al. 2003, pp. 7–9; Self and Callas 2006, entire; Hamm et al. 2012, pp. 421–422; Clayton 2013, pp.7–19; Niblett et al. 2015, entire), but there is no information on how different vegetation management activities affect fisher populations and their persistence within the west coast States. Analysis is further confounded because the category of vegetation management contains activities ranging from those that result in substantial loss of habitat attributes valuable to fishers (e.g., large clearcut harvests that remove almost all tree canopy and structural features) to activities that modify habitat at small-scale levels yet retain functionality (e.g., minor reductions in canopy cover and retention of structural features suitable for rest sites, den sites, or prey production).

We have found no empirical evidence that vegetation management is manifesting itself to a significant degree across the proposed West Coast DPS in a way that is causing habitat-related impacts that are causing fisher to decline across its range currently, or that suggests an expected decline across its range in the future. Furthermore, there are large areas of suitable but unoccupied habitat available throughout the west coast States where fisher populations occur, although to a greater extent in the northern portion of the proposed DPS’s range. Overall across the proposed DPS’s range, this suggests that habitat may not currently be a limiting factor for fisher populations in these States, and that these areas likely would help offset any potential future impacts to fisher habitat from potential future vegetation management activities. Overall, the best available scientific and commercial information summarized above and presented in detail in the final Species Report (Service 2016, pp. 98–111) leads us to conclude that impacts from vegetation management do not rise to the level of a threat given the lack of information indicating that these activities are significantly affecting habitat currently at either the population or rangewide scales. We also find that these activities are not likely to significantly affect habitat at either the population or rangewide scales in the foreseeable future because our analysis of loss/alteration of habitat shows the trend to be slightly declining (with actual increases in habitat in the
SSN population area); fishers can continue to utilize some managed landscapes; we have detected no population-level response of fishers to vegetation management activities; and habitat does not appear to be limiting for fishers across the proposed DPS.

**Development (Including Linear Infrastructure)**

We stated in the proposed listing rule and draft Species Report, and we reaffirm here, that human population density within the analysis area varies considerably, but density in all areas appear to be increasing. Human population growth within the analysis area may increase needs for housing, services, transportation, and other infrastructure, likely placing ever greater demands on land, water, and other natural resources. Specifically, human infrastructure growth includes recreational opportunities such as ski area developments, vacation cabins, trails, and campgrounds. Besides permanently removing potential fisher habitat, human developments in rural areas are changing land use from forest to other land cover types, which has the potential to fragment previously continuous habitat or hamper fisher movements. Overall, human developments associated with population growth (including linear and other infrastructure) will likely have an increasing impact on fisher habitat into the future, but the severity varies depending on the type and location of development.

We stated in the proposed listing rule that the scope of the human development stressor (which implied inclusion of linear and other infrastructure) is relatively low throughout the analysis area, with the majority of impacts most likely occurring within the Sierra Nevada, Coastal Washington, and Western Washington Cascades portions of the proposed DPS’s range. The best available scientific and commercial information indicates that, although an insignificant amount of suitable habitat is undergoing development such that individual fishers may be impacted, significant impacts to fisher habitat do not appear to be occurring at either the population or rangewide scales, nor is there any indication that these scales of impacts to suitable habitat are likely to occur in the future. Thus, we reaffirm our previous conclusion that development is not a threat to fisher habitat within the proposed West Coast DPS now and in the foreseeable future.

**Forest Insects and Tree Diseases**

Potential impacts associated with forest insects and tree diseases were described in the “Anthropogenic Influences” section of the draft Species Report (Service 2014, p. 72) and mentioned in the proposed listing rule within the context of potential “anthropogenic mortality stressors” that could be synergistically impacting fisher along with other stressors. Confusion in the draft Species Report resulted in conflation of anthropogenic stressors and stressors related to forest insects and diseases, because they were combined in a single section wherein only insects and diseases were discussed and not anthropogenic factors (Service 2014, p. 72). We revised the final Species Report to separate those stressor discussions and we have provided clarification in the final Species Report regarding these potential anthropogenic stressors (Service 2016, pp. 77–78), including correcting the title of the potential stressor to “Forest Insects and Tree Diseases,” and we provide a stand-alone summary of our analysis of this stressor below.

In the proposed rule, we found that the usual pattern of localized outbreaks and low density of tree-damaging forest insects and tree diseases are beneficial, providing structures conducive to rest and den sites used by fishers or their prey (Service 2014, p. 72). However, we noted that it is possible that large, area-wide epidemics of forest disease and insect outbreaks could potentially displace fishers if canopy cover is lost, and if salvage and thinning prescriptions in response to outbreaks degrade the habitat (Naney et al. 2012, p. 36). Examples of potential forest insect or tree diseases that have been present within the west coast States but to our knowledge have not resulted in impacts to fisher habitat include:

1. Mountain pine beetle, which is currently known in British Columbia (Weir and Corbould 2008, entire; 2010, entire); and
2. Sudden oak death (*Phytophthora ramorum*), which is currently known to impact forests in southwestern Oregon and northwestern California.

At this time, the best available information does not indicate that any forest insects or tree diseases are significantly affecting the proposed DPS currently. Moreover, although some diseases have been present within the west coast States for many years, the best available data do not indicate that they would result in significant impacts to fisher habitat at either the population or rangewide scales in the foreseeable future. Based on our evaluation of the best scientific and commercial information currently available, we find that fishers at the individual, population, and rangewide levels are beneficially affected by forest insects and tree diseases through their creation of structures used by fishers for denning and resting, as well as structures used by fisher prey. Localized outbreaks that result in canopy loss substantial enough to reduce the stand’s suitability for fisher habitat may affect individuals, but there is no evidence to indicate any impacts to fishers currently or in the foreseeable future. Thus, forest insects and tree diseases do not constitute a threat to the proposed DPS either currently or in the foreseeable future.

**Trapping and Incidental Capture**

Historical, unregulated fur trapping (prior to the 1930s) appears to have been the primary initial cause of the marked contraction in fisher distribution across the Pacific States. The effects of current trapping, which are limited to incidental capture and not an unknown amount of poaching, are significantly reduced compared to the previous effects of widespread unregulated legal trapping of fishers. In our proposed listing rule, we stated that the severity of the potential stressor of trapping and incidental capture is extremely low throughout the analysis area (Service 2014, pp. 106–108), and, therefore, we did not consider trapping to be a threat to the fisher, including in the future. Since that time, minimal new information has become available regarding trapping activities, none of which results in any significant changes or differences in our understanding of this stressor.

Based on our evaluation of the best available information currently known, we reaffirm our previous conclusion that the severity of trapping (and incidental capture) throughout the analysis area is extremely low, and is not expected to increase in the foreseeable future. Our current analysis reveals that where impacts occur as a result of trapping, those impacts are affecting few individuals (i.e., a total of eight individuals since 1975, including three in Washington (Happe 2015, pers. comm.) and five in Oregon (Robart 1982, pp. 3, 8; Oregon Department of Fish and Wildlife (ODFW) 1998, entire; ODFW 2007, p. 11) to a minor degree as opposed to significant impacts to entire populations or significant impacts rangewide. Given that widespread, unregulated legal trapping of fishers is not expected to occur in the future, potential future impacts from trapping and incidental capture are expected to remain extremely low. Thus, we...
conclude that the scope and magnitude of impacts resulting from trapping and incidental capture do not rise to the level of being a threat to the fisher in the west coast States, now or in the foreseeable future.

Research

Although scientific research is necessary to fully understand the various aspects of fishers’ life-history needs and population status in the west coast States, some research techniques (e.g., trapping, handling, and attachment of radio-telemetry transmitters to fishers) have potential risks to individual animals, including injury and mortality. Current research and monitoring efforts vary greatly by subregion across the three States. We concluded in the proposed listing rule and reaffirm here that research is not a threat to the continued existence of fisher, now or in the future. Both the draft Species Report (Service 2014, pp. 113–115) and final Species Report (Service 2016, pp. 127–128) describe impacts that have occurred to only a few individuals throughout the analysis area, which the best available data indicate will remain at an extremely low level into the future. Our evaluation of the best scientific and commercial information currently available lead us to conclude that research activities are not causing significant impacts at either the population or rangewide scales such that they constitute a threat to the proposed DPS now, nor are they expected to do so in the foreseeable future.

Disease or Predation

Several viral and bacterial diseases are known to affect mustelids, including fishers, but it is unclear how these diseases affect wild populations of fishers. Potential predators of fishers include mountain lions, bobcats, coyotes, and large raptors. Disease and predation are stressors that can cause direct mortality of fishers, and both are documented to occur throughout the analysis area. Minimal new information is available regarding disease or predation since the time of our proposed listing rule, none of which results in any significant changes or differences in our understanding of these stressors.

Based on our evaluation of the best scientific and commercial information currently available, neither disease nor predation are considered threats to fisher. Our analysis reveals that, for both disease and predation, impacts are affecting individuals to a minor degree within the various populations as opposed to significant impacts to entire populations or the proposed DPS rangewide. Additionally, the best available information does not indicate that disease or predation would increase in the future to a significant degree such that fishers in the west coast states are likely to experience significant impacts at either the population or rangewide scales. Thus, we reaffirm our conclusion that the scope and magnitude of impacts resulting from disease or predation do not rise to the level that are considered threats to the proposed DPS, now or in the foreseeable future.

Collision With Vehicles

In the proposed listing rule, we stated that roads are sources of vehicle-collision mortality of fishers and disrupt habitat continuity, particularly in high-use, high-speed areas. Collision with vehicles is a stressor that causes direct mortality of fishers, and thus, we found that collision with vehicles has the potential to be a stressor to extant fisher populations. We stated in the proposed rule that vehicle collisions have the potential to occur throughout all occupied areas, but we concluded that vehicle collisions are not a threat to fisher based on known impacts at the individual level. No new information has been discovered or provided since the time of the proposed listing rule to indicate that fisher collisions with vehicles are increasing or decreasing.

Based on our evaluation of the best scientific and commercial information currently available, we reaffirm our previous conclusion that vehicle collisions are not a threat to fisher, both currently and in the future (Service 2016, pp. 137–138). We found that individual fishers may be killed by vehicles in multiple populations, with a greater risk occurring in portions of the fisher populations that also harbor paved, major roads where vehicles travel at fast speeds and possibly at a higher volume of traffic compared to many dirt roads. The best available data indicate that vehicle collisions are a substantial source of anthropogenic mortality for fisher populations, but we have no information to indicate that the frequency of collisions with vehicles is going to increase in the future, or that this source of mortality is having or will have significant impacts at either the population or rangewide scales. Based on the scope and magnitude of this stressor, we reaffirm our conclusion that fisher collisions with vehicles are not a threat to the fisher in the proposed DPS, now or in the foreseeable future.

Exposure to Toxics

Anticoagulant rodenticides (ARs), which are intended to kill small pest mammals, impair an animal’s ability to produce several key blood clotting factors. Anticoagulant exposure is manifested by such conditions as bleeding nose and gums, extensive bruises, anemia, fatigue, and difficulty breathing. Anticoagulants also damage the small blood vessels, resulting in spontaneous and widespread hemorrhaging. A sublethal dose of an AR can produce significant clotting abnormalities and hemorrhaging, leading to a range of symptoms, such as difficulty moving and the decreased ability to recover from physical injury, which may increase the probability of mortality from other sources.

The final Species Report details the exposure of toxicants to fishers in the west coast States (Service 2016, pp. 141–159), which is summarized herein. Recently, these studies documenting exposure to toxicants in a number of fishers, and mortalities of individual fishers directly caused by ARs, has raised concerns regarding potential individual- and population-level impacts of toxicants. For example, ARs resulting in death in some cases, has been documented in fishers in the two native populations (NCSO and SSN), and the reintroduced ONP population. However, sources of AR exposure in fishers have not been conclusively determined.

The number of fishers determined to have had exposure to toxicants varies across the proposed DPS’s range, with the majority of records known from California. Large quantities of ARs have been found at illegal marijuana cultivation sites within occupied fisher habitat on public, private, and tribal lands in California (Gabriel et al. 2012a, p. 12; Thompson et al. 2014, pp. 97–98). In Oregon, AR residues were found in both fisher carcasses tested (Gabriel 2015, pers. comm.). Marijuana cultivation sites are not common in Washington and only three fishers can confidently be documented as having been exposed to rodenticides in Washington (Happe et al. 2015, pp. 38–39). Six other carcasses of fishers reintroduced in Washington have tested positive for AR, but those individuals may have been exposed in British Columbia before translocation (Happe in litt. 2015). Of the three fishers that were exposed in Washington, it appears that exposure occurred as a result of legal applications in residential areas given they were found near human habitation where ARs can be legally applied (Happe in litt. 2015).

We stated in the proposed listing rule that the scope of toxicants as a stressor varied across the landscape and that our determination regarding the scope was
influenced by the availability of data for different parts of the proposed West Coast DPS of fisher’s range. In those areas where data were available, we noted that the data used to estimate the severity of the stressor was comparable to that of disease, noting that the data used to estimate the severity of toxicants were based solely on mortality (i.e., four mortalities from California). We concluded at that time that ARs are likely a threat to fisher populations, but that we did not have specific information about the population-level effects.

Our evaluation of the best scientific and commercial information available regarding toxicants and their effects on fishers at this time leads us to conclude that individual fishers within three populations (i.e., NCSO, SSN, and ONP) have been found dead from other causes and also were found to be exposed to ARs at sublethal levels with an unknown degree of impact to those individuals. In addition, 15 mortalities directly caused by AR exposure have been documented in the NCSO and SSN populations in California (Gabriel et al. 2015, p. 5; Wengert 2016, pers. comm.). The best available information reveals little regarding the extent of AR exposure in Washington and Oregon, and no rangewide studies have occurred to evaluate the population-level impacts across the proposed DPS’s range. However, the broad use of ARs at illegal marijuana cultivation sites in California, which has been documented to occur within or adjacent to portions of the proposed DPS’s range, could be impacting portions of the California populations. The extent to which the legal use of ARs occurs at agricultural and commercial sites within the range of the fisher is unknown.

Our analysis of this stressor also includes a further evaluation of a variety of toxicant information (in response to comments by peer reviewers). New information included (but is not limited to):

1. Concentrations of active ingredients in bait (Erickson and Urban 2004) and a description of how exposure to ARs is confirmed (Vandenbrouke et al. 2008; Rattner et al. 2014). Erickson and Urban (2004, p. 94) specifically noted that no consistent trends associate residue concentrations with levels at which adverse effects occur. Thus, at what level of toxicant exposure fishers may be experiencing adverse impacts remains unknown.
2. Clarification or corrections related to ARs found in the dead fishers tested from the ONP population. Happe (2015, pers. comm.) noted that the first released individuals found dead were all captured near residential areas/private lands in British Columbia prior to their release into the Olympic Peninsula. Exposure from legal use of brodifacoum in British Columbia cannot be ruled out because their deaths occurred well within the half-lives reported for brodifacoum persistence in mammalian tissue. Two subsequent mortalities among the translocated individuals on the Olympic Peninsula tested positive for bromadiolone too long after their relocation from British Columbia to have been exposed there. These individuals were found near rural areas where rodenticides could have been used legally. The most recent fisher mortality that tested positive for an AR was born to a translocated female, and was found on the border of the Port Angeles city limits, surrounded by a low-density housing area and commercial development. Thus, AR impacts for the Olympic Peninsula reintroduction area could be from legally applied sources.
3. Rodent diversity at marijuana cultivation sites. Wengert (2015, pers. comm.) reports that rodent diversity is reduced to only mice at marijuana cultivation sites that are treated with rodenticides, as compared to nearby untreated sites where large-bodied rodents (e.g., woodrats, squirrels, chipmunks), which are the prey species that the fisher prefers, are found. This finding provides support for the possibility that fishers could experience indirect effects such as prey shifting outside of current home ranges, or prey depletion due to impaired reproduction, starvation (i.e., hibernation) (hematologic, biochemical and endocrine) changes.
4. Estimating the extent of fisher exposure to ARs and determining the source(s) is difficult because the delay in toxicity caused by ARs and their persistence within food webs can result in contaminated rodents being found within and adjacent to treated areas weeks or months after bait application (Geduhn et al. 2014, pp. 8–9; Tosh et al. 2012, pp. 5–6; Sage et al. 2008, p. 215). The only new regulatory measure of which we are aware is specific to ARs (in addition to those existing regulatory mechanisms identified in the proposed listing rule) is related to the State of California’s new 2014 prohibition on the sale of second generation ARs (brodifacoum, bromadiolone, difethialone, and difenacoum) to the general public. While the State of California has prohibited these sales to the general public, they are still widely available and can be purchased by anyone with a State-issued pesticide applicator’s license. No records are kept on the sale and use of rodenticides that can be used to determine whether this new measure will reduce the illegal and legal uses of the second-generation ARs (see Existing Regulatory Mechanisms, below, for additional discussion). Overall, our evaluation of new information, including the one new regulatory measure, provides clarity and corrections to some information presented in the draft Species Report.

Marijuana cultivation sites are present within or near both native fisher populations in the proposed West Coast DPS, and potentially other areas within the west coast States. There are other possible sources of ARs from legal applications in agriculture and around buildings in rural areas. Furthermore, the recent legalization of marijuana in the State of Oregon adds an additional element of uncertainty to evaluation of this stressor, as it is unknown whether or how this policy change may potentially affect exposure rates (for example, whether there may be a trend toward indoor-grow operations, which would potentially reduce exposure of wildlife to ARs). The incidence of fisher exposure to toxicants from all uses across its range is unknown and the best available data are very limited (including known mortalities of only 15 individuals in California). However, the best available information does not suggest that any of the fisher populations where exposure has been documented are in decline, nor does it suggest that significant AR impacts would occur as operative threats on the fisher populations in the west coast States as a whole to the degree that there are likely be significant impacts at either the population or rangewide scales in the future. The best available information at this time does not demonstrate there are significant deleterious sublethal effects in fishers at the population and rangewide scales. In addition, we are not aware of any information that indicates use of ARs will increase within the range of the proposed DPS in the future. Therefore, the best available information does not indicate that exposure to toxicants rises to the level of a threat, and this conclusion is supported by our finding that the proposed West Coast DPS of fisher is not experiencing significant impacts at either the population or rangewide scales, currently or in the foreseeable future.

Small Population Size and Isolation

A principle of conservation biology is that small, isolated populations are subject to an increased risk of extinction from stochastic (random) environmental, genetic, or demographic events. Fishers appear to have several characteristics related to small
occurred a very long time ago, possibly on the order of more than a thousand years, pre-European settlement (Tucker et al. 2012, pp. 1, 7). Despite their size and isolation, the native NCSO and SSN populations have persisted over a long period of time, and interchange between the native NCSO population and the reintroduced NSN and SOC populations may be beginning to occur (see Service 2016, pp. 38–41, 48).

Estimates of fisher population growth for the NCSO population and the portion of the SSN population surveyed do not indicate any overall positive or negative trend as a result of the various stressors acting upon those populations (Service 2016, pp. 42–50). At this point in time, we do not have information to indicate that these portions of the proposed DPS are expected to change to a negative trend in the foreseeable future given the projected current and future level of impacts from the various stressors, and, in some instances, offsetting beneficial effects from some stressors (e.g., wildfire, forest insects, and tree diseases that can create habitat components needed by fishers). The NCSO population, which encompasses the NSN reintroduced site, covers a relatively large geographic area of approximately 15,444 mi² (40,000 km²). Although the areas monitored for population trend are limited, for the Hoopa study, the population trend from 2005–2012 indicates a lambda (population growth rate) of 0.992 (C.I. 0.883–1.100) with a higher lambda rate for females 1.038 (0.881–1.196) than males 0.912 (0.777–1.047) (Higley et al. 2014, p. 102, Higley 2015, pers. comm.) and 1.06 (C.I. 0.97–1.15, years 2006–2013) for the EKSA (Powell et al. 2014, p. 23) (a population growth rate of 1.0 indicates a stable population; confidence intervals that bound 1.0 indicate the growth rate is not statistically different from 1.0). For the SSN population, which is smaller and estimated to range anywhere in size from 100 to 500 individuals (Service 2016, pp. 48–50), the population growth rate is estimated as 0.97 (C.I. 0.79–1.16, years 2007–2014) (Sweitzer et al. 2015a, p. 784). The population growth rate for the SSN population is slightly less than 1.0, but nonetheless because the confidence intervals include 1, this indicates a statistically stable trend. The reintroduced SOC population has now persisted for more than 30 years, despite a very small founding population (Service 2016, pp. 48–50). The ONP and NSN populations were reintroduced too early to determine the likelihood of long-term persistence, but initial results indicating that these populations are breeding and expanding are encouraging.

Overall, although fisher populations are relatively small and geographically isolated, our evaluation of the best scientific and commercial information leads us to conclude that the separation of the two native populations is longstanding. The best available information does not suggest any negative consequences in terms of population abundance or other indicators across the west coast States, or that small population size or isolation are likely to cause significant impacts at either the population or rangewide scales in the future. In addition, recent and ongoing reintroductions to establish additional populations of fishers within the west coast States reduce the likelihood of loss to random stochastic events. Based on all of these considerations, we now conclude that small population size and isolation are not threats to the proposed West Coast DPS of fisher, currently or in the foreseeable future.

Resiliency, Redundancy, and Representation

In this section, we synthesize the information above to evaluate resiliency, redundancy, and representation as they relate to fishers in the proposed West Coast DPS. Resiliency refers to the capacity of an ecosystem, population, or organism to recover quickly from disturbance by tolerating or adapting to changes or effects caused by a disturbance or a combination of disturbances. Redundancy, in this context, refers to the ability of a species to compensate for fluctuations in or loss of populations across the species’ range such that the loss of a single population has little or no lasting effect on the structure and functioning of the species as a whole. Representation refers to the conservation of the diversity of a species, including genetic makeup.

The degree of resiliency of a species (or DPS) is influenced by both the degree of genetic diversity across its range and the number of individuals. Resiliency increases with increasing genetic diversity or a higher number of individuals; it decreases when the species has less genetic diversity or fewer individuals. In the case of the proposed West Coast DPS of fisher, resiliency may be slightly lower to some degree because the total population size is considered by some as small, although forest carnivores generally occur at low densities (Ruggiero et al. 1994, p. 146).

From a genetics standpoint, fisher from the ONP population (as well as for
the new southern Washington Cascades reintroduction site) were sourced from British Columbia, and fisher from the SOC population were sourced from both British Columbia and Minnesota. Fisher from the NSN population area were sourced from native fishers in northwestern California. Fisher within this proposed DPS (NCSO, NSN, and SSN populations) contain unique genetic haplotypes not found elsewhere within the range of the fisher in North America (Knaus et al. 2011, p. 7). Wisely et al. (2004, pp. 642–643) demonstrated a gradient of genetic diversity in fisher populations along the Pacific Coast, with allelic richness highest in native populations in British Columbia and the reintroduced SOC population, and lowest in the southern Sierra Nevada.

Multiple, interacting populations across a broad geographic area (redundancy) provide insurance against the risk of extinction caused by catastrophic events. As was known at the time of the proposed listing rule, population redundancy continues to exist across the west coast States as a result of the presence of two native populations across southern Oregon (northern California and the Sierra Nevada (NCSO and SSN populations, noting that the SOC and SSN reintroduced populations now have overlapping boundaries with the native NCSO population)), as well as two reintroduction locations, including the ONP population and the new South Washington Cascades reintroduction site. There is also an additional reintroduction site (new as of December 2015 (see Species Information, above)) in the South Washington Cascades that is expected to start reproducing in the near future. The existence of the five broadly distributed populations (and the new reintroduction site) increases the probability that fisher populations in the west coast States will persist into the future and contribute to long-term genetic and demographic viability across the fisher’s West Coast range; however, more time is needed to determine with accuracy the viability of the reintroduced populations. If any of the five populations (particularly the native populations) were to be permanently lost, the fisher’s population redundancy in the west coast States would be lowered, thereby decreasing the fishers’ chances of survival in the face of potential environmental, demographic, and genetic stochastic factors and catastrophic events (extreme drought, wildfire, etc.). However, our evaluation of the best scientific and commercial information available does not indicate that there are any stressors acting upon any of the populations that are of such imminence or magnitude that we would anticipate the wholesale loss of any of these populations, and particularly not the native populations. Thus, we conclude there is sufficient redundancy at present to sustain the fishers in the west coast States over the long term, and continued and future reintroductions of fishers will continue to strengthen the degree of redundancy in the west coast States into the future.

The aggregate number of individuals across multiple populations increases the probability of demographic persistence and preservation of overall genetic diversity by providing an important genetic reservoir (representation). We consider representation across the west coast States to be high, with five different groups (two native (NCSO and SSN) and three reintroduced (ONP, SOC, and NSN)) across California, Oregon, and Washington (although we note it is early to conclude with certainty the persistence of two of these reintroduced populations). Although there may be some risk that any of the small reintroduced populations could fail to persist within the short-term future, the level of representation across the west coast States at this time reduces the likelihood of future extirpation of these fishers. In addition, preliminary results of the recent reintroductions are encouraging, demonstrating successful reproduction and population expansion, and additional reintroduction efforts are both ongoing and planned.

Our current analysis reveals that small population size by itself is not a threat to the proposed West Coast DPS of fisher. A species (or DPS) with a relatively small number of small populations may be a concern when there are significant threats to the species such that one or more populations are likely to be permanently lost. However, fishers in the west coast States comprise three geographically separated populations, including one (NCSO) that overlaps with two reintroduced populations (SOC and SSN), as well as a new (as of December, 2015) reintroduction site in the South Washington Cascades (see Species Information, above). While each of the populations is considered relatively small (except, perhaps for the NCSO), as discussed above, the two native populations have continued to persist for a long time in the face of all of the identified stressors (noting that fisher exposure to toxicants (ARs) is a recently identified stressor), and there is no indication that any of the monitored populations are exhibiting a population growth trend that is other than essentially stable. In addition, our evaluation of the best available information does not suggest that any of the stressors acting within the proposed DPS are likely to result in the extirpation of these populations, acting either singly or in concert, either now or in the future; this is particularly true for the established native populations of fisher. Furthermore, recent information suggests that three of these fisher populations (NCSO, NSN, and SOC population) may no longer be separate breeding populations, as indicated by at least one documented occurrence of dispersal and potential reproduction. Connectivity between populations reduces the potential risk posed by small population sizes. This information, combined with the absence of stressors that rise to the level of a threat, supports our position that the proposed West Coast DPS of fisher populations demonstrate resiliency, redundancy, and representation currently and in the future.

### Cumulative Effects

Consistent with our approach for the proposed rule, we took into consideration all of the stressors operating within the west coast States. We previously stated in the proposed rule that the sizes of the fisher populations within the proposed West Coast DPS are reduced from historical levels due to historical trapping and past loss of late-successional habitat and, therefore, are overall more vulnerable to extinction from random events and increases in mortality. We previously evaluated the potential for cumulative effects of multiple stressors, although we were unable in the proposed rule to quantify the scope and severity of these cumulative effects and the variation of these effects between subregions. We did, however, determine that the various stressors were not occurring in equal magnitude across the analysis area and that cumulative effects from these stressors may be occurring more in some subregions than others. The most likely scenarios for potential cumulative impacts on fisher that we identified previously and reaffirm here are:

- Alterations to habitat could increase fishers’ vulnerability to predation.
- Sublethal exposure to ARs could potentially increase the death rates from predation, collisions with vehicles, disease, or intraspecific conflict.
- Stressors associated with the effects of climate change, such as increased risk of wildfire and forest disease, and environmental impacts of human
development, could interact to cause large-scale ecotype conversion including shifts away from fisher habitat types, which could impact the viability of populations and reduce the likelihood of reestablishing connectivity.

- Diseases that are currently present among mammal populations and also overlap the fisher’s range in the west coast States could be exacerbated by climate change, such that fishers experience impacts at either the population or rangewide scales.

- Development activities could cause increases in fisher collisions with vehicles, conflicts with domestic animals, and infections contracted from domestic animals.

At this time, we find no indication that stressors are manifesting themselves to a significant degree on fishers, both singly or cumulatively, across the west coast States at either the population or rangewide scales. Currently, they are not expected to do so in the future. We reach this conclusion because the best available information does not indicate that one or more stressors (by themselves or cumulatively) are expected to interact to such a degree that they would significantly contribute to decreased reproductive viability, reduced distribution, or significant loss of habitat for the proposed West Coast DPS of fisher. Additionally, there is also suitable but unoccupied habitat available throughout the analysis area where fisher populations occur (including in the SSN population area, although to a lesser extent compared to the northern portion of the proposed DPS’s range). These areas likely would help offset any potential future impacts to fisher habitat from habitat-related cumulative impacts over the next 40 years.

Overall, we recognize that fishers in the west coast States have been exposed to multiple stressors, in some cases over many decades. The stressors may be impacting some individual fishers or habitat in one or more populations, but those stressors are not acting on the fisher’s habitat, populations, or the proposed DPS as a whole such that the stressors are functioning cumulatively as operative threats on the proposed DPS. Thus, the best available scientific and commercial data at this time do not show that combined impacts of the most likely cumulative impact scenarios are resulting in significant impacts at either the population or rangewide scales, including when taking into consideration population sizes. Fisher populations today in the west coast States are smaller and their range has been reduced compared to historical conditions, which potentially increases the vulnerability of the fisher to cumulative low- or medium-level impacts. However, the best available information does not suggest that current fisher populations in the west coast States are experiencing population declines or further reductions in distribution, which would be indicative of such impacts and likely to be demonstrated through survey information (which is not evident in the best available information).

Cumulatively, the stressors to the proposed West Coast DPS of fisher have not manifested in operative threats across the range of the DPS. Moreover, our analysis of the stressors does not indicate that they are expected to increase in the foreseeable future to a degree that their cumulative effects would be significantly different than current levels. Thus, the best available scientific and commercial data do not indicate that these stressors are cumulatively causing now or will cause in the future a substantial decline of the total extant populations of fishers across the range of the proposed West Coast DPS. Therefore, we have determined that the cumulative impacts of these potential stressors do not rise to the level of a threat, now or in the future.

**Existing Regulatory Mechanisms**

In the final Species Report, we evaluated whether existing regulatory mechanisms may be inadequate to address the stressors impacting fishers in the west coast States. We stated in the proposed listing rule and we reaffirm here that there are many Federal and State existing regulatory mechanisms that provide a benefit to fishers and their habitat. For example, trapping regulations have substantially reduced fisher mortality throughout the analysis area. There are places in the analysis area where forest management practices are explicitly applied to benefit fishers or other species with many similar habitat requirements, such as the northern spotted owl. In addition, some habitat conservation plans (HCPs) are in place and are intended to provide a benefit to fishers and their habitat. Also, as of August 6, 2015, the California Fish and Game Commission voted to list the southern Sierra Nevada Evolutionarily Significant Unit (ESU) of the fisher as a threatened species under the California Endangered Species Act (CESA). Consequently, take, under the CESA definition, is prohibited in the SSN population area.

Take of fishers in Oregon is also prohibited through its designation as a protected nongame species, although the definition of take under Oregon law is different from the definition of take under the Act. The fisher is State-listed as endangered in Washington, where take (e.g., hunting, trapping) is prohibited and environmental analyses need to occur for projects that may affect fishers. State and Federal regulatory mechanisms have abated the large-scale loss of fishers to trapping and loss of fisher habitat, especially on Federal land (Service 2014, pp. 117–141). Rodenticides are regulated under Federal and State laws. However, fishers may still be exposed to such rodenticides in certain areas where they can still be used legally. Fishers are also exposed to some degree to rodenticides used illegally (as discussed below).

**Federal Regulatory Mechanisms**

Forest Service and BLM

A number of Federal agency regulatory mechanisms pertain to management of fisher (and other species and habitat). Most Federal activities must comply with the National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 et seq.). NEPA requires Federal agencies to formally document, consider, and publicly disclose the environmental impacts of major Federal actions and management decisions significantly affecting the human environment. NEPA does not regulate or protect fishers, but requires full evaluation and disclosure of the effects of Federal actions on the environment. Other Federal regulations affecting fishers are the Multiple-Use Sustained Yield Act of 1960, as amended (16 U.S.C. 528 et seq.) and the National Forest Management Act of 1976, as amended (NFMA) (90 Stat. 2949 et seq.; 16 U.S.C. 1601 et seq.). NFMA specifies that the Forest Service must have a land and resource management plan to guide and set standards for all natural resource management activities on each National Forest or National Grassland. In addition, the fisher has been identified as a sensitive species by the Forest Service throughout the analysis area. BLM management is directed by the Federal Land Policy and Management Act of 1976, as amended (43 U.S.C. 1704 et seq.). This legislation provides direction for resource planning and establishes that BLM lands shall be managed under the principles of multiple use and sustained yield. This law directs development and implementation of resource management plans, which guide management of BLM lands at the local level. Fishers are also designated as a
sensitive species throughout the analysis area on BLM lands. In addition, the NWFP was adopted by the Forest Service and BLM in 1994 to guide the management of more than 24 million ac (9.7 million ha) of Federal lands in portions of western Washington and Oregon and northwestern California within the range of the northern spotted owl. The NWFP Record of Decision amends the management plans of National Forests and BLM Districts and is intended to provide the basis for conservation of the spotted owl and other late-successional and old-growth forest associated species on Federal lands. However, the BLM is currently revising their Resource Management Plan (RMP) (a draft RMP/Environmental Impact Statement (EIS) was published in April 2015 (USDI BLM 2015, entire), which, if approved, would change their management direction from the existing NWFP. Once signed, a revision would replace the NWFP for BLM-administered lands in western Oregon, totaling approximately 2.5 million ac (1.0 million ha). Although a decision has yet to be made, BLM’s preferred alternative (Alternative B), as stated in their EIS (USDI BLM 2015, p. 76), would allocate a slightly smaller amount of their landscape to timber harvest management as compared to the NWFP (22 percent and 28 percent, respectively). The BLM preferred alternative, however, shows a larger amount of LSR acreage than what is designated under the NWFP. Another reason is that BLM is adding all stands identified as structurally complex forest, creating scattered patches of older-forest reserves across BLM ownership (USDI BLM 2015, pp. 32–33, 50). Because BLM’s decision is not final, our analysis in the final Species Report and summarized in this document is limited to their existing management under the NWFP.

The NWFP is important for fishers because it created a network of late-successional and old-growth forests (LSRs) that currently provide fisher habitat and the amounts of habitat are expected to increase over time. Also, the National Forest and BLM units with anadromous fish watersheds provide buffers for riparian reserves on either side of a stream, depending on the stream type and size. With limited exceptions, timber harvesting is generally not permitted in riparian habitat conservation areas, and the additional protection guidelines provided by National Forests and BLM for these areas may provide refugia and connectivity among more substantive blocks of fisher habitat. Furthermore, the NWFP, while anticipating losses of late-successional and old-growth forests in the initial decades of plan implementation, projected that recruitment would exceed those losses within 50 to 100 years (Davis et al. 20XX, p. 6).

National Park Service Statutory direction for the 1.6 million ha (4 million ac) of National Park Service lands in the analysis area is provided by provisions of the National Park Service Organic Act of 1916, as amended (54 U.S.C. 100100) Land management plans for the National Parks within the west coast States do not contain specific measures to protect fishers, but areas not developed specifically for recreation and camping are managed toward natural processes and species composition and are expected to maintain fisher habitat. In addition, hunting and trapping are generally prohibited in National Parks (e.g., 16 U.S.C. 60, 98, 127, 204c, and 256b).

Tribal Lands Several tribes in the analysis area recognize fishers as a culturally significant species, but only a few tribes have fisher-specific guidelines in their forest management plans. Some tribes, while not managing their lands for fishers explicitly, manage for forest conditions conducive to fisher (for example, marbled murrelet (Brachyramphus marmoratus) habitat, old-forest structure restoration). Trapping is typically allowed on most reservations and tribal lands, and is frequently restricted to tribal members. Whereas a few tribal governments trap under existing State trapping laws, most have enacted trapping laws under their respective tribal codes. However, trapping (in general) is not known to be a common occurrence on any of the tribal lands.

Rodenticide Regulatory Mechanisms The threats posed to fishers from the use of rodenticides are described above under “Exposure to Toxicants.” In the final Species Report, we analyzed whether existing regulatory mechanisms are able to address the potential threats to fishers posed from both legal and illegal use of rodenticides. As described in the final Species Report, the use of rodenticides is regulated by several Federal and State mechanisms (e.g., Federal Insecticide, Fungicide, and Rodenticide Act of 1947, as amended, (FIFRA) 7 U.S.C. 136, et seq.; California Final Regulation Designating Brodifacoum, Bromadiolone, Difenacoum, and Difethialone (Second Generation Anticoagulant Rodenticide Products) as Restricted Materials, California Department of Pesticide Regulation, 2014). The primary regulatory issue for fishers with respect to rodenticides is the availability of large quantities of rodenticides that can be purchased under the guise of legal uses, but are then used illegally in marijuana grows within fisher habitat. The amounts of rodenticides commercially available for purchase (but which could then be used for illegal purposes) are greater than the amount of rodenticides that could be expected to kill or harm individual fishers. Both the Environmental Protection Agency (EPA), through its 2008 Risk Mitigation Decision for Ten Rodenticides (EPA 2008, entire), which issued new legal requirements for the labelling, packaging, and sale of second generation anticoagulants, and California’s Department of Pesticide Regulation, through a new rule effective in July 2014, which restricts access to second generation anticoagulants, are attempting to reduce the risk posed by second generation anticoagulants. Although it is currently not clear that these mechanisms have yet been effective in addressing the potential threat of rodenticide and its effects on fishers, the best available information does not support concluding that rodenticide impacts rise to the level of a threat. We reach this conclusion because there is no evidence that ARs are having significant impacts to fishers at either the population or rangewide scales (see additional discussion under Exposure to Toxicants, above).

State Regulatory Mechanisms Washington The fisher is listed as endangered in Washington (Washington Administrative Code 232–12–014, Statutory Authority: RCW 77.12.020 WSR 98–23–013 (Order 98–232), § 232–12–014, filed 11/6/98, effective 12/7/98). This designation imposes stringent fines for poaching and establishes a process for environmental analysis of projects that may affect the fisher. The primary regulatory mechanism on non-Federal forest lands in western Washington is the Washington State Forest Practices Rules, title 222 of the Washington Administrative Code. These rules apply to all commercial timber growing, harvesting, or processing activities on non-Federal lands, and they give direction on how to implement the Forest Practices Act (Revised Code of Washington (RCW) 76.60) and State and Federal Water Code (RCW 76.13). The rules are administered...
by WDNR. The Washington State Forest Practices Rules do not specifically address fishers and their habitat requirements; however, some habitat components important to fishers, like snags, downed wood, and canopy cover, are likely to be retained in riparian management zones as a result of the rules. Land conversion from forested to non-forested uses is interrelated to private timber harvest, but is primarily regulated by individual city and county ordinances that are influenced by Washington's Growth Management Act (RCW 36.70a). In some cases, these ordinances result in maintaining forested areas within the range of the fisher.

Oregon In Oregon, the fisher is a protected nongame species (Oregon Administrative Rules (OAR) 635–044–0130). In addition, ODFW does not allow trapping of fishers in Oregon. Although fishers can be injured and/or killed by traps set for other species, known fisher captures are infrequent. State parks in Oregon are managed by the Oregon Parks and Recreation Department, and many State parks in Oregon provide forested habitats suitable for fisher. The Oregon Forest Practice Administrative Rules (OAR chapter 629, division 600) and Forest Practices Act (Oregon Revised Statutes (ORS) 527.610 to 527.770, 527.990(1)) also contain rules specific to fishers, but they are not designed to maintain the economic viability of the State’s forest products industry while preventing environmental degradation. FPRs do not contain rules specific to fishers, but they may provide some protection of fisher habitat as a result of timber harvest restrictions.

California At the time of the proposed rule, fishers were a Candidate Species in California; thus, take (under the CESA definition) was prohibited during the candidacy period. On June 10, 2015, the California Department of Fish and Wildlife (CDFW) submitted its status review of the fisher to the California Fish and Game Commission, indicating that listing of the fisher in the Southern Sierra Nevada ESU as threatened was warranted, but that fishers in the Northern California ESU were not threatened (CDFW 2015, entire). On August 6, 2015, the California Fish and Game Commission voted to list the southern Sierra Nevada ESU of the fisher as a threatened species under the CESA. Consequently, take, under the CESA definition, is prohibited only in the southern Sierra Nevada portion of the proposed DPS’s range. It is also illegal to intentionally trap fishers in California.

The California Environmental Quality Act (CEQA) can provide protections for a species that meets one of several criteria for rarity (CEQA 15380). Fishers throughout the proposed DPS’s range in California meet these criteria, and under CEQA a lead agency can require that adverse impacts be avoided, minimized, or mitigated for projects subject to CEQA review that may impact fisher habitat. All non-Federal forests in California are governed by the State’s Forest Practice Rules (FPR) under the Z’Berg Nejedly Forest Practice Act of 1973, a set of regulations and policies designed to maintain the economic viability of the State’s forest products industry while preventing environmental degradation. FPRs do not contain rules specific to fishers, but they may provide some protection of fisher habitat as a result of timber harvest restrictions.

Determination As required by the Act, we considered the five factors listed in section 4(a)(1)(b) of the Act in assessing whether the proposed West Coast DPS of fisher meets the definition of a threatened or endangered species, including: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

We examined the best scientific and commercial information available regarding the current and foreseeable future potential threats faced by fishers in the west coast States. We relied on an evaluation of the foreseeability of those stressors and the foreseeability of the effect of the stressors on the proposed DPS, extending this time period out only so far as we can rely on the data to formulate reliable predictions about the status of the proposed DPS, and not extending so far as to venture into the realm of speculation. In this case, many of the stressors fell into a foreseeable future timeframe within which we concluded the effects of stressors on the proposed DPS could be reliably projected out over a time period of approximately 40 years. Thus, for the purposes of this determination, we consider the foreseeable future to extend over a time period of roughly 40 years, as previously described in the proposed listing rule, based on the time horizons for which the effects of the various stressors on the proposed DPS can be reliably projected into the future (as described under the various stressor discussions in the Species Report (Service 2016, pp. 54, 58–162)).

Summary of Previous Determinations At the time of our 2004 12-month finding, the proposed West Coast DPS of fisher was described as having lost much of its historical habitat and range. Specifically, the 2004 12-month finding stated (69 FR 18771, April 8, 2004) that the fisher is considered to be extirpated or reduced to scattered individuals in California. At the time of our 2004 12-month finding stated (69 FR 18771, April 8, 2004) that the fisher is considered to be extirpated or reduced to scattered individuals in California. Extensive fisher populations in California are managed by ODF, and many State parks in Oregon are managed by the Oregon Parks and Recreation Department, and many State parks in Oregon provide forested habitats suitable for fisher. The Oregon Forest Practice Administrative Rules (OAR chapter 629, division 600) and Forest Practices Act (Oregon Revised Statutes (ORS) 527.610 to 527.770, 527.990(1)) also contain rules specific to fishers, but they are not designed to maintain the economic viability of the State’s forest products industry while preventing environmental degradation. FPRs do not contain rules specific to fishers, but they may provide some protection of fisher habitat as a result of timber harvest restrictions.

Determination As required by the Act, we considered the five factors listed in section 4(a)(1)(b) of the Act in assessing whether the proposed West Coast DPS of fisher meets the definition of a threatened or endangered species, including: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

We examined the best scientific and commercial information available regarding the current and foreseeable future potential threats faced by fishers in the west coast States. We relied on an evaluation of the foreseeability of those stressors and the foreseeability of the effect of the stressors on the proposed DPS, extending this time period out only so far as we can rely on the data to formulate reliable predictions about the status of the proposed DPS, and not extending so far as to venture into the realm of speculation. In this case, many of the stressors fell into a foreseeable future timeframe within which we concluded the effects of stressors on the proposed DPS could be reliably projected out over a time period of approximately 40 years. Thus, for the purposes of this determination, we consider the foreseeable future to extend over a time period of roughly 40 years, as previously described in the proposed listing rule, based on the time horizons for which the effects of the various stressors on the proposed DPS can be reliably projected into the future (as described under the various stressor discussions in the Species Report (Service 2016, pp. 54, 58–162)).
a stochastic event would result in the extirpation of fishers in the west coast States, and we would evaluate any conservation strategy developed to determine whether the strategy sufficiently removes threats to the fisher so that it no longer meets the definition of a threatened species under the Act (69 FR 18792). Since the 2004 12-month finding, reintroductions have occurred in the ONP and NSN populations, and another has begun in the South Washington Cascades; however, a multi-State conservation strategy has not been finalized and implemented.

At the time of our proposed listing in 2014, we found that the proposed West Coast DPS of fisher met the definition of a threatened species (likely to become endangered throughout all or a significant portion of its range within the foreseeable future) based on our analysis of the scope and severity of threats impacting the DPS. We found that the main threats to the proposed West Coast DPS of fisher were habitat loss from wildfire and vegetation management, as well as toxicants, and the cumulative impact and synergistic effects of these and other stressors in small populations. We also stated that the proposed West Coast DPS of fisher was not in danger of extinction throughout all of its range because it existed in: (1) Two separate native populations (one small population estimated at approximately 300 fishers and one with population size estimates ranging from 258 to 4,018 fishers) that have persisted; and (2) three reintroduced populations that provide redundancy, representation, and resiliency for the extant populations. We also determined that the threats acting on the proposed West Coast DPS of fisher were not all imminent and not evenly distributed across the DPS. We found at that time that the proposed DPS was likely to become endangered throughout all of its range in the foreseeable future based on multiple threats impacting the two extant native populations and the cumulative and synergistic effects of the threats on small populations in the west coast States. We reached that conclusion based on an analysis of the best available and relevant information available at that time, as presented in detail in the draft Species Report (Service 2014, entire).

At the time of our proposed listing in 2014, we found there to be considerable uncertainty regarding the level of impacts (magnitude and immediacy of threats) from various stressors potentially affecting the proposed West Coast DPS of fisher. Specifically because of this uncertainty, we sought peer review and public comment on what we clearly identified as several complex issues with regard to the status of the DPS (see Information Requested section of the proposed rule (79 FR 60419)) and our proposal to list it as a threatened species. For example, we requested information to assist us in evaluating the magnitude and overall immediacy of threats to fisher populations within the proposed DPS (including toxicants, wildfire, climate change, and vegetation management), and comments on the methodology for developing stressor scope and severity, adequacy in revealing assumptions and uncertainties, appropriateness of data extrapolations, and applicability and interpretation of quantitative stressor values presented in the draft Species Report. Through our initial evaluation of peer review and public comments received, we determined that these complex issues, as they related to our 2014 analysis and the status of fishers in the west coast States, deserved additional analysis. Consequently, we published a 30-day extension of the initial comment period (79 FR 76950; December 23, 2014) and then later opened an additional comment period concurrent with our announcement of a 6-month extension of the final determination of whether to list the West Coast DPS of fisher as a threatened species (80 FR 19953; April 14, 2015). We received a variety of opinions and material (e.g., conflicting information, some scientific disagreement) from the peer reviewers and from the public and conservation partners.

Current Determination

As indicated above regarding feedback from peer reviewers, the public, and conservation partners, we received a substantial amount of varied scientific, other agency, and public input on our proposal to list the West Coast DPS of fisher. In addition, we held numerous internal Service discussions regarding interpretation of the best available information and what it meant for the status of fishers in both prior to and following the October 7, 2014 (79 FR 60419), proposed listing of the West Coast DPS of fisher. During these internal discussions, varied opinions were expressed and vetted. The extensive disparity in comments received (including those from peer reviewers and others) during the open comment period highlighted the fact that considerable uncertainty remained as to potential threats to fisher and its current and future status.

Our regulations direct us to determine if a species is endangered or threatened due to any one or combination of the five threat factors identified in the Act (50 CFR 424.11(c)). We consider cumulative effects to be the potential threats to the species in totality and combination; this finding constitutes our cumulative effects analysis. The discussions summarized above and provided in detail in the final Species Report evaluated the individual impact of the following potential threats to the proposed West Coast DPS of fisher and its habitat: (1) Wildfire and fire suppression (Factor A); (2) forest insects and tree diseases (Factor A); (3) effects of climate change (Factors A and E); (4) vegetation management (Factor A); (5) development, including linear infrastructure (Factor A); (6) trapping and incidental capture (Factor B); (7) research activities (Factor B); (8) disease or predation (Factor C); (9) collision with vehicles (Factor E); (10) exposure to toxicants (Factor E); (11) small population size and isolation (Factor E); and (12) cumulative or synergistic effects. We also evaluated the inadequacy of existing regulatory mechanisms (Factor D). Our determination as reflected in this document thus is based upon an analysis of these stressors in accordance with the five factors required by the statute. Although this determination utilizes a different structure than what was presented in the proposed rule, where each stressor was analyzed under its particular statutory factor, it contains the same types of analyses that we have previously depicted under the five factor framework.

Upon careful consideration and evaluation of all of the information before us, we have arrived at a different conclusion regarding the status of fishers in the west coast States. In our proposed determination, we identified stressors that could impact the species negatively and identified three of those stressors (wildfire and fire suppression, vegetation management, and small population size and isolation) as threats. We also identified exposure to toxicants (specifically ARs) and cumulative effects from multiple stressors as threats, although there were uncertainties at that time. We applied the standards we had laid out in our proposed rule, which set forth that this determination does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of stressors that could impact a species negatively is not sufficient to make this finding that listing is appropriate; we require evidence that these stressors are
operative threats that act on the species to the point that the species meets the definition of an endangered or threatened species under the Act (October 7, 2014; 79 FR 60419, p. 60427). Following our analysis of all the best available scientific and commercial information, we now conclude that, although fishers in the west coast States have clearly been exposed to multiple stressors, in some cases over many decades, the best available data do not indicate significant impacts at either the population or rangewide scales, currently or in the foreseeable future. In other words, stressors may be impacting some individual fishers or habitat in one or more populations, but the information we have does not show that the stressors are functioning as operative threats on the fisher’s habitat, populations, or the proposed DPS as a whole to the degree we considered to be the case at the time of the proposed listing. Thus, the stressors acting upon fisher populations are not of such immensity, intensity, or magnitude that they are manifesting themselves at either the population or rangewide scales, nor is there evidence to suggest that they will do so in the future (i.e., the next 40 years). Absent evidence of significant impacts at either the population or rangewide scales, in this case we cannot conclude that the stressors acting on fishers or their habitat within the proposed West Coast DPS are so great that the DPS is currently in danger of extinction (an endangered species), or that it is likely to become an endangered species within the foreseeable future (definition of a threatened species). Therefore, the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species, and we are withdrawing the proposed rule to list the West Coast DPS of fisher as a threatened species.

**Significant Portion of the Range**

Under the Act and our implementing regulations, a species may warrant listing if it is an endangered or a threatened species throughout all or a significant portion of its range. The Act defines “endangered species” as any species which is “in danger of extinction throughout all or a significant portion of its range,” and “threatened species” as any species which is “likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.” The term “species” includes “any subspecies of fish or wildlife or plants, and any distinct population segment (DPS) of any species of vertebrate fish or wildlife which interbreeds when mature.” On July 1, 2014, we published a final policy interpreting the phrase “Significant Portion of its Range” (SPR) (79 FR 37578). The final policy states that (1) if a species is found to be an endangered or a threatened species throughout a significant portion of its range, the entire species is listed as an endangered or a threatened species, respectively, and the Act’s protections apply to all individuals of the species wherever found; (2) a portion of the range of a species is “significant” if the species is not currently an endangered or a threatened species throughout all of its range, but the portion’s contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range; (3) the range of a species is considered to be the general geographical area within which that species can be found at the time FWS or NMFS makes any particular status determination; and (4) if a vertebrate species is an endangered or a threatened species through an SPR, and the population in that significant portion is a valid DPS, we will list the DPS rather than the entire taxonomic species or subspecies. It is important to note that we do not base a determination to list a species on the status of the species in lost historical range; in other words, lost historical range cannot be considered an SPR. The focus of an SPR analysis is the status of the species in its current range. The SPR policy is applied to all status determinations, including analyses for the purposes of making listing, delisting, and reclassification determinations. The procedure for analyzing whether any portion is an SPR is similar, regardless of the type of status determination we are making. The first step in our analysis of the status of a species is to determine its status throughout all of its range. If we determine that the species is in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range, we list the species as an endangered (or threatened) species and no SPR analysis will be required. If the species is neither an endangered nor a threatened species throughout all of its range, we determine whether the species is an endangered or a threatened species throughout a significant portion of its range. If it is, we list the species as an endangered or a threatened species, respectively; if it is not, we conclude that listing the species is not warranted. When we conduct an SPR analysis, we first identify any portions of the species’ range that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be significant and either an endangered or a threatened species. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that (1) the portions may be significant and (2) the species may be in danger of extinction in those portions or likely to become so within the foreseeable future. We emphasize that answering these questions in the affirmative is not a determination that the species is an endangered or a threatened species throughout a significant portion of its range—rather, it is a step in determining whether a more detailed analysis of the issue is required. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are affecting it uniformly throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats apply only to portions of the range that clearly do not meet the biologically based definition of “significant” (i.e., the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species), those portions will not warrant further consideration. If we identify any portions that may be both (1) significant and (2) endangered or threatened, we engage in a more detailed analysis to determine whether these standards are indeed met. The identification of an SPR does not create a presumption, prejudgment, or other determination as to whether the species in that identified SPR is an endangered or a threatened species. We must go through a separate analysis to determine whether the species is an endangered or a threatened species in the SPR.

Depending on the biology of the species, its range, and the threats it faces, it may be more efficient to address the “significant” question first, or the status question first. Thus, if we determine that a portion of the range is not “significant,” we do not need to determine whether the species is an endangered or a threatened species there; if we determine that the species is not an endangered or a threatened species in a portion of its range, we do not need to determine if that portion is “significant.” Because we determined that the proposed West Coast DPS of fisher is neither endangered nor threatened
throughout all of its range, we must next determine whether the proposed DPS may be endangered or threatened in a significant portion of its range. To do this, we must first identify any portion of the proposed DPS’s range that may warrant consideration by determining whether there is substantial information indicating that: (1) The portions may be significant, and (2) the proposed DPS may be in danger of extinction in those portions or is likely to become so within the foreseeable future. We note that a positive answer to these questions is not a determination that the proposed DPS is endangered or threatened within a significant portion of its range, but rather a positive answer to these questions confirms whether a more detailed analysis is necessary.

Our current evaluation of the best scientific and commercial data available, as described earlier in this document and in our final Species Report, leads us to conclude that the stressors acting upon fishers in the west coast States are not of sufficient magnitude, intensity, or magnitude to indicate that they are singly or cumulatively resulting in significant impacts at either the population or rangewide scales currently or in the foreseeable future. Thus, the proposed DPS does not meet the definition of endangered or threatened under the Act. For this SPR analysis we first evaluated whether the proposed West Coast DPS of fisher may be in danger of extinction in portions of its range or likely to become so within the foreseeable future. To make this determination we considered whether the stressors affecting the entire proposed DPS might be manifesting themselves in the form of significant impacts at the population scale only in certain portions of the range, such that the fisher in those portions may be an endangered or threatened species under the Act.

We have determined that currently and in the foreseeable future:

1. The stressors affecting the proposed West Coast DPS of fisher occur in most populations within the west coast States but are not having significant impacts at the population scale in any portion of the proposed DPS’s range. For example, ARs may be more problematic in certain populations (e.g., NCSO, SSN); however, as described above in the Exposure to Toxicants section, they are not resulting in significant impacts at either the population or rangewide scales.

2. The fisher is not exhibiting population declines in any portion of its range.

Thus, at this time, fishers in any portion of their range in the west coast States do not meet the definition of an endangered or threatened species under the Act. Because we determined that no portion of the proposed West Coast DPS of fisher’s range may be in danger of extinction in those portions or is likely to become so within the foreseeable future, it was not necessary to assess whether any portion of the range may be significant under the SPR policy. Therefore, in accordance with our SPR policy, no portion of the range of the proposed West Coast DPS of fisher warrants further consideration to determine whether the West Coast DPS of fisher is endangered or threatened throughout a significant portion of its range.

We encourage the continuing development and implementation of positive conservation actions for the benefit of fishers and their habitat, as exemplified by the CCAAs currently underway in association with our State and private conservation partners, to ensure against the future need to reconsider the listing of fisher in the west coast States.

Summary of Comments and Recommendations

In the proposed rule published on October 7, 2014 (79 FR 60419), we requested that all interested parties submit written comments on the proposal by January 5, 2015. This proposed rule also announced one public hearing and seven public informational meetings held in California, Oregon, and Washington. This comment period was subsequently extended an additional 30 days, as announced on December 23, 2014 (79 FR 76950), and closed on February 4, 2015. Finally, the Service announced the reopening of the comment period on April 14, 2015 (80 FR 19953), for an additional 30 days, and we announced a 6-month extension of the final determination of whether or not to list the proposed West Coast DPS of fisher due to substantial disagreement regarding available information related to toxics and rodenticides (including law enforcement information and trend data) and related to surveyed versus unsurveyed areas (including data on negative survey results) to help assess distribution and population trends. This second comment period on the proposed listing rule closed on May 14, 2015.

We contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposed solicited peer review at this time; see Peer Review, below). We also received requests for public hearings. We held one public hearing in Redding, California, on November 17, 2014. We held seven public informational meetings in: (1) Yreka, California, on November 13, 2014; (2) Medford, Oregon, on November 17, 2014; (3) Arcata, California, on November 20, 2014; (4) two meetings in Lacey, Washington, on November 20, 2014; (5) Visalia, California, on December 3, 2014; and (6) Turlock, California, on December 4, 2014. Newspaper notices inviting general public comment and advertisement of the information and public hearings were published in the Seattle Times, The Oregonian, Herald and News, Medford Tribune, Eureka Times-Standard, Siavikyo Daily News, Redding Record Searchlight, Sacramento Bee, Modesto Bee, and Fresno Bee.

During the two comment periods, we received more than 460 comment letters directly addressing the proposed listing of the West Coast DPS of fisher. Submitted comments were both for and against listing the DPS, including some for and against listing different geographic configurations of the DPS. During the November 17, 2014, public hearing, 12 individuals (3 from the same organization) commented on the proposed rule; all were opposed to the proposed listing. All substantive information provided during the comment periods has been incorporated into the final Species Report and, where applicable, summarized or addressed in this withdrawal. As noted in our proposed rule, comments that merely express support for or opposition to a particular action may not meet the standard of information required under section 4(b)(1)(A) of the Act, which directs that determinations as to whether any species is an endangered or threatened species must be made “solely on the basis of the best available scientific and commercial data available” (79 FR at 60422).

A substantial amount of new information was received from peer reviewers and the public, including old information of which we were not aware and some literature published just prior to the proposed listing rule publication, all of which we have reviewed, considered, and incorporated (where applicable and appropriate) into the final Species Report, this Federal Register document, or our files. We also reviewed and considered other new information such as recently published journal articles and unpublished reports associated with management activities or research projects. All of this new information was considered for this final decision.
Peer Review

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from 27 appropriate and independent specialists with scientific expertise that included familiarity with fisher and their habitat in the west coast States, including biological needs and threats. We received responses from 22 of the peer reviewers.

We reviewed all comments received from the peer reviewers for substantive issues and new information regarding the listing of the proposed West Coast DPS of fisher. Peer reviewer comments are addressed in the following summary and incorporated into this withdrawal document as appropriate.

Peer Review Comments Received

Climate Change

(1) Comment: Two peer reviewers did not believe that the Service’s summary of climate change impacts in the proposed rule matched the analysis of climate change in the body of the draft Species Report. The peer reviewers disagreed with the Service’s conclusion that climate change is not a threat now or in the future. A third peer reviewer pointed to several statements in the draft Species Report that the reviewer believed supports climate change as a threat, such as “ectotypes that support fisher habitat may decrease in area;” “where habitat area decreases the number of fishers that can be supported by the habitat will also decrease;” and “loss of habitat could threaten the viability of native and reintroduced populations, and would reduce the likelihood of reestablishing connectivity between populations.” This peer reviewer noted that the Service found other complex and unpredictable stressors to pose a threat to the fisher, such as wildfire and vegetation management; the peer reviewer believed that if those issues can conclusively be determined to pose a threat to the fisher, then climate change should also be found to pose a significant threat to the species. On the other hand, a fourth peer reviewer was pleased that the Service acknowledged uncertainty where it exists and agreed with the Services’ conclusion in the proposed rule [79 FR 60434–60435] that we do not have sufficient data to reliably predict the effect of climate change on fisher populations at this time.

Our Response: The summary of climate change in the proposed rule [79 FR 60429] stated that, although many climate models generally agree about the changes in temperature and precipitation, the consequent effects on vegetation are more uncertain. Therefore, it is not clear how changes in forest type, species composition, or growth rate will affect the availability of fisher habitat and its ability to support fisher populations (Service 2014, pp. 71–84). Consequently, at this time, climate change is not viewed as a threat to fisher habitat now or in the future. We have not received any new information that would lead us to change this conclusion; all of the best scientific and commercial data available to us continues to underscore the uncertainty with regard to the projected effects of climate change specific to fishers and fisher habitat.

In the Summary of the Effects of Climate Change on Fisher Habitat section (Service 2014, p. 80), the draft Species Report stated: “In all or most sub-regions of the analysis area, fisher habitat will be altered, with likely shifts away from conifer forest and towards an increased hardwood component, or from maritime conifer forest to drier temperate conifer forest. It is uncertain how these habitat shifts will affect fisher populations. Modeling projections are done at a large scale and effects to species can be complex, unpredictable, and highly influenced by local level biotic and abiotic factors.” Although we did not consider climate change to be a threat to fisher or their habitat, we did discuss in the proposed rule (79 FR 60434–60435) that we considered climate change to be one of multiple synergistic factors acting on small population size, although the impacts would depend on the scope and severity of each of the stressors. We also noted the potential for climate change-induced habitat shifts in the future according to modeling projections and how these may affect fisher populations, although it is important to note that there are inherent uncertainties in modeling climate change habitat effects into the future and across the fisher’s range in the west coast States. We do not agree that modeling future wildfire and vegetation management habitat effects are as complex and unpredictable as modeling those of climate change because we used past effects of these stressors to predict into the future. We have no information on past effects of climate change to project into the future.

Our analysis of all the best scientific and commercial data available, including new information received during the open comment periods, reaffirms our initial conclusion that we do not have sufficient data to reliably predict the effect of climate change on fisher populations at this time. For example, some models project that ectotypes that support fisher habitat may decrease in area in response to the effects of climate change. However, as noted in both our draft and final Species Reports, depending on the emissions scenario considered and other variables, various models also predict that fisher habitat may increase in area, remain relatively stable, or shift in range.

We have clarified in the final rule that climate change, by itself, is not a threat. In addition, the cumulative and synergistic effects of climate change and other stressors acting on small populations do not pose a threat to the proposed West Coast DPS of fisher, based on insufficient evidence that climate change acting alone or synergistically on small populations is having significant impacts at either the population or rangewide scales, or is likely to do so within the foreseeable future.

(2) Comment: Several peer reviewers noted that, because fishers prefer habitat at low- to mid-elevations and areas with no snowfall, there would likely be an increase in their habitat if global temperatures increase. One peer reviewer mentioned that a decrease in snowpack could lead to more fisher habitat at higher elevations, and allow increased habitat connectivity through those mountaintops. Another peer reviewer stated that the Service should consider how alterations in snowpack could benefit the fisher, but opined that there would not be any significant net benefit to such decreases in snowpack when compared to the other negative impacts of climate change.

Our Response: The draft Species Report (Service 2014, p. 13) discussed the effects of snow conditions and ambient temperatures on fisher activity and habitat use and concludes that fishers’ reaction to snow likely depend on a myriad of factors and are variable across the range of the species. We mentioned the possible benefits of lower snowfall amounts, and the drawbacks of less precipitation falling as snow, to fishers and their habitat (Service 2014, p. 76). Peer reviewers also pointed us to more recently available modeling efforts that additionally suggested fishers may benefit to some degree from climate change as a consequence of reduced snowpack; we have incorporated this information into our final Species Report (Service 2016, pp. 78–98).

(3) Comment: One peer reviewer believed that climate change would have a positive impact on fishers because climate change is expected to result in increased hardwood species, which develop the cavities used by nesting fishers much more rapidly than conifers do, and because an increase in hardwood species in a forest usually...
results in increased diversity in prey species.

*Our Response:* The “Climate Change Effects on Fisher Habitat” section of the final Species Report contains an in-depth discussion of the effects of climate change across the fisher’s range in the west coast States. In the Klamath region, for example, Lawler et al. (2012, pp. 385–386) predict a shift from conifer to hardwood-dominated mixed forests and woodlands, by the end of the twenty-first century. We agree that in some instances, climate change may have a positive impact on fishers because of an increase in the diversity of hardwood species, which in turn may lead to an increase in the number of den structures, and abundance and diversity of prey species. However, it is important that we note the distinction between any possible benefits of increased hardwoods and the potentially negative impacts of a vegetation shift toward a woodland community.

However, as stated in both the draft and final Species Reports, it is uncertain how these habitat shifts will affect fisher populations, and because modeling projections are done at a large scale, effects to species can be complex, unpredictable, and highly influenced by local level biotic and abiotic factors (Service 2014, p. 80; Service 2016, p. 84, 87–88, 91–95). Because of the uncertainty of the effects of climate change on fisher populations, the Service does not agree with the peer reviewer that we can conclude climate change will have an overall positive impact on fishers.

(4) **Comment:** One peer reviewer suggested that the mid-century projections of climate change presented in the draft Species Report are flawed because they were developed by extrapolating predictions out 100 years and then adjusting backward in time. The peer reviewer pointed out that projections for the late 21st century are an order of magnitude less certain than those for mid-century because of the cumulative error associated with longer runs of the models plus the multiple errors associated with the many feedbacks in the global system. The peer reviewer claimed that the approach used in the draft Species Report, in which effects projected for the late 21st century were halved, magnifies these errors and is inappropriate. The peer reviewer suggested it would be more accurate to rely on models that are designed for mid-century projections, even if there are fewer available. The peer reviewer further noted that this problem undermines the conclusions drawn in the draft Species Report regarding the timing, scope, and severity of the effects of climate change on fisher habitat.

*Our Response:* We agree with these criticisms. Taking end of century projections and then adjusting backward in time is not appropriate, as it improperly assumes that the rate of change is linear and constant over time, which is not the case and leads to misleading results. We have modified our final Species Report to present projections only in the timeframes over which they were modeled and reported. We have used mid-century results only if they were available to us, but as so many models project out over a roughly 100-year timeframe, we have reported late century results as well. We note that late century results are provided for informational purposes only, as we consider predictions on that long-term timeframe to be beyond our foreseeable future for the purposes of making reliable predictions about the effects of stressors on the conservation status of the fisher. As described in our final Species Report, most climate change models are in agreement until mid-century, or approximately 40 years from now, at which point they diverge in magnitude and severity depending on the emissions scenario. For this reason we chose 40 years in the future as that period of time over which we could make reliable predictions with regard to the potential effects of climate change on fishers and fisher habitat.

(5) **Comment:** One peer reviewer stated that the assumption in the draft Species Report that vegetation change would occur rapidly and begin immediately was not supported by studies that use empirical data. The peer reviewer cited several studies that suggest that shifts in tree distribution caused by climate change will be slow, and that these changes will be slowed or prevented by interspecific competition. The peer reviewer further noted that climate is not a strong predictor of tree growth or species limits in low-elevation forests, and that existing data (Ettinger and Lambers 2013) predict a much slower effect of climate change on tree species than was described in the draft Species Report, and that some shifts may be outside of the foreseeable future range described in the proposed listing rule.

*Our Response:* We have incorporated discussion of additional studies and models into our final Species Report. Although we acknowledge the ongoing debate and uncertainty as to the potential rate of vegetation change and tree species range shifts in response to climate change, we are required use our expertise to make a determination based on the best available evidence. In most cases, as suggested by the peer reviewer, the best available scientific data suggests that range shifts for long-lived tree species are likely to occur relatively gradually, and likely extend beyond our foreseeable future timeframe. However, we also recognize the possibility of some more relatively rapid range shifts in some portions of the analysis area, particularly in response to significant disturbance events. For example, models are in agreement regarding biogeographic shifts in vegetation cover over time, and the uncertainty as to when these shifts will occur and how they may specifically affect fishers within the analysis area is too great for us to rely upon these predictions with any confidence in our evaluation.
studies predicting that large areas of the fisher's current range will remain relatively stable. In sum, our review of the best available information for the time period beyond a 40-year time horizon did not produce any clear, consistent predictions for the consequences of climate change with regard to fishers and fisher habitat across the west coast States over the time horizon considered here. However, within the 40-year timeframe (i.e., foreseeable future), we have concluded that there is no information to suggest that climate change will result in significant, negative impacts to fishers or their habitat at either the population or rangewide scales. Thus, climate change does not rise to the level of a threat (see Climate Change, above).

(7) Comment: Two peer reviewers recommended that the Service assess the effects of climate change on prey and prey habitat. One peer reviewer highlighted multiple new recent studies assessing the future impacts of climate change on small mammals, as well as on mustelids.

Our Response: We have incorporated additional discussion of the potential effects of climate change on the abundance and diversity of fisher prey species into our final Species Report (Service 2016, pp. 83–86). However, like so many of the projections with regard to climate change, the results of studies are equivocal with regard to the potential impacts of climate change on prey populations. Although some studies suggest a possible decrease in prey, other prey populations may shift in range in response to climate change (e.g., Moritz et al. 2008, entire), others suggest that prey populations may remain steady or even increase in response to predicted changes in vegetation, such as increased areas of shrubland, that will result in increased ecotype diversity and thus greater foraging opportunities for fisher (e.g., Safford 2006, and references therein). In addition, the fact that fishers are generalist predators helps buffer fishers from potential declines in any particular prey species, as they are able to take advantage of a wide variety of prey species that may be available.

(8) Comment: One peer reviewer commended the way that the Service outlined concerns related to climate change. However, the peer reviewer also expressed puzzlement that the proposed listing rule did not identify climate change as a threat to fisher. The peer reviewer noted the fisher is a habitat specialist, and California is the southernmost part of its range on the west coast, and stated that the effects of climate change have been shown to have the highest effects on species in the southern portion of their ranges. Based on the number, scope, and severity of the stressors associated with climate change, and particularly the way that climate change interacts with other stressors facing the fisher, the peer reviewer asserted that climate change is a threat to the fisher.

Our Response: Please see response to Comment (1) above.

(9) Comment: One peer reviewer stated that the uncertainty inherent with climate change predictions should not preclude its recognition as a stressor, as there is some degree of uncertainty present in all stressors. The peer reviewer stated that climate change was the only stressor in the draft Species Report that was not recognized as a threat due to uncertainty, and the rationale for that was not clear. The peer reviewer stated that, due to the synergistic effects of climate change with other stressors, it should be considered as an important threat impacting the fisher and its habitat.

Our Response: Please see our response to Comment (1) above. As described in our final Species Report, we carefully evaluated all existing and new information provided by peer reviewers and public comment regarding the potential effects of climate change specific to fishers in the proposed West Coast DPS. Based on the best scientific and commercial information available at this time, we conclude that, although we can make general predictions about future environmental conditions as a consequence of climate change on a relatively broad scale, this information does not allow us to draw any reliable conclusions with regard to the future availability of the specific habitat elements and conditions required to sustain the proposed West Coast DPS of fisher. In addition, the best available scientific and commercial data do not indicate likely significant impacts to fisher in terms of direct mortality as a consequence of climate change in the analysis area. Studies specific to fishers in the face of predicted climate change scenarios are equivocal in their results, and there is no general scientific agreement that points to ongoing or future significant impacts at either the population or rangewide scales to the West Coast DPS of fisher as a consequence of climate change. Therefore, although we recognize the effects of climate change as a stressor, we cannot conclude that climate change rises to the level of a threat to the proposed West Coast DPS of fisher now or in the foreseeable future.

(10) Comment: One peer reviewer considered the estimates of tree species distributional changes to be too rapid, stating that they were calculated at less than 100 years, whereas the lifespan of forest trees in the Pacific Northwest is typically greater than 100 years. Based on the lifespan, the peer reviewer stated that shifts in tree species distribution will occur on a much longer time scale.

Our Response: We have incorporated discussion of additional studies and models into our final Species Report (Service 2016, pp. 83–89), and acknowledge the ongoing debate and uncertainty as to the potential rate of vegetation change and tree species range shifts in response to climate change. In most cases, as suggested by the peer reviewer, the best available scientific data suggests that range shifts for long-lived tree species are likely to occur relatively gradually, and likely extend beyond our foreseeable future timeframe. However, we also recognize the possibility of some more relatively rapid range shifts in some portions of the analysis area, particularly in response to significant disturbance events (for example, drought and severe fire). Nonetheless, although we may observe the beginning of shifts in tree species distribution in response to climate change in the relatively near future, we conclude there is no evidence to suggest that widespread, wholesale changes in tree species distribution are likely to be realized within the analysis area in the foreseeable future. We have updated the final Species Report to more clearly express this interpretation of the best available scientific data. See also our response to Comment (5).

(11) Comment: One peer reviewer noted that the references from the work of the Intergovernmental Panel on Climate Change (IPCC) used in the draft Species Report are out of date, and suggested that we use the most recent data from the Fifth Assessment Report, which uses new model runs using the Representative Concentration Pathways instead of older emissions scenarios. The peer reviewer noted that results are similar enough that much of the substance remains unchanged, but urges the Service to use the most up-to-date data.

Our Response: We have updated the final Species Report with information from the IPCC Fifth Assessment Report.

Collision With Vehicles

(12) Comment: One peer reviewer referenced unpublished data about 11 fisher deaths due to collisions with vehicles on the Olympic Peninsula, and asked if those deaths had been included in calculations of vehicle mortality in Table 22 of the draft Species Report. The peer reviewer noted that the
number of fisher collisions with vehicles in the Olympic Peninsula appear to be higher than elsewhere in the range of the proposed DPS.

Our Response: At the time of writing the draft Species Report, we were aware of the 11 documented fisher deaths by vehicles (Service 2014, p. 147). However, the severity scores presented for Washington (1 to 4) were based on severity calculated for the NCSO population (as part of our quantitative analysis) because we lacked data for quantifying Washington-specific severity. We acknowledge that Lewis (2014, p. 2) reported 20 percent mortality from vehicle strikes and that this percentage is higher than many other reported mortality rates for vehicle strikes. However, we are not updating the calculations of severity in the final Species Report for any of the stressors evaluated. We received comments indicating that the quantitative approach we used in the draft Species Report implies a greater level of precision, accuracy, and certainty than we have, nor, for that reason (as described earlier in this document), we now present our assessment of the stressors in qualitative, rather than quantitative, terms, to avoid creating a false sense of precision with regard to the level of scientific accuracy underlying our estimates. In the final Species Report and the “Collision With Vehicles” section of this document, we conclude (including consideration of information specific to fishers on the Olympic Peninsula) that vehicle strikes do not rise to the level of a threat to fishers in Washington or any portion of the fisher’s range in the proposed West Coast DPS.

Completeness and Accuracy

(13) Comment: One peer reviewer suggested that transparency would be aided by making reports of fisher observations public information, and suggested that if these observations were considered sensitive material, they could be presented at a relatively coarse scale to avoid precise location information.  

Our Response: All comments, including location data submitted as part of the public comment periods for the proposed rule are available on the Internet at http://www.regulations.gov at Docket No. FWS–R8–ES–2014–0041. We received many detection data sets during the public comment period, and this information is currently being reviewed for redundancy against the survey records we had obtained previously. The fisher locality database currently consists of more than 17,000 positive and negative locality data records. When this quality control process is complete, we hope to be able to create an updated map of positive and negative survey information. We will make maps of this information available when we have completed this quality control process.

(14) Comment: One peer reviewer suggested that some additional, upfront discussion of taxonomy would help clarify the relationship between fishers in the west coast states (now recognized in the monotypic genus Pekania) and what were until recently recognized as three subspecies of Martes pennanti—M. p. pennanti, M. p. Columbiana, and M. p. pacifica. The peer reviewer believed the relationship between fishers in the west coast States and these three formerly recognized subspecies was not clear. Furthermore, the peer reviewer stated that it was unclear when the word “fisher” was used in the draft Species Report whether it referred specifically to fishers in the proposed West Coast DPS or possibly to fishers in general. The peer reviewer suggested this distinction is important, as Rocky Mountain or Eastern North American populations of fishers, although potentially used for surrogate information, may be biologically very different.

Our Response: Because we have never referred to fishers in the proposed West Coast DPS as a portion of a subspecies, we have not revised the history of fisher taxonomy in the final Species Report, as the peer reviewer requested. Both the draft and final Species Reports distinguish between references to the species as a whole (Pekania pennanti) and to fishers in the west coast States, in those instances where the distinctions were unclear. We agree that there are important biological and habitat differences among fisher populations that are found in the eastern, central, northwestern, and Pacific regions of the species’ range, most studies of which were conducted in regions outside of the proposed West Coast DPS, as indicated in the draft and final Species Reports.

(15) Comment: One peer reviewer suggested that the draft Species Report adopt some standard nomenclature for the various regions and subregions referenced throughout the document. The peer reviewer noted that many readers may not be familiar with the geography of the area in question or the alternate systems of geographical classification that have been used historically. In particular, the peer reviewer suggested that the report should present its system of geographic units to be used early in the document to provide clarity for the reader.

Our Response: We appreciate the suggestion by the peer reviewer. However, we used different descriptions of subregions in the draft Species Report depending on whether we were referring to the review of stressors or to the habitat model regions. Figure 11 in the draft Species Report (Service 2014, p. 49) provided a map of the analysis area subregions for review of the stressors and now appears in the final Species Report (Service 2016, on page 56).

(16) Comment: One peer reviewer stated that it was unclear from the presentation in the draft Species Report that there was supporting methodology behind the habitat modeling. The peer reviewer asked that the methods either be integrated into the final Species Report itself, or be cited directly within the report to provide transparency as to how the models were derived.

Our Response: We thank the reviewer for the suggestion. The supporting methodology for the habitat modeling results presented in the draft Species Report was in the document “Habitat Modeling Methods For The Fisher West Coast Distinct Population Segment Species Assessment,” which was made available on the Internet at http://www.regulations.gov at Docket No. FWS–R8–ES–2014–0041. We have included the methodology as Appendix D in the final Species Report, as suggested. In addition, we have revised the final Species Report so that it refers to this methodology document.

Detection Probability

(17) Comment: One peer reviewer requested a more detailed discussion of the way detection probability estimates from different studies were calculated. The peer reviewer noted that there were considerable differences between the methodologies in the quoted studies.

Our Response: The purpose of the draft and final Species Reports is to summarize the best available scientific and commercial information regarding the fisher. A detailed discussion of the various methodologies used to calculate detection probabilities in different studies is beyond the scope of the species report. However, to aid the reader, we have provided in the final Species Report citations to the literature concerning the different studies to allow readers easier access to the details of the methodologies. We appreciate the comment.

(18) Comment: One peer reviewer appreciated the thorough analysis of known fisher detections, but requested more clarity on any negative detections for fishers, particularly given the secretive nature of fishers. The peer
reviewer queried if detections outside of the expected range of fisher indicated an expanding population, males in search of mates, or increased survey effort combined with improved detection ability through use of digital cameras. The peer reviewer recommended including a map of all positive and negative surveys for fisher that followed appropriate detection protocols.

**Our Response:** Figure 6 in the draft Species Report included all opportunistic and systematic surveys (with both positive and negative results), as well as fisher trapping efforts for research and other verifiable records (e.g., fisher telemetry data) since 1993. Opportunistic and systematic surveys (with both positive and negative results), fisher trapping efforts for research, and other verifiable records (e.g., fisher telemetry data) from 1993–2013. A comparison of Figure 6 with Figure 7 (which presents all locality records from 1993 to the present with reliability ratings 1 and 2) illustrates the areas where surveys, trapping efforts, or research have occurred, but fishers have not been detected at a reliability rating of 1 or 2 since 1993.

We received many detection data sets during the public comment period, and this information is currently being reviewed for redundancy against the survey records we had obtained previously. The fisher locality database currently consists of more than 17,000 positive and negative locality data records. As we received new detection information, we reviewed information, and in particular, sought instances where such detections occurred outside the currently expected range. At this time, we cannot reliably conclude whether these new detections are based on improved or increased monitoring methods, or a biological response by fishers, nor is it possible to determine the reason for the detections (i.e., whether it is a male in search of a mate, etc.). However, as discussed in the final Species Report, we do have some evidence of potential contact among the NCSO, NSN, and SOC populations. Several comparative and comparable carnivore detection surveys are underway this winter throughout the Oregon Cascades that will aid in our understanding of fisher distribution in western Oregon.

**Development**

**Comment:** One peer reviewer provided comments on the assessment of human population growth as a threat to fisher. The peer reviewer noted that recent telemetry data in Oregon supports the Service’s assessment that human population growth is not a threat to fishers because much of rural Oregon is experiencing slow to no population growth even as urban areas increase in size; yet the reviewer believed our assessment may still overestimate the overall effect, with parts of rural Oregon experiencing slow to no population growth and other rural areas expected to decrease in population size through 2040. The peer reviewer also noted that Oregon’s Land Use Planning System makes the development of forested areas difficult and requested that this situation be acknowledged in the final Species Report.

**Our Response:** We reviewed the information on Oregon’s Land Use Planning system and have incorporated this information into our description of regulatory mechanisms in the final Species Report. In addition, we have reviewed the information regarding projected population growth in rural Oregon and incorporated that information into the final Species Report. Any overestimate of the development stressor (which is what we assume the peer reviewer was referring to when describing “human population growth” impacts) as observed by the commenter is within the realm of precision provided by our current analysis. Furthermore, any error as a result of a possible overestimate of this stressor did not change our final determination that development is not a threat to fishers in the proposed West Coast DPS.

**Disease or Predation**

**Comment:** Peer reviewers suggested that the assessment of disease or predation may be overstated.

**Our Response:** We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for fishers in the west coast States. We recognize and appreciate that there are many possible approaches to delineating potential DPSs, and that there may be valid arguments in support of (or against) aspects of each. However, at this time, our end decision is to use the original DPS configuration as presented in the proposed listing rule. Per section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding the potential threats to the proposed West Coast DPS of the fisher and have herein withdrawn our proposal to list this DPS.

**Dispersal**

**Comment:** One peer reviewer provided data on incidences of canine distemper in southern Oregon between 2010 and 2014, which was an outbreak that affected multiple species of mid-sized carnivores, including fox, coyote, and raccoon. The peer reviewer stated that fisher may have been affected by this outbreak.

**Our Response:** We have included this information on the incidences of canine distemper in southern Oregon between 2010 and 2014 in the final Species Report. However, we note that we lack evidence that fisher were affected.

**Distinct Population Segment (DPS)**

**Comment:** One peer reviewer provided data on incidences of canine distemper in southern Oregon between 2010 and 2014, which was an outbreak that affected multiple species of mid-sized carnivores, including fox, coyote, and raccoon. The peer reviewer stated that fisher may have been affected by this outbreak.

**Our Response:** We have included this information on the incidences of canine distemper in southern Oregon between 2010 and 2014 in the final Species Report. However, we note that we lack evidence that fisher were affected.

**SSN population**

**Comment:** Peer reviewers noted differences between the proposed West Coast DPS and the SSN population.

**Our Response:** The SSN population harbors distinctly different habitat, fire regimes, geography, and ownership patterns, suggesting that fishers in this area behave differently, have different needs, and will require a different conservation strategy than the rest of the West Coast fishers.

**SOC and NCSO populations**

**Comment:** Peer reviewers noted differences between the proposed West Coast DPS and the SOC and NCSO populations.

**Our Response:** The SOC and NCSO populations show no genetic exchange despite their relatively close proximity, and thus should not be part of a single DPS.

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Oregon.

suitable habitat in Washington and range of the proposed DPS to reoccupy the native genetics and expanding the overlap of reconnecting all fisher populations to should be a long-term conservation goal scientifically justified. return via management actions is should not exclude areas where their distribution from British Columbia to DPS's recovery given the species past distribution from British Columbia to California, and the habitat modeling results that indicate future suitable habitat focused north of both the Alternative 1 and 2 boundaries. Neither alternative is supported by strong evidence for the historical distribution of fishers in significant portions of Washington and Oregon; thus, an effort to conserve the taxon should not exclude areas where their return via management actions is scientifically justified. Neither alternative includes the SOC population. Both alternatives prevent what should be a long-term conservation goal of reconnecting all fisher populations to Canada. Neither alternative provides the combined conservation of preserving the native genetics and expanding the range of the proposed DPS to recoup suitables habitat in Washington and Oregon.

One of these eight peer reviewers stated that Alternative 1 or 2 should only be considered if they were found to be the only politically feasible path at the current time to ensure the long-term conservation of fishers in the west coast States. Another one of the eight peer reviewers also stated that a separate DPS for the SSN population would likely be beneficial to allow special management for recovery. Our Response: Listing decisions made under section 4(b)(1)(A) of the Act are to be made solely on the basis of the best scientific and commercial data available. Although we recognize that our DPS policy (61 FR 4722; February 7, 1996) provides relatively great latitude in terms of the identification of a potential DPS—that is, there may be numerous possible configurations of DPSs identified for any one vertebrate species—the fundamental evaluation of whether any potential DPS meets the criteria of our DPS policy remains grounded in science. We first evaluate any potential DPS to determine whether it meets our criteria for discreteness and significance; the latter criterion, in particular, is specifically identified as a measure of the population’s “biological and ecological significance.” Considerations as to whether a particular DPS may be politically feasible do not enter into our evaluation. Additionally, we note it would be predecisional to draw a DPS boundary with an eye to where the species should be.

As noted above, we solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast populations of fisher. However, at this time, our end decision is to use the original DPS configuration as presented in the proposed listing rule.

Comment: One peer reviewer who did not specify a preferred DPS configuration (but provided concerns related to each as described in the proposed rule) stated that if the Service proceeds with listing the DPS as proposed in 2004, then the cumulative population size and effective population size are so large that the threats leading to the proposed DPS’s extinction would be diminished, which comes into play regarding the Service’s concerns about small population dynamics. The peer reviewer expressed a much graver concern if the DPS configuration was splitting the proposed DPS in California. Neither alternative provides the combined conservation of preserving the native genetics and expanding the range of the proposed DPS to recoup suitables habitat in Washington and Oregon.

Our Response: We appreciate the peer reviewer’s opinion. Our end decision at this time is to use the original DPS configuration as presented in the proposed listing rule. As this single DPS encompasses most of the fisher’s historical range in Washington, Oregon, and California, the question of whether to potentially combine the SOC and NCSO populations for the purposes of delineating any smaller DPS is moot. This information will be useful and an important consideration, however, as we continue to develop management strategies and to work toward the conservation of fisher throughout its range, and we thank the peer reviewer for the information. We note that in our final Species Report we have combined both the SOC and NSN populations within the greater NCSO population.
(25) Comment: One peer reviewer asserted that the Service did not use recent molecular genetic information (e.g., Knaus et al. 2011, Tucker et al. 2012, Tucker 2013, Tucker et al. 2014) to distinguish potential separation of DPSs between the NCSO and SSN populations. The peer reviewer stated that these literature sources suggest long-term isolation of the NCSO and SSN populations (similar to DPS Alternative 2 as opposed to one large three-State DPS as outlined in the proposed listing rule).

Our Response: We have expanded our discussion of the available information regarding the molecular genetics of fisher populations in our final Species Report (Service 2016, pp. 133–137). We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for fishers in the west coast States. We also recognize that molecular genetic information could be utilized to delineate potentially different population segments. Many different biological or ecological considerations may come into play in delineating potential DPSs; as a result, it is often possible to identify multiple possible DPS configurations, all of which may technically meet our DPS criteria of discreteness and significance. However, at this time, our end decision is that the original DPS configuration as presented in the proposed listing rule is most appropriate.

(26) Comment: One peer reviewer asserted that if the proposed DPS configuration changes to Alternative #2, the Service should account for a recovery area large enough in the SSN population area to support a population size that would not suffer the stochastic genetic and demographic effects of small populations. The peer reviewer stated that this may require expanding the current SSN population boundary outlined in DPS Alternative #2 further north.

Our Response: At this time, we are withdrawing the proposed rule to list the West Coast DPS of fisher under the ESA, and our decision is to use the original DPS configuration as presented in the proposed listing rule. If in the future we consider an alternative DPS that includes the SSN population, we will thoroughly consider the most appropriate northern boundary of the SSN population area.

Distribution

(27) Comment: One peer reviewer requested clarification on how the range extent for the Olympic Peninsula population was calculated, and provided new information from Lewis (2014) on range expansion in Western Washington.

Our Response: In regard to Table 1 in the draft Species Report, the range extent for fisher on the Olympic Peninsula was calculated using GIS by roughly approximating the area of the Olympic Peninsula where we knew reintroduced fishers to have been generally reported. The peer reviewer is correct that Lewis (2014) reported a larger study area, thus our estimate of current range extent for the Olympic Peninsula is slightly undervalued. We have not amended Table 1 in the final Species Report, however, as the differences are relatively minor. We did use the best available information to conclude that the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act (see Determination, above).

(28) Comment: One peer reviewer stated that evidence indicated fishers have expanded their range and probably increased in density and abundance in north coastal California and possibly other portions of the NCSO region, though they acknowledged that such an increase was not a large area and may not be significant relative to the overall proposed DPS. The peer reviewer’s conclusions were based on historical information from maps (e.g., Grinnell et al. 1937), photographs, and tracking records as compared to the current fisher distribution. The peer reviewer stated that the historical trapping of martens and not fishers in the redwood zone (west coast) is compelling evidence that fishers did not historically occur in this coastal strip of old-growth redwood forests, yet current fisher distribution records indicate fishers are “commonly found” in the redwoods, and cites Thompson (2008) in reporting one of the highest densities of fishers on the west coast. The peer reviewer also stated that this comparison suggests that there are several other areas where the current fisher distribution may have increased, although information on historical trapping effort in those areas was not available. The peer reviewer further observed that expansion into the redwood region occurred in spite of extensive logging and loss of old-growth forest that occurred there since the time of Grinnell et al.’s (1937) map, speculating that historical logging practices left more of the structural features that fishers depend upon (e.g., snags, downed woody debris, den and rest trees), and that clearcutting redwood forests increases the densities of prey species such as dusky-footed wood rats.

Our Response: The peer reviewer specifically mentioned northern coastal California as an example of where fisher distribution may have expanded, but didn’t elaborate on what other portions of the NCSO population may also exhibit an expansion. As such, we limit our response to the northern coastal California region described by the peer reviewer.

We agree with the peer reviewer that there may be localized expansion of fisher distribution. The peer reviewer’s comment that fishers did not historically occur in the coastal strip of old-growth redwood forests is supported by Grinnell et al.’s (1937, p. 216) historical distribution map, which excludes coastal coniferous forest habitat in north coastal California in Del Norte, Humboldt, and Mendocino counties. Zielinski et al. (1997, p. 385) reported several fisher detections within coastal “redwood-Douglas fir” habitat in southern Del Norte and northern Humboldt counties based on surveys conducted between 1989 and 1994.

Figure 7 in the draft and final Species Report (Service 2014, p. 31; Service 2016, p. 34) and Figure 1 of the proposed listing rule show numerous recent (i.e., since 1993) fisher detections within coastal coniferous forest habitat throughout Del Norte County and in northern Humboldt County.

The peer reviewer’s assertion that an increase in “...population density and abundance in north coastal California” is similar to conclusions presented by Slauson et al. (2003, pp. 10–11). Slauson et al. (2003, pp. 10–11) noted that, although fishers were not historically known to be common in old-growth redwood forests, they have more recently been found in this area, despite over 90 percent of the old-growth redwood forest being logged and most of the area being managed on short rotations. Slauson et al. (2003, pp. 10–11) also noted that fisher detections suggested they used second-growth forest habitats more than old-growth redwoods in this area.

Because the proposed listing rule and draft Species Report (Service 2014, pp. 13–17) cite numerous studies that suggest fishers are consistently associated with low to mid-elevation coniferous and mixed-conifer and hardwood forests with abundant physical structure. The key aspects of fisher habitat are best represented in areas that are comprised of forests with diverse successional stages containing a high proportion of mid- and late-successional characteristics. In addition, fishers avoid large open areas such as meadows and clearcuts. Extensively logged areas may contain...
suitable habitat for some fisher prey species, but generally lack abundant large structural elements (e.g., trees, snags, logs) required for denning and resting. However, Raley et al. (2012), cited in the Habitat Associations section of the draft Species Report (Service 2014, p. 15), reported that it may benefit fishers to have a diversity of forest conditions within their home ranges to increase access to prey, provided important habitat features supporting reproduction (den sites) and thermoregulation den and rest sites) are available. Consistent with Raley et al.’s (2012) assertions, Slauson et al. (2003, p. 11) found that the redwood second-growth stands in which fishers were found were among the most structurally complex, as well as near old-growth redwood patches.

Multiple commenters provided information on fisher use of managed landscapes and this information was also presented in the draft Species Report (Service 2014, p. 17). In addition, we have noted the historical change in fisher occurrence in the redwood portion of the proposed DPS.

Existing Regulatory Mechanisms

(29) Comment: One peer reviewer requested further details on the Forest Service’s Fisher Analysis Suitability Tool, which was mentioned in the draft Species Report. The peer reviewer was particularly interested in determining how the tool has been used by Forest Service biologists and what impacts, if any, it has had on project planning.

Our Response: We appreciate the interest; however, further elaboration regarding the use of the Forest Service’s Analysis Suitability Tool in project planning for fishers is outside the scope of this rulemaking. We recommend that questions regarding the tool or impacts of its use be directed to the Forest Service.

(30) Comment: One peer reviewer discussed the Service’s use and interpretation of a study by Zielinski et al. (2006) in our discussion of “Existing Regulatory Mechanisms that may Address Stressors” in the draft Species Report (Service 2014, p. 123). The peer reviewer urged caution “when considering expanding late-successional reserves for a species that can use managed forests.” The peer reviewer also cautioned extrapolation of the study’s results because the analysis generates a theoretical set of new reserves based on models for fisher and northern spotted owls. The peer reviewer claimed that the draft Species Report does not adequately take into account the fisher’s ability to use managed forest reserves because: (1) The study did not address the necessary size of a reserve to support fisher, (2) much of the suitable habitat predicted by the fisher model occurred on Federal land, and (3) the study asserted that the fisher’s use of private timber lands was due to climatic factors and vegetation types rather than seral stage (it does not fully investigate the possibility that fishers may use younger forests).

Our Response: The peer reviewer may have misunderstood our reason for including Zielinski et al. (2006, pp. 409–430) in the draft Species Report. The purpose of the “Existing Regulatory Mechanisms that may Address Stressors” section in the draft and final Species Reports is to present the best available information on any regulatory mechanisms that are currently in place and to discuss how these mechanisms affect stressors acting on the proposed DPS. For example, a regulatory mechanism could ameliorate, exacerbate, or have no effect on the stressors. Our discussion in the draft and final Species Reports does not anticipate expanding late-successional reserves, but merely attempts to gather all pertinent information that may inform the topic of the benefits or drawbacks of existing regulatory mechanisms. We did not intend to suggest that Zielinski et al. (2006, pp. 409–430) is a source for the approximation of reserve sizes for fishers, that fisher habitat is only present on Federal land, or that fishers avoid younger forests. Nevertheless, we did add to the final Species Report the caveats noted by Zielinski et al. (2006, p. 426) to qualify their conclusions (Service 2016, pp. 166–167).

We acknowledge fishers’ use of managed landscapes (Federal and non-Federal), multiple seral stages, and potential climate-related influences. We received numerous comments in that regard. Please see our responses to peer review Comments (37), (39), and (57), below.

(31) Comment: One peer reviewer suggested adding more detail on the Oregon State Wildlife Action Plan and its conservation strategy to the final Species Report, and provided some suggested language. The peer reviewer also discussed the Oregon Forest Practices Act (FPA) and provided clarification on protections that benefit fisher habitat within Riparian Management Areas. Finally, the peer reviewer discussed the protections afforded to forested habitat from Goal 4 of the Land Use Planning Act, and one LMP, and recommended adding more detail on these protections to the final Species Report. The peer reviewer believed that, without these additions, the Species Report would overestimate the threats to fisher in Oregon.

Our Response: We have added fisher-specific information from the Oregon Conservation Strategy to the final Species Report, as well as expanded the description of the riparian regulations from the Oregon Forest Practices Act. In addition, we added information on Oregon’s Land Use Planning Act into the regulatory mechanisms description in the final Species Report.

(32) Comment: One peer reviewer disagreed with the Service’s conclusion about the effectiveness of NEPA and the Forest Service’s Sensitive Species Program in conserving the fisher. The peer reviewer stated that NEPA analyses often find effects to individuals rather than populations, and that these analyses do not account for cumulative population effects as a result of vegetation management activities. The peer reviewer concluded that these two programs result in superficial analyses and are less effective for protecting species than described in the draft Species Report.

Our Response: The Service considers NEPA to be an important environmental disclosure statute. Our discussion of NEPA in the draft Species Report and proposed rule in the Federal Register clearly states that the evaluation of projects under NEPA does not regulate or protect fisher nor does it require or guide potential mitigation for project impacts. Our characterization of the Forest Service sensitive species program was that protections afforded the fisher as a sensitive species largely depend on LMPs or LRMPs and on site-specific project analyses and implementation. We appreciate the peer reviewer’s comment, but stand by our characterization of these two mechanisms (NEPA and the Forest Service’s Sensitive Species Program).

Fisher Biology

(33) Comment: One peer reviewer was surprised that the draft Species Report did not include a section on community ecology or community interactions, particularly on potential negative interactions between fishers and martens or other forest carnivores. The peer reviewer stated that a discussion of community ecology (including consideration of the references provided) would allow exploration of potential synergistic interactions with existing stressors.

Our Response: Our decision to withhold our proposed rule to list the West Coast DPS of fisher as a threatened species is based on our determination
that the stressors (including predation by other forest carnivores) acting upon the proposed DPS are not of sufficient imminence, intensity, or magnitude such that they are singly or cumulatively resulting in significant impacts at either the population or rangewide scales now or in the foreseeable future. Our analysis of cumulative effects of stressors including predation by other forest carnivores adequately considers interaction between fishers and other forest carnivores.

(34) Comment: One peer reviewer was surprised to note that all estimates of fisher population size and habitat occupancy were all from unpublished reports. The peer reviewer thought that more estimates should be taken from peer-reviewed papers or official reports, but did not provide any references or examples.

Our Response: Contrary to the peer reviewer’s observation, we included available published and peer-reviewed information in describing fisher population size and occupancy in the draft Species Report, such as Zielinski et al. (2004, 2013) (Service 2014, pp. 40, 43). We also added newly published information, such as Sweitzer et al. (2016) that became available for the final Species Report (Service 2016, pp. 60, 66, 69). We acknowledge that most of the population information used is in unpublished reports, but, as required by the Act, we must use the best scientific and commercial information available to reach our determination. Thus, in addition to the published information, we also used information concerning population size and habitat occupancy found in several unpublished reports (see Species Information section of this document and the “Distribution and Abundance” section of the final Species Report (Service 2016, pp. 25–53)).

(35) Comment: One peer reviewer called attention to a sentence in the habitat stressors summary of the draft Species Report that stated, “. . . habitat loss, modification, and fragmentation appear to be significant stressors to fishers.” The peer reviewer noted that, though the document provides support for conclusions about habitat alteration and habitat loss through supporting literature or original analysis, there is no analysis of habitat fragmentation. The peer reviewer suggested that any analysis of habitat fragmentation should use a landscape metric, such as a comparison of patch size distribution over time, or a change in inner patch distances, the peer reviewer noted that the draft Species Report needs to cite references or original analysis to support conclusions made about fragmentation.

Our Response: The peer reviewer is correct that we did not specifically model the effects of habitat fragmentation on fishers in the proposed West Coast DPS. However, the results of the Fisher Analysis Area Habitat Model (Service 2014, Figures 2 and 3) did show that, in certain areas, connectivity within fisher population areas is disrupted as a result of habitat quality. We have revised the final Species Report to include references to the results of the Fisher Analysis Area Habitat Model and other literature that relates to habitat fragmentation (Service 2016, pp. 58–62, Appendix B).

Forest Management

(36) Comment: One peer reviewer believed that the draft Species Report overstated the scope and severity for the stressor of timber harvest in Washington. The peer reviewer suggested that the reason for this issue might be that the analysis combined private and State lands, which have different levels of timber harvest. The peer reviewer further noted that low-density rural land in Washington seems to support fishers.

Our Response: Although the scope is correct as presented in the draft Species Report, we agree with the peer reviewer that including State lands with other non-Federal lands in the Washington portion of this analysis leads to an overestimation of severity (we stated this on page 95 of the draft Species Report). In any case, we have revised our assessment of stressors presented in the draft Species Report, as our presentation of the scope and severity of stressors in quantitative terms may have created a false sense of precision with regard to the level of scientific accuracy underlying these estimates. As described earlier in this document, in our final Species Report we use quantitative data wherever available, but if specific data are lacking, we rely on qualitative evidence to derive a qualitative descriptor of each stressor, based on the best scientific and commercial information available, rather than extrapolating. We, therefore, present a qualitative description of timber harvest on State lands and other non-Federal lands in our final Species Report, which we have concluded is most appropriate for our analysis; this adjustment should address any concerns expressed by the peer reviewer in regard to the potential overestimate of scope and severity of this stressor in Washington. Finally, although fisher may be able to persist on low-density rural lands in Washington in some instances as the reviewer suggests, we do not have sufficient data to confirm or evaluate fisher use of this habitat type.

(37) Comment: One peer reviewer believed the draft Species Report failed to consider that managed forests may preserve or create new habitat for fisher, even in the face of climate change. The peer reviewer asserted that not all fisher habitat will be left subject to “natural processes” and, therefore, recommended that the Service consider whether managed forests may serve as refugia for fisher.

Our Response: The effects of vegetation management, and by proxy managed forests, on fishers, and the range of impacts that silvicultural treatments may have on fisher habitat, are discussed in the draft Species Report (Service 2014, pp. 86–87, 94–95), and expanded discussion is provided in the final Species Report (Service 2016, pp. 98–111). Because the outcomes of forest management are variable depending upon the objectives of the treatments, it is not appropriate to consider all managed forests as potential refugia for fisher. Both the draft and final Species Reports acknowledge that managed forests provide habitat for fishers if those forests provide sufficient amounts and adequate distribution of keystone habitat structural elements required by fishers. The revised discussion on this topic in the final Species Report addresses the concerns of the peer reviewer.

We further interpret the peer review comment to suggest that forest management may ameliorate the effects of climate change on fisher habitat by shifting forest tree species to those that are more drought resistant (e.g., pine) or by reducing stocking levels so that forests are more resistant to catastrophic wildfires. While there is much uncertainty about the localized effects of climate change within the various subregions of the proposed West Coast DPS of fisher, we agree that active management of forests may improve drought tolerance and reduce the severity and intensity of wildfires.

(38) Comment: One peer reviewer commented that while a certain population had high tolerance for both fuels reduction and recreational use, other populations may not show the same tolerance. The peer reviewer also noted that while fishers in the southern Sierra Nevada had shown some tolerance to fuel treatments, all watersheds had not seen such pressure. The peer reviewer concluded that more work is needed on the issue of commercial logging and thinning, and its effect on fisher.
Our Response: Fisher response to disturbance is likely to vary depending upon the ambient levels of noise and activity that occur within individual home ranges, as well as the existing condition and configuration of habitat. The scale, intensity, and distribution of disturbance events, such as vegetation management and recreation, may alter the overall ability of the landscape to support fishers (Powell and Zielinski 1994, p. 64; Weir and Corbould 2010, pp. 408–409; Naney et al. 2012, entire). Although there is no published work evaluating the direct effects of fuel treatments on fisher populations, various studies indicate that management to reduce fire risk or restore ecological resilience may be consistent with maintaining landscapes that support fishers in both the short and long term, provided that treatments retain appropriate habitat structures, composition, and configuration (Spencer et al. 2008, entire; Scheller et al. 2011, entire; Thompson et al. 2011, entire; Truex and Zielinski 2013, entire; Zielinski 2013, pp. 17–20). However, some recent research also indicates that certain types of fuels reduction treatments, such as mechanical thinning, may result in fisher avoidance of treated areas, at least in the short term (e.g., Garner 2013; see final Species Report, p. 68). We agree that more research is needed to fully understand the impacts of vegetation management on fisher habitat and the ability of fishers to persist in managed landscapes. (39) Comment: One peer reviewer asserted that habitat features described for the fisher in the draft Species Report were too narrow. The peer reviewer pointed out that fishers have been documented on managed forest lands, and concluded that the Service should consider a broader range of habitat features in the final Species Report, including younger forests and stands with residual black oak.

Our Response: The draft and final Species Reports acknowledge that managed forests provide habitat for fishers if those forests provide sufficient amounts and adequate distribution of key habitat and structural elements (Service 2014, p. 17, citing Self and Callas 2006, entire and Reno et al. 2008, pp. 9–16; Service 2016, p. 19). The peer reviewer comment cited personal communications and unpublished data that were not provided to us and are not available to us; therefore, we are unable to include these data in our final Species Report. Through the public and peer review process, however, we did receive additional documentation of fisher habitat use that was used in an expanded discussion of fisher use of managed forests that we have incorporated into our final Species Report. (40) Comment: One peer reviewer agreed with the Service that there are no estimates available of the fitness of fisher populations in different habitats, and that obtaining this information is unlikely given the difficulty of estimating demographic parameters for fishers. Thus, the peer reviewer questioned how the Service was able to assess impacts of habitat management on fishers. Given that timber harvesting was primarily responsible for the complete extirpation of fishers in some areas concurrent with the persistence or recovery of fishers in other areas, the peer reviewer suggested that the amount, spatial pattern, or type (silvicultural technique) of timber harvesting be assessed to determine whether a different impact—trapping—had a serious effects on fishers everywhere in the west coast (as suggested in the draft Species Report). The peer reviewer suggested that there should be a strong correlation between the relative amount of late-seral and old-growth forests modeled as high quality fisher habitat not subjected to timber harvest and the persistence of fishers in the west coast. The peer reviewer’s brief analysis of this situation suggested that the persistence or recolonization of fishers may not strongly correlate with past timber harvest, particularly in portions of the NCSO population that may have experienced high levels of past timber harvest with fragmented regions of high-quality habitat.

Our Response: As noted in the draft Species Report, individual stressors potentially acting on fisher or fisher habitat may also be acting in concert with other stressors. Though not explicitly discussed in the draft Species Report, the combined effects of past trapping and past timber harvest may have influenced the patterns of extirpation/recolonization the peer reviewer is questioning. Past trapping of fishers appears to have been the primary initial cause of fisher population losses in the Pacific States (Service 2014, p. 112). Trapping and unregulated harvest varied by location, and were likely influenced by topographic features (Service 2014, pp. 110–111). Localized extirpations or greatly reduced numbers of individual fishers as a result of trapping mean that it became more difficult for remaining fishers to find one another and successfully recolonize previously occupied areas. Acting together, that scenario, large-scale loss of important habitat components from timber harvest also reduced the available habitat and increased fragmentation, making it difficult for remaining fishers to encounter other fishers.

Specific data are not available to quantify the severity of trapping by each sub-region (Service 2014, p. 112). Because of this lack of data, it is difficult to determine if the NCSO population was either not subjected to the trapping pressures observed in other areas, or that the types of timber harvest in the area were more conducive to the persistence of fishers on the landscape. (41) Comment: One peer reviewer questioned the Service’s statement that the magnitude and intensity of timber harvest is “one of the main reasons that fisher have not recovered on the west coast as compared to the northeast U.S.” The peer reviewer agreed that timber harvest has been a primary impact; however, the peer reviewer questioned the Service’s statement implying that timber harvest in the northeastern United States has been less severe than the western United States. The peer reviewer requested clarification, given that there have been substantial losses of old-growth on the east coast and current estimates indicate that only 1 percent of old-growth forests remain there, and given there is little Federal ownership and significantly higher human population densities that create more fragmented and intensively managed forests in the east as compared to the west coast.

Our Response: We did not mean to suggest that timber harvest in the eastern United States was more or less severe than in the western United States. We reviewed the statement questioned by the peer reviewer and offer the following clarification. The draft Species Report (Service 2014, p. 56) stated: “Consequently many fisher researchers have suggested that the magnitude and intensity of past timber harvest is one of the primary causes for fisher declines across the United States (Douglas and Strickland 1987, p. 512; Powell 1993, pp. 77–88, 84; Powell and Zielinski 1994, p. 41) and has been offered as one of the main reasons fishers have not recovered in Washington, Oregon, and portions of California as compared to the northeastern United States (Aubry and Houston 1992, p. 75; Powell 1993, p. 80; Powell and Zielinski 1994, pp. 39, 64; Lewis and Stinson 1998, p. 27; Truex et al. 1998, p. 59).” This was not meant to be a comparison of the relative severity of timber harvest in the west or the east. Rather, timber harvest and trapping declined in the 1930s in the eastern United States, and abandoned farmland began to return to a forested condition.
Large-scale loss of important habitat components resulted from previous forest management practices that began in the 1800s and ended in the early 1990s in the west (Service 2014, p. 55). Thus, habitat in the eastern United States was recovering while much of the western United States continued to be harvested. Fisher in the eastern United States, therefore, have had more time to recolonize habitats under reduced trapping pressure and increased habitat availability than fisher in the west.  

(42) Comment: One peer reviewer commented that the draft Species Report did not include any consideration of habitat recruitment from riparian buffer and leave trees, features that the peer reviewer asserts will increase habitat connectivity and lead to the eventual creation of structural features essential to fisher. The peer reviewer noted that private industrial and managed lands make up a substantial portion of the analysis area, and that these lands are subject to forest practice rules to preserve these features. The peer reviewer provided references regarding legacy structures and dead wood in managed forest lands.  

Our Response: The draft and final Species Reports (Service 2014, pp. 119–144; Service 2016, pp. 162–189) and the “Existing Regulatory Mechanisms” section of this document provide discussion of the Federal, tribal, and State regulatory mechanisms for Washington, Oregon, and California. Protection measures for riparian areas are a widespread standard in managed forests lands, with larger buffers and more stringent retention requirements typically associated with Federal and State lands than on other ownerships (Service 2014, p. 143). Many areas retained as riparian buffers or for other management goals (e.g., spotted owl special emphasis areas under Washington Forest Practice Rules, anchor habitats on Oregon State Forests, occupied site buffers on multiple ownerships, and Watercourse and Lake Protection Zones on private land in California) are not large enough to support a fisher home range (Service 2014, p. 143). However, they may provide habitat patches that allow fisher to move across the landscape, providing connectivity to and facilitating dispersal between larger blocks of fisher habitat either within existing ownerships among neighboring ownerships (Service 2014, p. 143). We reviewed the references provided by the peer reviewer and updated the final Species Report, as appropriate. Please see also our responses to Comments (171) and (188), below.  

(43) Comment: One peer reviewer asserted that the severity ranking given to stressors related to vegetation management was too high, as it did not adequately consider the ability of the fisher to use managed forest habitat. The peer reviewer provided several references that demonstrate the use by fishers of fire-treated forest stands. Overall, the peer reviewer stated that the Service should reevaluate the severity of habitat stressors in light of the fisher’s use of managed forest habitat.  

Our Response: We received multiple comments suggesting that we had understated the degree to which fishers may utilize a variety of successional stages of forests as well as actively managed forests. Our final Species Report incorporates a more robust discussion of the types of habitats used by fishers for their various life-history needs. With the exception of the fisher habitat trend analysis done for the southern Sierra Nevada, our final analysis of vegetation management was limited to looking at trends in vegetation classification based on predefined vegetation and structural classes that we related to fisher habitat quality. We considered fisher use of managed forests and structurally complex younger forests in selecting these predefined vegetation and structural conditions, when available, and noted their use in our vegetation management analysis in the final Species Report (Service 2016, pp. 98–111). Based on our thorough evaluation of the best scientific and commercial data available with regard to the present and future effects of vegetation management, as well as other stressors identified for fishers, fisher populations do not currently appear to be in decline, and no specific threats were identified as having significant impacts to the fisher or its habitat at either the population or rangewide scales. For more discussion, see the Vegetation Management section of this document and the final Species Report.  

Fuels Treatments  

(44) Comment: One peer reviewer noted that the draft Species Report seemed to lack a section that evaluated the comparative negative direct effects and indirect beneficial effects of fuel treatment on fisher habitat. The peer reviewer noted that the coefficient of vegetation management calculated in the draft Species Report seems to assume that all forest acres affected by fuel treatment are degraded, when some studies have shown that fishers seem to tolerate the level of fuel treatment necessary to reduce fire severity. The peer reviewer stated that, although there are negative impacts from fuels treatment, there are also indirect benefits, and it is important for the Service to consider that tradeoff in the final Species Report.  

Our Response: The peer reviewer is correct in that the draft Species Report primarily (but not completely) focused on the negative aspects of fuels treatments on fisher habitat. In the data sets we used to calculate the coefficient of vegetation management, we could not determine the degree of habitat modification or removal that was planned in the treated areas. On private lands, we did not estimate amount of habitat lost to fuels treatments because we only had information for commercial timber harvest plans. Further, we recognize, as described in the final Species Report, that fuels treatments may indirectly benefit fisher habitat by reducing the severity and extent of fires occurring within or adjacent to fisher habitat, but we could not filter such types of treatment out of the available data, as acknowledged in the draft Species Report (Service 2014, p. 93). See also our response to Comment (58).  

Our assessment in the final Species Report has been updated to include additional discussion of the effects of fuels reductions treatments on fishers and fisher habitat; although there are many indirect benefits from some treatments, we note that our assessment of the best available scientific information additionally identified some potentially negative effects as well (Service 2016, pp. 99–111).  

(45) Comment: One peer reviewer observed some tolerance by fishers to light fuel reduction activities. The peer reviewer provided three examples of female fishers inhabiting areas currently or recently subject to fuel treatment, but noted that the treatment in that area had been minimal. The peer reviewer also thought that one fisher may have remained in a fuel treatment area because she was surrounded on all sides by other female fishers and may have been unable to relocate. The peer reviewer concluded that some fishers may experience delayed responses to fuel treatment, but overall may also tolerate areas treated for fuels that maintain large-diameter trees and canopy closure.  

Our Response: We appreciate the observations provided by the peer reviewer. The peer reviewer also provided a monitoring report to support the observations, and we considered this new information in addition to other information received from other commenters, in our final analysis.
Genetics

(46) Comment: One peer reviewer suggested that the genetic separation of the Southern Sierra Nevada population might not be due to geographic separation, but due to a genetic bottleneck caused by overharvesting. Our Response: We thank the peer reviewer for this suggestion, and acknowledge there are a variety of historical mechanisms that may have contributed to the genetic structure currently observed in native fisher populations (see the new genetic information discussion in the “Small Population Size and Isolation” section of the final Species Report (Service 2016, pp. 133–136).

(47) Comment: One peer reviewer commented that, although the Service reviewed recent fisher genetic information, it did not appear that this information was used in distinguishing the proposed DPS boundaries (for example, the peer reviewer noted the genetic separation of the NCSO and SSN populations). The peer reviewer provided multiple sources to back up the assertion.

Our Response: In the proposed listing rule we solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for fishers in the west coast States. We thank the peer reviewer for the information provided, but note that genetic information represents only one of the criteria that we may consider in determining whether a population may meet the requirements of our 1996 DPS policy. We did use genetic information along with other information, including that provided by the peer reviewer, to aid in our final decision regarding the DPS boundary. For our final analysis, we also provided an expanded discussion of genetics in the final Species Report (Service 2016, pp. 133–136). At this time, our end decision is to use the original DPS configuration as presented in the proposed listing rule, which is consistent with Congressional direction that the Services apply the DPS policy “sparingly.” See also our response to Comment (25).

(48) Comment: One peer reviewer provided new information from the individual’s nearly completed study on fisher DNA. The results show that the SSN population was the most genetically separate from any other sampled area. The peer reviewer stated that these results support the SSN as a DPS, with the second DPS as everything north of this population. The peer reviewer also stated that these results support the NCSO as a separate management unit, but not a separate DPS from the SOC introduced population. A second peer reviewer concurred that the SSN population is genetically separate from the NCSO population.

Our Response: Please see our response to Comment (47).

(49) Comment: One peer reviewer noted that the draft Species Report did not discuss low genetic diversity related to small population size, and suggested that discussion of low genetic diversity be added to the final Species Report.

Our Response: We direct the peer reviewer to our discussion of low genetic diversity in relation to small population size in the section “Small Population Size and Isolation,” which was presented on pages 145–147 of the draft Species Report. We have expanded this discussion in the final Species Report to incorporate the additional information provided by the peer reviewer, particularly with regard to the relatively low genetic diversity of the SSN population.

(50) Comment: One peer reviewer, while acknowledging that he was a senior author on one of the references cited, stated that genetics studies support long-term genetic differentiation of fisher populations in northern California and in the southern Sierra Nevada (citing to Knaus et al. 2011 and Tucker et al. 2012). The peer reviewer stated that it is possible that gene flow may once have occurred between these populations, since fishers have been observed historically in the region that currently separates the two populations. However, the peer reviewer believed that the genetic data suggest if some level of connectivity did once exist, it was relatively minor and may not have contributed to the currently observed population structure.

Our Response: We received many comments regarding the genetic separation of the NCSO and SSN populations, particularly with regard to the question of whether connectivity should be “restored” between these populations. Several commenters believed that, given the evidence for longstanding genetic differentiation between these populations, introducing gene flow between them at this point would do more harm than good. Others believed that introducing additional genetic diversity to the SSN population might be beneficial. Clearly, there are mixed opinions on this matter.

Regardless of listing status, all of these considerations will be taken into account in future management efforts for West Coast populations of fisher.

(51) Comment: One peer reviewer requested that we add a table to the final Species Report that shows the sources of reintroduced fishers and the dates when they were reintroduced. The peer reviewer also requested clarification on whether the genetic origin of the reintroduced fishers had been determined, if these fishers were distinct from the origin population at the Great Lakes, and what the presence of this genetic material might mean for the management and recovery of the west coast fisher.

Our Response: The information showing the sources of reintroduced fishers and dates when they were introduced can be found in the draft (Service 2014, pp. 35–37) and final Species Reports (Service 2016, pp. 37–41; 50–53). Although the peer reviewer brings up a good point in terms of the potential implications of genetic differences between reintroduced and native populations in terms of future management considerations for West Coast fisher populations, such considerations are beyond the scope of this rulemaking.

(52) Comment: One peer reviewer provided new information on genetic analyses done on fishers found in the southwest portion of the reintroduced SOC population area. The analyses detected one male fisher in the range of the Cascades population (east of Interstate 5) that was genetically grouped with the NCSO population, and another fisher that did not have enough DNA for complete genetic analysis, but that appeared to match the NCSO population. Given these examples, the peer reviewer believed that the NCSO and SOC populations should be grouped as a single population, as it is possible that in the foreseeable future time horizon used in the draft Species Report, these populations could exchange enough individuals to become genetically indistinguishable. As such, any revision to the DPS boundary should not separate the NCSO population from the SOC population.

Our Response: We thank the peer reviewer for the new information indicating geographic overlap from individuals genetically associated with both the NCSO and SOC populations; this information will be useful in future management considerations for fisher, and we have updated our final Species Report to reflect this information. For the purposes of considering different DPS delineations, we solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast population of fishers. We received many comments expressing support or opposition for various DPS options, or suggesting entirely new
options. Following our careful consideration of all information, at this time, our decision is to use the original DPS configuration as presented in the proposed listing rule.

**Habitat**

(53) **Comment:** One peer reviewer suggested that the percentage of National Park area in “high elevation” and not expected to contain suitable fisher habitat reported on page 126 of the draft Species Report (67 to 85 percent of National Parks in the analysis area) is too large. Based on telemetry information from the Olympic Peninsula population, this peer reviewer recommended using 4,700 ft (1,433 m) as the elevation cut-off.

**Our Response:** Delineations of suitable habitat for fishers in the draft Species Report were not made with elevation-based cut-offs; areas of suitable habitat were predicted based on snow pack, temperature, forest cover and other variables (see Appendix C of the final Species Report). The clearest and most accurate presentation of suitable habitat in National Parks is provided by the data presented in Appendix A of the final Species Report. The sentence that prompted this peer review comment has been removed and replaced with the following: “In addition, higher elevation areas comprise much of National Park lands in the analysis area; these areas are typically classified as alpine and above elevations expected to contain suitable fisher habitat.” (Service 2016, p. 170).

(54) **Comment:** One peer reviewer questioned why we did not include discussion or evaluation of the factors that may have allowed fishers to continue to persist in some but not other portions of its historical range, and relatedly, whether or not much of the west coast was ever good habitat for fishers. For example, the peer reviewer noted that the fisher has completely disappeared from much of its range in Washington and Oregon even though the current habitat models suggest that 40 million ac (16.2 million ha) of high- and intermediate-quality habitat currently exist (albeit fragmented in areas but with extensive blocks of habitat that should have the potential to support substantial populations of fishers).

**Our Response:** We agree with the peer reviewer that fishers likely completely disappeared from Washington by trapping (both direct and incidental) and by predator control (poisoning) (e.g., Lewis and Hayes 1998). In our draft Species Report, we acknowledged that a significant amount of high-quality habitat remains unoccupied by fishers in the analysis area. In addition, based on our consideration of comments received and our current analysis, in our final determination we now underscore the point suggested by the peer reviewer, that lack of suitable habitat does not appear to be a limiting factor for the proposed West Coast DPS of fisher throughout the majority of its range.

(55) **Comment:** One peer reviewer asked about the assessment of habitat fragmentation in the draft Species Report. The peer reviewer noted that, although the draft Species Report refers to habitat in the NCSO population as highly fragmented, there are no formal assessments of habitat fragmentation in the draft Species Report, and no reasoning to support habitat fragmentation as a stressor to the fisher. The peer reviewer also stated that it is not clear why the NCSO population area is called the most fragmented landscape in the draft Species Report; the peer reviewer thought that the SSN population would be more fragmented, given that the habitat occurs in a narrow elevation band. The peer reviewer also found it odd that the NCSO population area is fragmented but considered occupied, while much of Washington and Oregon is considered unfragmented but also unoccupied. The peer reviewer requested that the final Species Report include a summary of both known and potential effects of habitat fragmentation.

**Our Response:** The relatively more fragmented habitat of the NCSO population is considered occupied due to documented contemporary observations of fisher in that geographic region, as opposed to large areas of apparently suitable unfragmented habitat in Oregon and Washington where we lack detections of fisher (thus these areas are considered unoccupied). The peer reviewer’s comparison to unoccupied and unfragmented habitat in Washington is not directly relevant because the likely cause of fisher extirpation on the Olympic Peninsula and in the Cascades was historical trapping (both direct and incidental) and predator control (poisoning) and not a result of habitat conditions. See also our responses to Comment (54).

(56) **Comment:** One peer reviewer asserted that there is no evidence that fishers are associated with riparian habitat.

**Our Response:** In many previous reviews and summaries of fisher habitat, riparian areas and buffers have often been highlighted as one of the key habitat features that improve a landscape’s ability to support fishers (69 FR 18770, April 8, 2004, p. 18773; USDA Forest Service and USDI BLM 1994a, pp. J2–54, J2–56–J2–57, J2–79). Powell et al. (2003, p. 644) found that in forest types subject to frequent fires that remove woody structures near the ground, fishers are closely associated with riparian areas which do not burn as often. Although recent analysis of information across the west indicates that the fisher’s pattern of use of riparian areas is not consistent among studies (reviewed by Lofroth et al. 2010, p. 94), the best available data do indicate that fishers utilize riparian areas (for example, Engstrom (2015, in litt., pp. 1–4) recently detected fishers in riparian areas located approximately one mile within the 1992 Fountain Fire perimeter). Many of the riparian areas may also provide habitat patches that allow fisher to move across the landscape, providing connectivity to and facilitating dispersal between larger blocks of fisher habitat either within existing ownerships or among neighboring ownerships.

(57) **Comment:** Multiple peer reviewers questioned how heavily the draft Species Report relied on old-growth forests in the description of fisher habitats. Several of these peer reviewers asserted that fishers used more habitat types than just old-growth forests, and that the analysis of stressors overemphasized the importance of old-growth forests.

One peer reviewer noted that the Ashland fisher monitoring project has found that fishers use multiple habitat types, including chaparral (the peer reviewer hypothesizes that the fishers utilize this habitat in the winter while searching for prey). The peer reviewer noted that all habitat types used by fisher in the monitoring project had greater than 60 percent canopy cover. Another peer reviewer noted that fishers in the ONP population seem to be selecting a mosaic of mixed-ownership partially managed forests over old-growth.

Another peer reviewer agreed with the draft Species Report that prey availability may impact the distribution of fishers. The peer reviewer asserted that late-successional habitat, regardless of elevation, was not a limiting factor for fisher home ranges. A fourth peer
reviewer noted that the fisher’s use of managed forests and more diverse forest types is supported in the literature and in successful reintroductions in places like Michigan and Pennsylvania. That peer reviewer noted that because of the draft Species Report’s overreliance on old-growth forest, the recruitment of forest structures in the late-successional reserves as set aside by the NWFP were not accounted for in the overall measurement of the stressor of habitat loss. The fourth peer reviewer also believed that this oversight would lead to an overestimation of the impacts of habitat loss.

Finally, another peer reviewer asserted that fishers in central British Columbia are well-adapted to a mosaic of forest ages and structural types that result from normal fire intervals. The peer reviewer suggested that, based on this evidence, large amounts of old-growth forests might not be ideal for the fisher.

Our Response: As a basic life-history requirement, fishers need large standing and down trees with cavities to give birth and raise their young, and these cavities must be sufficiently large to accommodate the mother and her kits (reviewed by Lofroth et al. 2010, p. 119; Coulter 1966, p. 81). Depending upon the tree species and ecological conditions, cavity formation in large trees or snags may require greater than 100 years to develop (Raley et al. 2012, pp. 242–244; Weir et al. 2012, pp. 234–237). These trees often have characteristics associated with late-seral conditions (e.g., large diameter, large limbs, mistletoe brooms) that are most commonly associated with old-growth stands. We acknowledge that these trees may exist outside of intact old-growth stands, as remnants from previous natural (e.g., fire) and anthropogenic (e.g., timber harvest) disturbances. Because these cavities are essential for fisher, we placed a fair amount of emphasis on the importance of historical and current distribution of old-growth to fisher in our draft Species Report. We did not state, nor did we mean to imply, that fishers are obligate users of old-growth forests.

In our draft Species Report, we discuss the use of managed, younger, and mid-seral forests (e.g., Service 2014, pp. 15, 17, 56, 88). Fisher will use these forest types if high canopy cover and complex structural elements are present to provide denning, resting, and foraging opportunities. We also recognize that habitat recruitment was not quantified in the draft Species Report, and important for understanding fisher use of habitat in the future. We received many comments on this topic, and have data available that allow us in the final Species Report to evaluate expected ingrowth of forests likely to provide suitable fisher habitat throughout most of the proposed DPS (see additional discussion on ingrowth in the “Vegetation Management” section of the final Species Report (Service 2016, pp. 98–111)).

(58) Comment: One peer reviewer requested more information on the calculation of the stressor of timber harvest on fisher. The peer reviewer believed that the way timber harvest was measured in the proposed listing rule resulted in an overestimation of the degree of threat attributed to timber harvest. The peer reviewer noted that many even-age harvest plans and permits report gross acres rather than net harvested acres, and that regulated and non-regulated or voluntary retention areas are not accounted for by the permits. The peer reviewer also stated that it was unclear if the Service’s analysis of timber harvest distinguished between even-aged and uneven-aged harvest. The peer reviewer noted that uneven-aged harvest can result in increased levels of removal of structural components required by fishers. Finally, the peer reviewer asserted that the analysis of habitat loss due to forestry and vegetation management focused only on acres removed and did not consider any enhancements to habitat due to managed forestry on private timberlands, including increases in prey available to fisher.

Our Response: Quantifying the effects to fisher habitat from vegetation management across the west states is challenging and complex due to many factors, including, but not limited to differences in forest types, silvicultural practices, project-specific objectives, and regulatory mechanisms. We received numerous comments on our draft calculations of scope and severity of stressors potentially impacting the proposed West Coast DPS of fisher. As described more fully elsewhere in this document, we found that our initial quantification of stressors may have conveyed a false sense of precision in our assessment, as we had to rely on extrapolation in areas where we did not have specific quantitative data available. In our final Species Report, we provide a qualitative description of stressors to explain the degree of impact a stressor may have on fishers or their habitat, as demonstrated by the best scientific and commercial data available. We recognize and acknowledge that reporting mechanisms for harvested acres may over- or underestimate the actual amount of acres treated; however, information is not readily available to inform further refinement of that estimate. Similarly, data are not readily available across the west coast States to assess differences between even- and uneven-aged management.

In our final Species Report, we have used the best available information to estimate the effects of vegetation management on the proposed West Coast DPS of fisher, including consideration of all comments and new information received during the comment periods on this rulemaking. Excellent sources of new information became available to us for the analysis of the effects of vegetation management within the analysis area, including the recently released NWFP 20-year late-successional old-growth monitoring report (Davis et al. 20XX, entire) within the area covered by the NWFP (most of the proposed DPS except the Sierra Nevada and eastern portions of the Oregon and Washington Cascades), the Gradient Nearest Neighbor (GNN) vegetation trend analysis for the Sierra Nevada portion of the analysis area outside of the NWFP area, and fisher habitat modeling associated with the southern Sierra Nevada fisher conservation strategy.

We received multiple comments on the recruitment of fisher habitat on Federal and non-Federal lands and the extent to which regulatory mechanisms may provide for fisher habitat. Please see additional related responses, such as Comments (38) and (42) above, and (75), (189), (215), and (229) below.

Finally, we received two other peer review comments regarding managed lands and prey, and we have incorporated additional discussion of how some forms of vegetation management may affect prey species composition or abundance in our final Species Report. See also our response to peer review Comment (83).

(59) Comment: One peer reviewer provided references to demonstrate that fishers in Oregon have been found in managed forests and even brush fields, and that fishers have been found in heavily logged areas elsewhere in their range. The peer reviewer noted that although fishers do require structures related to late-successional forests, fishers can use a mosaic of habitats with managed forest stands next to old-growth forests, particularly if the managed stands retain high canopy closure.

Our Response: We thank the commenter for the additional information regarding fisher use of managed landscapes; we received multiple comments on this subject from various commenters, and have incorporated an expanded discussion of
other researchers could provide the opportunity to collaboratively participate with researchers interested in developing a telemetry-based model. However, this particular type of model was less useful for the large-scale analyses presented in the draft and final Species Reports.

(62) Comment: One peer reviewer alleged that the habitat model was at too coarse a scale to be of assistance with fine-scale management for fishers on Federal land. The peer reviewer did not object to the use of the habitat model for large-scale analyses such as the draft Species Report, but was concerned that others may try to use the model inappropriately for more fine-scale uses, such as slowing or stopping proposed projects within fisher habitat.

Our Response: We agree with the peer reviewer that our habitat model, which is intended for use at the landscape scale, is not appropriate at the fine scales necessary for many forest management decisions. Use of the model at fine scales, such as the forest stand scale, would not be appropriate. The documentation that accompanies the model makes it clear that it is intended for use at the landscape scale, and we hope that all potential users of the model will read the documentation carefully and avoid such misuse.

(63) Comment: One peer reviewer stated that the current habitat models, which the Service relied on in the draft Species Report, may have focused on the wrong primary signal for why fishers currently occur where they do. Specifically, the peer reviewer indicated that the current habitat models focus on mature and older forests as the most important habitat feature for high-quality habitat (thus resulting in millions of acres of habitat projected to be high and intermediate quality for fishers) as opposed to forested stands that support abundant food sources.

Our Response: We disagree that the habitat models developed for the draft Species Report focus on mature and older forests as the primary feature for high-quality habitat. In the Oregon and Washington Cascades and Olympic Mountains, where an expert modeling approach was used, the most important variable was density of trees, which could be of any age class. The expert models do include one component that is correlated with mature or older forests, but also include another component that represents prey diversity, which is in line with the peer reviewer’s suggestion. In the remainder of the range, the Maxent computer algorithm, rather than human judgment, was used to select variables and fit models of relative habitat suitability for fishers. Only one of the variables selected (i.e., basal area-weighted canopy height) is likely to be related to the age of the forested stand, and this variable was not included in the models for the Sierra Nevada modeling regions. For more information
on the variables included in the models, please see the updated version of the document entitled “Habitat Modeling Methods For The Fisher West Coast Distinct Population Segment Species Assessment,” which is now included as Appendix B in the final Species Report.

(64) Comment: One peer reviewer noted that occupancy modeling in the Sierra Nevada does not distinguish between source and sink habitat, such as source areas that contain highly productive females, and sink habitat where juvenile males may be dispersing. The peer reviewer requested that we add more information on this subject to the species report.

Our Response: We agree with the peer reviewer that occupancy modeling only indicates whether or not a fisher is detected at a site and does not tell how the fisher is using the site or whether the site is high-quality (source) or low-quality (sink) habitat.

(65) Comment: One peer reviewer requested that the service add references to the published fisher habitat model into the final Species Report. It was not initially clear to the peer reviewer that the habitat model had been published as a separate report.

Our Response: Please see our response to Comment (16).

(66) Comment: One peer reviewer questioned whether reports of fisher observations could be made public in an online database, stating that doing so would aid in transparency.

Our Response: We received many detection data sets during the public comment period, and this information is currently being reviewed for redundancy against the survey records we obtained previously. The fisher locality database currently consists of more than 17,000 positive and negative locality data records. We are currently working through a quality control process to evaluate the data; therefore, the data are not in a format that is readily shareable at this point.

(67) Comment: Multiple peer reviewers suggested that the presentation of habitat modeling in the species report would be improved by including a more detailed discussion of how the habitat model was created. One peer reviewer specifically requested detail on which of the 22 environmental predictors considered were determined to be useful in predicting fisher habitat, as well as those that were identified as not making a significant contribution to the predictive power of the model. Another peer reviewer specifically requested information on model performance and parameter weighting. That peer reviewer also noted that there seemed to be more data available for California than Oregon and Washington, and recommended that the Service discuss the implications of that difference in data availability on model performance, interpretation, and results. A third peer reviewer noted that the habitat model seemed “off” for a portion of the Olympic Peninsula, and suggested the Service compare the baseline locality data to the model results.

Our Response: We encourage these peer reviewers to read the updated white paper describing how the habitat model was developed (Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, now included as Appendix B in the final Species Report). The appendix discusses the differences in data availability between California, Oregon, and Washington, and describes the variety of approaches (fitted Maxent, projected Maxent model, or expert model) we used to address these differences. We also added information regarding the variables that were selected by the model for use in the modeling regions where the Maxent models were used. We have not added detailed information about parameter weighting or model performance, as these are beyond the intended scope of the document.

With regard specifically to Washington data in the habitat model, we acknowledge that the habitat model is an approximation of fisher habitat on the Olympic Peninsula, and that actual fisher use of the landscape may suggest different areas that are or are not likely to be used by fishers. However, fisher home range data on the Olympic Peninsula is based on the habits of the first reintroduced animals over an approximately 5-year period, and may not reflect all of the habitats that will be used by fishers in the future. Therefore, the habitat model has an appropriate level of accuracy for the purposes of our analysis. We thank the peer reviewer for providing the information, which will be useful in guiding future management decisions.

(68) Comment: One peer reviewer stated that there were several factors not accounted for in the habitat models, including annual tree growth, the process by which forest stands develop into seral stages, the influence of natural disturbance events on the fisher and its prey, and the overall distribution and vulnerability of fisher prey.

Our Response: We agree with the peer reviewer that the habitat model did not account for every variable that might be useful in understanding fisher habitat and its development over time. We note that we are not required to create the best possible information products, but rather, according to section 4(b)(1)(A) of the Act, we are required to use the best available scientific and commercial information in determining a species’ status under the Act. Here, we took the additional step of developing a seamless model of potential habitat quality for fishers across the west coast evaluation area.

Every habitat model is not necessarily a simplification of reality. The type of model used and the particular simplifications to be made in a given model must be selected based on the purpose of the model, the input data available, and other practical considerations such as the timeframe allotted for the model’s creation. The main purpose of our fisher habitat model was to identify areas on the landscape that might be expected to support some level of fisher presence, both within the current range of fishers and in the portions of the historical range where fishers are rare or absent. Therefore, where reliable fisher detection data were available, we used Maxent models, which are empirically fitted models widely used to answer questions of this nature. Where reliable fisher detection data were not available, we constructed an expert model, which is another standard type of model used in situations where empirically fitted models are not feasible. We note that, contrary to the peer reviewer’s comment, we did incorporate information about prey distribution and diversity into the expert models. The dynamic, detailed models of habitat development suggested by the peer reviewer would be needlessly complex for the primary purpose of our modeling effort, although they might have been helpful in analyses of vegetation management (for which we did not use our fisher habitat model) and wildfire (for which we did use our habitat model, but with some caveats). However, even if a model of the type suggested by the peer reviewer were adequately appropriate for the purposes of our evaluation, such a model was not available for us to use.

(69) Comment: One peer reviewer requested information on why the results of the habitat model used in the species report differed so widely from the model in Lewis and Hayes (2004).

Our Response: The peer reviewer did not specify any particular differences between the two models. There are a number of differences in the overall framework and purpose for the two models, their input data, and the format of the output, as shown in maps of the two models’ results. However, the
differences between the two models are relatively minor. Please see our response to Comment (220) for more information about two specific differences (i.e., the amounts of habitat at high elevations and in the Eastern Washington Cascades), and some of the general similarities between the two models.

(70) Comment: One peer reviewer stated that the habitat model was likely over parametrized, particularly in the portions of the analysis area where data are scarce, and that there were likely too few data points per model parameter for the scale at which the habitat model was being extrapolated.

Our Response: We assume the peer reviewer may have mistakenly interpreted the methods for the expert models (used in areas where data were scarce or nonexistent) as applying also to the Maxent models (used in areas where data were available). The parameters the peer reviewer discusses were used in the expert models, but not in the Maxent models. The expert models were not fitted to data, and, therefore, the concept of over-parametrization is not applicable. We added more information about the variables used for the Maxent models to the document “Habitat Modeling Methods For The Fisher West Coast Distinct Population Segment Species Assessment,” which is now included as Appendix B in the final Species Report.

(71) Comment: One peer reviewer was concerned that private and industrial forest lands may have been poorly sampled for the data set used as inputs for the habitat model.

Our Response: We disagree that private industrial forest lands were underrepresented in the data used as input for the habitat model. The data set we used was compiled from a number of sources, including surveys of private industrial forest lands. We have added more information on these data sources to the document “Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment,” which is now included as Appendix B in the final Species Report.

(72) Comment: One peer reviewer asserted that the method of relating survey results to predicted habitat by assigning occupancy to hexagons was potentially circular and involved too many assumptions. The peer reviewer asked: If fisher survey data were used to build the habitat model, wouldn’t the hexagons with high-valued habitat also correspondingly contain a high number of positive surveys? Further, the peer reviewer noted that the results showing negative surveys in modeled habitat supported or contradicted the Service’s assertion that there is considerable habitat in the NCSO region that is unoccupied.

Our Response: The peer reviewer is correct that the model was based on survey results, as was the hexagon analysis of the survey results. However, the model input data consisted of only positive detections that were filtered to a minimum nearest-neighbor distance of 3.1 mi (5 km). The data set used in the hexagon analysis was a larger dataset that contained negative survey results and additional positive survey results that were not included in the model input data set. The hexagon analysis showed that there were quite a few areas of predicted habitat that had been surveyed for fishers, but only with negative results. There are several possible interpretations of this result that we took into consideration, such as:

(1) The habitat model may have overpredicted the amount of suitable habitat in the NCSO region, and that these areas with negative surveys are not truly habitat, perhaps due to the influence of some factor that was not included in the set of environmental inputs to the model.

(2) There may be unoccupied suitable habitat in the NCSO region, which we further discuss in the draft Species Report (Service 2014, p. 39). This possibility could, in turn, have multiple explanations, including a population that has not yet reached carrying capacity following the population reductions due to trapping in the early 20th century, or internal fragmentation preventing the population from occupying all available habitat within the NCSO region.

(73) Comment: One peer reviewer noted that the habitat model has assigned all forest lands within a Federal forest as high-quality habitat. The peer reviewer noted that this designation would make managing for fisher difficult on Federal lands.

Our Response: The habitat model used in our evaluation was intended as an analysis tool, not as a management tool. As noted in our response to Comment (61), it is intended for use at the landscape scale, and should not be used at finer scales to identify forest stands to be treated or avoided.

Habitat Recruitment

(74) Comment: Two peer reviewers suggested that the Service add an analysis of the effects of habitat recruitment to the final Species Report. One peer reviewer asserted that if only habitat losses are considered without any attempt to quantify gains, then the resulting analysis will significantly overestimate the degree of threat from logging and vegetation management practices. The second peer reviewer requested more information be added, particularly with regard to when the transition from existing low-quality forest to high-quality, late-successional habitat might be expected. The peer reviewer acknowledged the inherent difficulties in estimating recruitment, but suggested an analysis on the differences in habitat recruitment for different land ownerships and forest management regimes, and suggested some potential methods for estimating total habitat recruitment.

Our Response: We agree with the commenter regarding the need to incorporate vegetation recruitment, which we have done in our final Species Report by incorporating the results of the NWFP 20-year late-successional/old-growth monitoring results (Davis et al. 20XX, entire); this report, as well as additional sources, allowed us to estimate ingrowth within the analysis area. This report looks at changes in forests with old-forest structural characteristics for the past 20 years (the extent of NWFP implementation), categorizing forest loss by different disturbance mechanisms, including timber harvest, and also recording ingrowth of older forests. This analysis also records activities on non-Federal as well as Federal ownership. Based on our analysis of the best available information regarding the availability of suitable habitat for fisher throughout the west coast states, including new information, we agree with the commenter that vegetation management is not a threat to fishers in the west coast States and that, ultimately, the proposed West Coast DPS of fishers is not threatened with extinction now or in the foreseeable future.

(75) Comment: One peer reviewer believed that habitat recruitment needed to be considered for effects on fisher within the foreseeable future. The peer reviewer noted that within the period of foreseeable future detailed in the draft Species Report, many forests would develop characteristics suitable for occupation by fisher. The peer reviewer also noted that though the estimates of gross forest loss in the draft Species Report provide information on habitat disturbance, these calculations ignore potential forest growth. The peer reviewer provided information on forest growth rates and potential calculations for how to measure volume of forest added in the foreseeable future range used in the draft Species Report, and suggested adding that method or another to quantify forest recruitment to the final Species Report.
Our Response: As stated in our draft Species Report, there is a high degree of uncertainty when modeling changes to forest conditions and the point at which the forested condition becomes suitable (Service 2014, p. 86). We recognize that forested ecosystems are not static and that, if allowed to grow, forested stands may become suitable habitat for fisher. During our comment periods, we received information and suggestions for methods to use to estimate habitat recruitment for fisher. We have reviewed this information and incorporated it into the final Species Report. Included in the new scientific and commercial data available to us was the NWFP 20-year late-successional old-growth monitoring report (Davis et al. 20XX, entire); this report, as well as additional sources, allowed us to estimate ingrowth within the west coast States. As described in the conclusion of the “Vegetation Management” section of our final Species Report, while historical loss of older forests through timber harvest resulted in a substantial historical loss of fisher habitat, harvest volume has sharply declined since 1990, primarily on Federal lands, but on non-Federal ownership as well. Modeling in the southern Sierra Nevada region indicates that ingrowth of fisher habitat has replaced habitat loss by all disturbances in the southern Sierra Nevada region since 1990, resulting in a net gain of habitat since that time. On Federal lands in the NWFP region, habitat ingrowth has been greater than that lost due to timber harvest in all fisher subregions except for the western Oregon Cascades.

Maps/Sightings

(76) Comment: Three peer reviewers discussed how the regional boundaries were drawn for Western Washington. One peer reviewer asserted that if the Olympic Mountains region was defined by elevation, the Quimper Peninsula and the Coastal Plains should not be separated. A second peer reviewer was unclear on the exact boundary of the Olympic Mountains region; the reviewer noted that Table 3 and Figure 11 in the draft Species Report present conflicting information on whether the eastern side of the Olympic Mountains was included in that region. A third peer reviewer recommended including the eastern Olympic Mountains in the Washington coast region rather than the Olympics Mountains region.

The second peer reviewer also stated that the eastern Olympic Peninsula and the Kitsap Peninsula are more similar to each other than they are to the Willamette Valley-Puget Trough area, and that that portion of the peninsula has been frequently used by the reintroduced fisher population. The peer reviewer recommended that the entire Olympic Peninsula be included in the Coastal Washington subregion as outlined in the draft Species Report. The third peer reviewer recommended omitting the Kitsap Peninsula entirely due to human development.

Our Response: Our draft Species Report relied upon geographic subregions as identified in a recent threats assessment specific to fisher conducted by Naney et al. (2012). We acknowledge that the regional boundaries used are an approximation of ecoregions that could potentially have been delineated differently. The peer reviewers correctly pointed out that there may be good reasons to have included portions of Puget Trough subregion into the Coastal Washington subregion instead. However, the analysis area subregions we utilized are sufficiently accurate for the purposes of our analysis. Therefore, in the final Species Report, we have retained the analysis area subregions, as originally presented.

(77) Comment: Two peer reviewers provided feedback on Figure 4 in the draft Species Report. One peer reviewer suggested that Figure 4 should be updated to clarify which of the more than 5,000 fisher records were used as the 456 verified records in the habitat model. The peer reviewer stated that a visual display of the two categories of records would also help by highlighting any potentially problematic areas on a geographic scale for the habitat model. The second peer reviewer requested that the 456 verified records be identified in Figure 4, or that a map showing just those records be added to the final Species Report.

Our Response: We developed a supplement to the draft Species Report entitled “Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment” by Fitzgerald et al. (2014, entire), which is included as Appendix B in the final Species Report. This methodology paper describes which locality records were used to model habitat as follows: “Fisher detection points were filtered by removing non-verified detections (no physical evidence to verify fisher identification), detections prior to 1970, detections of translocated animals, and telemetry detections. Remaining localities were further filtered to ensure spatial independence by using a minimum nearest-neighbor distance of 3.1 mi (5 km). If two or more detections were within 3.1 mi (5 km) of one another, the most reliable and recent was retained, or in case of a tie, by random selection. A total of 456 detections remained after filtering for model calibration, with 72 from the Southern Sierra Nevada, 185 from the Klamath and Southern Cascades, and 199 from the California and Southern Oregon Coast” (Fitzgerald et al. 2014, p. 2).

We agree that a map showing which verified records were used in the habitat model could improve understanding of our habitat modeling methodology. This would be a good addition to Fitzgerald et al. 2014 and will consider adding this map during future revisions to that document.

(78) Comment: One peer reviewer objected to many of the categories of reliability ratings. The peer reviewer referenced a study by McKelvey et al. (2008), which states that for an area from where a species is believed to have been extirpated, only the most reliable ratings should be used (those defined in the species report as reliability rating 1). The peer reviewer noted that the draft Species Report mentions these issues, and that it is confusing that maps subsequent to that discussion still include all categories of reliability rating. The peer reviewer noted that the distinction between reliability ratings is particularly important in the gap between the NCSO and SSN populations, as there have been no confirmed (reliability rating 1) records in the central Sierra north of Yosemite since the nineteenth century. The peer reviewer recommended adding or revising maps (e.g., color coding, clarifying map legends) to clarify all of the reliability ratings within the proposed DPS, and overall increasing the number of maps in the report to include more that show the most reliable fisher detections.

Our Response: We appreciate the opinion of the peer reviewer and concerns about appropriate use of reliability ratings to describe the contemporary distribution of fisher. We evaluated McKelvey et al. (2008), referenced by the peer reviewer, in our draft Species Report and used it in conjunction with Aubry and Lewis (2003, entire) to minimize the potential overestimation of the species’ current distribution (Service 2014, p. 28). We have appropriately described and mapped the best available data in the area of concern expressed by the peer reviewer (i.e., the “gap” between the NCSO and SSN populations). In addition, we have added new information in the final Species Report on historical detections of fishers in the “gap” (Service 2016, pp. 32, 39–40). We included a number of maps showing reliability ratings to visually
demonstrate the variation of the location data within historical and contemporary time periods. Figure 7 in the draft Species Report showed the locality records that we determined represent the best available information for the contemporary distribution of fisher (Service 2014, p. 31), and additional maps are not necessary to make this point.

Northern Spotted Owl (NSO) Habitat Surrogate

Comment (79): Multiple peer reviewers and other commenters questioned the suitability of northern spotted owl habitat as a surrogate for fisher habitat in our draft Species Report, particularly noting that although the two species may overlap in terms of habitat requirements for breeding, in general fishers are capable of using a wider variety of habitats than northern spotted owls. They stated that using the northern spotted owl consultation data on habitat removed or degraded would thus lead to a potential overestimate of habitat loss for fishers. On the other hand, some peer reviewers (and commenters) believed that northern spotted owl habitat is an appropriate surrogate for fisher habitat and represents the best available science. These peer reviewers (and commenters) believed that although the shortcomings of the approach were acknowledged and described, the Service should provide more detail in this regard. We received many peer review and public comments on this subject, expressing mixed opinions.

Our Response: In our final Species Report, additional data were available that allowed us to evaluate the stressor of vegetation management without using northern spotted owl habitat as a surrogate. The available data also allowed us to measure net vegetation change (that is, account for vegetation ingrowth), and address concerns raised regarding our previous analysis potentially overestimating habitat loss for fishers. The data used in our final analysis were the recently released NWFP 20-year late-successional old-growth monitoring report (Davis et al. 20XX, entire) within the analysis area covered by the NWFP (most of the proposed DPS except the Sierra Nevada and eastern portions of the Oregon and Washington Cascades), the Gradient Nearest Neighbor (GNN) vegetation trend analysis for that portion of the proposed DPS outside of the NWFP area, and fisher habitat trends associated with the southern Sierra Nevada fisher conservation strategy. (80) Comment: One peer reviewer called into question the initial calculation of northern spotted owl critical habitat, and believed that the issues with the owl analysis would be exacerbated when the model was extrapolated to predict fisher occupancy. The peer reviewer stated that the GNN modeling approach used in the northern spotted owl critical habitat rule was a poor predictor of owl occupancy in several forests in the fisher analysis area, and that the owl model did a poor job of estimating nesting and roosting habitat. The peer reviewer added that it may not be appropriate to use the northern spotted owl model outside the Sierra Nevada, and cited a report that demonstrated that the owl’s roosting and nesting habitat outside of the Sierras was poorly predicted by the critical habitat model. The peer reviewer concluded that the northern spotted owl surrogate may underestimate required habitat for fisher, as northern spotted owls tend to forage in younger forest types outside of their core nesting and roosting habitat.

Our Response: The commenter appears to have misunderstood the nature of the northern spotted owl habitat data used as a surrogate for our evaluation of fisher habitat negatively affected by management activities in our draft Species Report. We did not rely on designated critical habitat for the northern spotted owl; we used documented section 7 consultations on activities that removed or downgraded northern spotted owl habitat within the NWFP area as a proxy for estimating the potential effects of vegetation management on the loss of fisher habitat on Federal lands throughout the proposed DPS (Service 2014, p. 88). In any case, our final Species Report does not rely on northern spotted owl habitat as a surrogate for fisher habitat in any form, as better data became available to us. See also our response to Comment (79).

Population Estimates

(81) Comment: One peer reviewer believed that the Service’s use of genetic data to estimate an effective population size and then extrapolate to an actual population size was inappropriate. The peer reviewer demonstrated this belief by noting that the Service’s estimates resulted in the NCSO population being substantially smaller than the SSN population, which contradicted the Service’s characterization that the SSN population is vulnerable and is a smaller population than the NCSO population. Further, the peer reviewer stated that the number of fisher detections reported by the NCSO region make the Service’s lower limit estimate appear flawed and unsupported.

Our Response: Species face an increased vulnerability to extinction when the effective population size is low and where there is limited genetic exchange (Kyle et al. 2001, p. 343; Wisely et al. 2004, p. 646). The effective population size is not an estimate of the entire population as a whole, rather it is an estimate of the breeding individuals in a population, often based on genetic information (Service 2014, p. 145). The current population information presented in the final Species Report is updated and presented in Species Information, above.

Population size estimates provided in the draft Species Report (Service 2014, pp. 37–43) and final Species Report (Service 2016, pp. 42–53) come from multiple sources and were not all derived in the same manner. We use these estimates as the best available information for overall population size and recognize the uncertainty associated with these estimates. The estimate of NCPSO population size as derived from the effective population size was at the lower end of the range of estimates for that population, as presented in the draft Species Report; we note that the upper range estimate of 4,018 individuals that was also presented well exceeds all estimates of population size for the SSN population. Updated population estimate information is found in the Species Information section of this document.

The peer reviewer also raised a concern about an apparent disparity between the population size estimates and detections reported in the draft Species Report. We assigned a numerical reliability rating to each fisher detection and presented the locality records from 1993 to the present for detections with reliability ratings 1 and 2 in Figure 7 of the draft Species Report (Service 2014, pp. 28, 31). The locality data include information from research studies, Federal and non-Federal landowners, and members of the public. This data set includes more records than those presented (and ultimately extrapolated to population estimates) in the scientific studies conducted within portions of the proposed West Coast DPS subregions. Therefore, we understand the concern of the peer reviewer, but we do not agree that the difference between population estimates and detection data is flawed or otherwise undermines support for our conclusions.

Throughout the draft and final Species Reports, we discuss the geographic extent of stressors potentially acting on the NCSO and SSN populations. The SSN population is at the southern extent of the species’
distribution and occupies a smaller overall area than the NCSO population, which is more central to the species’ distribution. The separation of the SSN population from other populations in the proposed DPS’s distribution may mean that this population is less able to respond to stochastic events than other populations (e.g., NCSO) (Service 2014, p. 145). Our assessment of the SSN and NCSO populations and potential stressors is based upon the best available scientific and commercial information.

Prey

(82) Comment: One peer reviewer suggested adding a discussion of the impact of highly variable mast crops on prey variability. They also suggested further analysis on how those changes affect fisher prey in the SSN population given historical extirpation of prey species (porcupine and snowshoe hare) that are still available elsewhere in the fisher’s range across the west coast States.

Our Response: The peer reviewer did not provide specific references for us to consider regarding mast crops or the historical extirpation of prey in the SSN population. The draft Species Report acknowledges the potential impacts of Sudden Oak Death on fisher habitat and habitat for prey species (Service 2014, p. 72). As also noted in the draft Species Report, fishers are opportunistic predators and have a diverse diet (Service 2014, p. 13). Though porcupine and snowshoe hare numbers may be less abundant, as suggested by the peer reviewer, we did not find that prey were limited in the SSN population. Thus, an analysis of the impact of mast variability on fisher prey species in the SSN population is not necessary.

(83) Comment: Two peer reviewers believe that the draft Species Report overlooked the positive effects that vegetation management has on the fisher prey base. One peer reviewer referenced several studies that found a positive effect on small mammal species from a variety of timber thinning activities. The peer reviewer noted that, although data are available to quantify the effect of thinning specifically on fisher prey, the data have not been analyzed, and so the importance of this factor as compared to other requirements (denning locations, other demographic factors) is not well understood.

Our Response: We discussed the importance of a diversity of available forest conditions within fisher home ranges to increase their access to a greater diversity and abundance of prey species, as long as important habitat features supporting reproduction and thermoregulation are available (Service 2014, p. 14). We also reviewed the references cited by the peer reviewer (Verschyl et al. 2011; Klenner and Sullivan 2003; Waldien 2005; Carey and Wilson 2001), and the final Species Report incorporates information from these sources where applicable.

Reintroductions

(84) Comment: One peer reviewer did not agree that there are any current indications from the Olympic National Park reintroduction (ONP population) that are encouraging, as was stated in the draft Species Report. The peer reviewer speculated that fisher may not survive at the ONP population, similar to the near extirpation of northern spotted owl in this same area, which has similar habitat needs as the fisher.

Our Response: Based on a review of reintroduction results not referenced by this peer reviewer in his comments (Happe et al. 2014; Lewis 2014; Happe et al. 2015), we maintain our assessment that current indications from the reintroduced ONP population are encouraging. In the 7 years since animals were first translocated to ONP, researchers have found the reintroduced fishers to be widely distributed, reproducing, and in some cases long-lived. Habitat models suggest an adequate quantity of suitable habitat, and actual fisher use has included an even broader range of habitat, both in terms of elevation and age-class. We disagree with this peer reviewer’s comparison to northern spotted owl survival for two reasons: first, spotted owls have experienced a severe threat from the invasion of barred owls that is not likely relevant to fishers. Second, although fishers do depend on many of the same habitat characteristics as northern spotted owls, as acknowledged in our final Species Report, fishers are not as specialized in their use of habitat and can make use of a broader range of habitats than can northern spotted owls.

(85) Comment: One peer reviewer believes that the Service presented an accurate summary of available data on fisher reintroduction efforts. The peer reviewer asserted that reintroductions throughout California, Oregon, and Washington were the best method for reconnecting these populations to those in Canada.

Our Response: The reintroduction of fishers into the west coast States is one means to augment the reestablishment of extirpated or depleted populations within their historical range. While it is too soon to determine if our new introductions are successful, we (and our partners) continue to monitor the stability of translocated fisher in the new reintroduction areas. The final Species Report identifies a number of stressors that may be acting on fisher in the analysis area, including the reintroduced populations. Though we are withdrawing our proposal to list the West Coast DPS of fisher as threatened, we will continue to monitor stressors as we develop management strategies and work with our partners toward the conservation of fisher throughout its range.

(86) Comment: One peer reviewer noted that, although the draft Species Report cited research by Knaus et al. (2011), that study’s main conclusion was not explicitly stated in the draft Species Report. The peer reviewer noted that mitochondrial DNA evidence supports the idea that fisher may have existed as disjunct populations rather than a metapopulation with continuous gene flow before European settlement. This molecular research may indicate that reestablishing fisher along the Sierra Nevada to allow for gene flow may not correspond with the history of the species, and has important implications for the proposed listing. The peer reviewer also noted that the conclusions from Knaus et al. (2011) may be in contradiction to a study by Drew et al. (2003), who supported reintroductions with fishers from British Columbia.

Our Response: The final Species Report incorporates information from these comments. The source of fisher for potential future reintroductions is a management issue beyond the scope of the listing process.

(87) Comment: One peer reviewer asked how a severity rating could be assigned to an area where no fishers are currently extant.

Our Response: The severity of a stressor is the “level of damage to fisher populations or their habitat that can reasonably be expected from the stressor” (Service 2014, p. 51). This commenter is correct—a severity rating is not appropriate where the species is assumed to be extirpated (e.g., Eastern Washington Cascades, Western Washington Cascades, and Coastal Oregon subregions) based on the best available information. In the final Species Report, we moved the analysis quantifying stressors to Appendix C and we instead provide a qualitative categorization of stressors to identify each stressor’s magnitude of impacts to those fisher populations that are known to occur across the west coast States. Our explanation of this change and conclusions are outlined in detail in Background, above.
Rodenticides

(88) Comment: One peer reviewer asserted that rodenticide exposure from illegal marijuana grow sites in northern California and southern Oregon is a significant concern, although they believe the magnitude of impacts in Oregon are far lower than California. The peer reviewer also stated that recent legalization of recreational marijuana in Washington and Oregon may reduce the scope and severity of this threat across the proposed DPS. Similarly, another peer reviewer claimed that rodenticide impacts are an emerging threat to fishers in some parts of its range, but that it is speculative to consider the use of rodenticides to be an overall threat to fisher populations by relying on numerous assumptions (e.g., density of marijuana growing operations, whether each operation uses ARs).

Our Response: We have reviewed the best scientific and commercial information available, including new information received, which enabled us to provide clarity and corrections in the final Species Report (Service 2016, pp. 141–159) and this document with respect to illegal marijuana grow sites and associated rodenticide exposure. The extent to which the legal use of ARs occurs at agricultural and commercial sites within the range of the fisher is unknown. Two fisher carcasses from Oregon have been tested for rodenticides, both of which tested positive, and only three fishers can be confidently documented to have been exposed in Washington. None of these were in the vicinity of a known marijuana grow, and the Washington fishers were found near rural areas where rodenticides could have been used legally.

The contention that recent legalization of recreational marijuana in Washington and Oregon may reduce the scope and severity of this threat is unlikely (given the main application of the stressor has not been in Washington or Oregon), and it is too soon to tell what, if any, effect the recent legalization will have on illegal marijuana grow sites and exposure of fishers to rodenticides. There are, as yet, no rodenticide labels that allow application to marijuana as a crop; thus, any use of rodenticides within a marijuana grow, legal or otherwise, would be illegal under State and Federal laws.

We note the uncertainty as to the severity of impact that this stressor may have, given data are minimal across Oregon and Washington in particular, including the lack of information rangewide regarding potential sublethal effects of toxicants to fishers within the proposed West Coast DPS (i.e., we only have information on 15 mortalities rangewide). Therefore, the best available information does not support concluding that these impacts rise to the level of a threat, based on the insufficient evidence that ARs are functioning as an operative threat on the fisher such that the proposed DPS is experiencing significant impacts at either the population or rangewide scales.

(89) Comment: One peer reviewer asserted that the impact of rodenticides is a concern in particular to adult female fishers, although the data that demonstrate impacts (e.g., 4 of 58 radiotagged individuals in California for one study were found dead from rodenticides) does not appear to represent a population- or DPS-wide impact. The peer reviewer is concerned about the high rate of rodenticide residues discovered in fishers. However, the peer reviewer noted that detection of these compounds does not prove that rodenticides are an etiologic (causal) agent of mortality. Additionally, the peer reviewer stated that secondary consequences of poisons on immune response, reproductive output, etc., have some uncertainties.

Our Response: We have reviewed and added information on the potential for reproductive effects from rodenticide exposure to the final Species Report (Service 2016, pp. 156–159) and this document (see Exposure to Toxicants, above). Exposure to ARs has been documented to cause fetal abnormalities, miscarriages, and neonatal mortality in mammals. The timing of AR use at cultivation sites (April–May) may also be important, because this timeframe coincides with increased energetic requirements of pregnant or lactating female fishers, and the reduction of prey has been documented at illegal grow sites where ARs were applied. We also added information to the final Species Report on the sublethal effects of rodenticides, including the symptoms of toxicosis (Service 2016, pp. 150–157), which without treatment can lead to mortality. Symptoms include lethargy, anorexia, ataxia, anemia, lameness from bleeding in the joints, and difficulty breathing. Finally, we included a summary of the literature discussing the association between liver residue concentrations, symptoms of toxicosis, other adverse effects, and mortality.

The new information we have evaluated provides clarity and correction to the information presented in the draft Species Report, including the lack of information rangewide regarding potential sublethal effects of ARs to fishers within the proposed West Coast DPS (i.e., we have information on only 15 mortalities rangewide (Gabriel et al. 2015, p. 5; Wengert 2016, pers. comm.). Despite additional information regarding potential sublethal effects, the level of exposure that would be expected to result in such effects in fishers remains unknown. The best available information does not support a conclusion that these impacts rise to the level of a threat, based on our review of the best available data, which indicates that ARs are not functioning as an operative threat on the fisher (i.e., the proposed DPS is not experiencing significant impacts at either the population or rangewide scales), currently or in the foreseeable future.

(90) Comment: One peer reviewer was unable to determine the percentage of illegal marijuana grow sites at which ARs have been detected, as presented in the draft Species Report. Further, the peer reviewer stated that, if ARs are assumed to be at all sites, the Service overestimated the scope and severity of this threat.

Our Response: We do not know the percentage of illegal marijuana grow sites where ARs have been detected. We also note the uncertainty as to the severity of impact that this stressor may have (including at illegal marijuana grow sites across the west coast States), given data are minimal across Oregon and Washington in particular. There is also a lack of information rangewide regarding potential sublethal effects of toxicants to fishers within the proposed West Coast DPS (i.e., we have information on only 15 mortalities rangewide; see our response to Comment (91)). Therefore, the best available information does not support a conclusion that these impacts rise to the level of a threat, our review of the best available data, which indicates that ARs are not functioning as an operative threat on the fisher (i.e., the proposed DPS is not experiencing significant impacts at either the population or rangewide scales), currently or in the foreseeable future.

(91) Comment: One peer reviewer requested that we explain the differences in prevalence of large marijuana grow operations using rodenticide between private and public lands. The peer reviewer also articulated that there is an unrecognized benefit to fisher from private forest management operations as a result of the increased scrutiny of private land areas by managers and resulting in less likelihood of illicit marijuana grow sites on those lands.
Given the knowledge of grow operation locations from flight-based inventories, the peer reviewer ascertained that it could be possible to determine the proportion of large grow operations on private versus public lands, and incorporate the differences in the calculated stressors and impact categories.

Our Response: Detection of grow operations from the air does not provide any information on whether or not rodenticides are being used. In addition, if rodenticides are used, air surveys would not identify which rodenticides are used or how much may be applied and when. Furthermore, there are no rodenticide labels that allow application to marijuana as a crop; thus, any use of rodenticides within a marijuana grow would be illegal under State and Federal laws.

Stressors

(92) Comment: One peer reviewer disagreed with the Service that reduction in the amount of late-successional forest had been responsible for the extirpation of fishers in Washington. The peer reviewer stated that trapping, fur harvest, and predator control efforts were in fact responsible for the disappearance of fishers in the State, particularly in Olympic National Park where logging did not occur.

Our Response: We agree with the peer reviewer’s assessment that trapping, fur harvest, and predator control efforts were predominantly responsible for the extirpation of fishers from Washington State. This situation is certainly true for areas that were not logged, like Olympic National Park, just as the peer reviewer suggests. The reduction of late-successional forests, however, is likely to have been a factor in the significant decline of fisher occupancy across some of Washington State, particularly in the Puget Trough and other areas now developed and densely populated. Our statement in the draft Species Report (p. 57) that the peer reviewer specifically disagreed with said, “a reduction in the amount of late-successional forests occurred . . . and has been implicated as a primary cause of fisher declines across the analysis area.” We maintain that this sentence is correct; however, to clarify this sentence is in reference to historical declines of fisher across the analysis area, because there have been numerous peer-reviewed journal articles that make this implication, and implications at the scale of the analysis area would not necessarily apply to mountainous regions in Washington State.

(93) Comment: One peer reviewer recommended including a discussion of accidents (i.e., drowning, falls, being struck by limbs or trees, lightning strikes, wildfire) as natural sources of mortality. The peer reviewer specifically described documentation of 10 fishers jumping into large, empty tanks/bins on Green Diamond property, suggesting their natural curiosity, inquisitive attitude, and potential for “accident prone” situations.

Our Response: The draft Species Report included a discussion of natural causes of mortality for fishers (Service 2014, p. 10). The discussion highlights interspecific and intraspecific conflict and starvation as non-predation and non-disease related sources of natural mortality. While it is not feasible to provide an exhaustive list and analysis of all natural mortality sources in the final Species Report, we revised the information therein to include the data provided by the peer reviewer.

(94) Comment: One peer reviewer thought it was not logical that the proposed listing rule considered disease and predation occurring as naturally occurring stressors, but did not consider naturally occurring wildfires or climate change the same way.

Our Response: The distinction with regard to disease and predation is intended to underscore the fact that these are natural sources of mortality that are to be expected in every animal population, and to make the point that we would only consider these stressors to pose a threat to fisher if they were occurring at levels outside the range of normal variability. We agree that wildfire and climate change could potentially be considered natural processes; we did not specifically identify them as such here, however, because of the strong suggestion that these processes are synergistically intertwined and potentially elevated above natural background levels due to anthropogenic forcing. In any case, whether we call a stressor “naturally occurring” or not has no bearing on our analysis; whether naturally occurring or otherwise, we evaluate all stressors above natural background levels due to anthropogenic forcing. In any case, whether we call a stressor “naturally occurring” or not has no bearing on our analysis; whether naturally occurring or otherwise, we evaluate all stressors under the same standard as laid out in section 4(a)(1) of the Act to determine whether a species may meet the definition of an endangered species or a threatened species as a consequence of the effects of that stressor.

(95) Comment: One peer reviewer suggested that the draft Species Report’s estimate of 90–95 percent scope for loss of late-successional forest for Coastal Washington was too high. The peer reviewer requested clarification on whether areas such as national parks, high-elevation forests, or other remote areas were included in the calculation of scope.

Our Response: The data used to estimate scope for loss of late-successional forests from past activities and disturbances comes from Bolsinger and Waddell (1993, p. 3). The authors found that less than 10 percent of logging or other activities occurred in old-growth stands on National Forests in Oregon and Washington combined, indicating that these stands were generally undisturbed (Bolsinger and Waddell 1993, p. 8). As the draft Species Report states (Service 2014, pp. 57–58), we assumed that timber harvest occurred ubiquitously on both public and private land in the past, except for in national parks, high-elevation areas, and more remote inaccessible areas. In addition, the Coastal Washington region has been highly urbanized throughout the Puget Trough for a long time. Therefore, we disagree with the peer reviewer that an estimate of 90–95 percent scope is unreasonable. However, for reasons described earlier in this document, in the final Species Report we have changed our evaluation of scope and severity from quantitative values to qualitative values, so we no longer refer to a scope of 90–95 percent.

(96) Comment: One peer reviewer believed that the scope of the stressor for research was overestimated in Coastal Washington. The peer reviewer provided information from a study on the rates of collar shedding and mortalities, and other information on research practices (which do not include trapping or anaesthetizing fishers).

Our Response: The draft Species Report identified a number of factors that were considered as potential lethal or sublethal effects of research-related activities on fisher (Service 2014, p. 113). We similarly acknowledged that research in Coastal Washington does not involve live-trapping, but that fishers in this reintroduced population are exposed to radio-collar related stressors. We based our scope and severity analyses on the best available information at the time, which included survival rates and population growth estimates. The information provided by the peer reviewer indicates that eight fishers shed their collars and none of the recovered mortalities in the study area were collar-related.

The draft Species Report provided the figures used to determine the scope of research-related stressors in Coastal Washington (Service 2014, p. 114). The draft Species Report used the data from ongoing research in the SSN and NCSO populations to calculate severity for research-related stressors (Service 2014, p. 114). We have updated our analysis in the final Species Report to include...
the information specific to Coastal Washington provided by the peer reviewer. In addition, we have changed from a quantitative to a qualitative assessment of stressors.

(97) Comment: One peer reviewer questioned why the scope and stressors focused only on negative changes in fisher populations. The peer reviewer asked if there were any forecast circumstances that were expected to result in positive changes for fishers.

Our Response: The peer reviewer is incorrect that the draft Species Report defined stressors as those activities or processes resulting in the “destruction, degradation, or impairment of west coast fisher populations or their habitat” (Service 2014, p. 46). Within the discussion of both wildfire and vegetation management, however, we do identify positive elements. For example, in our draft Species Report we identified wildfire as having the potential to increase vegetative diversity and create snag and down wood habitat elements (Service 2014, p. 59). Further, we indicated that not all vegetation management activities are “detrimental to fisher habitat, depending upon their objectives and implementation” (Service 2014, p. 87). The beneficial effects of wildfire and vegetation management may be realized later in time, such as while vegetation that remains post-fire or vegetation treatment recovers, or while prey communities respond to understory treatments. Our final Species Report presents an expanded discussion on these topics.

(98) Comment: One peer reviewer asked why the scope and severity impacts for each stressor were not combined to calculate an overall numeric impact, or ranked according to severity of threat to the fisher.

Our Response: As described more fully elsewhere in this document, we found that our initial quantification of stressors required us to make assumptions or extrapolate impacts in an effort to quantify stressors in areas where stressor-specific information was not available. We believe our presentation of the scope and severity of stressors in quantitative terms may have created a false sense of precision with regard to the level of scientific accuracy underlying these estimates. To avoid this perception, in our final Species Report we use a qualitative approach to describe stressors (i.e., stressors are categorized as low, moderate, or high, as defined in that Report). We use quantitative data wherever available, but if specific data are lacking, we rely on our best scientific and qualitative descriptor of each stressor, based on the best scientific and commercial information available, rather than extrapolating. See the introductory text to the “Magnitude of a Stressor’s Impact” discussion under the “Review of Stressors” section of the final Species Report.

Synergistic (Cumulative) Effects

(99) Comment: One peer reviewer asserted that climate change and its secondary effects, including effects on wildfire regimes, pose the most serious long-term threat to fisher populations in California.

Our Response: In our draft Species Report, we concluded that the synergistic effects of climate change and wildfire combined with forest insect and disease agents may cause widespread ecotype conversions. We similarly acknowledged that habitat loss may be greater in some subregions due to synergistic effects, and identified synergistic increases in wildfire associated with climate change as a population-level stressor (Service 2014, p. 171). However, upon review and consideration of all of the best scientific and commercial information available, including comments and new information received during the open comment periods on our proposed rule, we now acknowledge the possibility of widespread ecotype conversions, but additionally recognize the uncertainty associated with such predictions in regard to their specific effects on fishers or fisher habitat. In addition, we recognize the uncertainty surrounding the timeframe within which such conversions are likely to occur, should they do so. We do not have evidence to suggest that synergistic increases in wildfire associated with climate change are resulting in any significant impacts at either the population or rangewide scales, nor does that information suggest significant impacts at these scales in the foreseeable future. Overall, taking all of this information into consideration, we conclude that we do not have sufficient evidence to suggest that the synergistic effects of these stressors were such that we consider fisher populations in danger of extinction throughout all or a significant portion of their range, now or within the foreseeable future. Please also see our response to Comment (1), above.

(100) Comment: One peer reviewer suggested that we consider using the term “compounded effects” instead of synergistic effects, given that the analysis of stressors does not address additivity or potentiation.

Our Response: The term synergistic effect is used to describe the situation when one or more stressors exacerbate the effects of another stressor, causing effects that are greater than the sum of individual stressors. Similarly, we use the term cumulative effect to address the additive or compensatory effects of multiple stressors. These terms appropriately describe how multiple stressors may interact with one another. We appreciate the reviewer’s point that synergistic effects are not necessarily the same as compounded effects.

(101) Comment: One peer reviewer requested that the Service add an analysis of the synergistic effects between human development in vegetation management, particularly in wildland/urban interfaces. The peer reviewer pointed out that, in those areas, vegetation management and fuels treatment are often especially aggressive in order to prevent wildfire. The peer reviewer asked if the Service had considered this point in its conclusion that human development is of low concern to fishers and their habitat.

Our Response: We agree with the peer reviewer and have added this consideration in the Synergistic effects section of the final Species Report (Service 2016, pp. 160–162).

Wildfire

(102) Comment: One peer reviewer suggested that it is inappropriate to present predicted habitat loss to wildfire in such definitive terms, such as a projected 8-fold increase in area burned in the Western Washington Cascades over the next 60 years, because the models on which this projection are based are subject to great variability. As presented in the draft Species Report, the peer reviewer stated the analysis implies that the Service has greater precision in our predictions than is actually available, especially in west-side forests. The peer reviewer said the same applies to projections made in the draft Species Report with regard to the projected increases of fire severity and extent in response to climate change.

The peer reviewer suggested that the best analysis to date on this subject is Gedalov et al. (2004).

Our Response: We agree that providing a quantitative estimate of scope and severity—even with a broad range of potential values—implies that we have greater precision in our assessment than is accurate. As a result, in our final Species Report we describe what is known and what is not known about the scope and severity of each stressor in qualitative terms, as supported by the best available scientific and commercial information.

(103) Comment: One peer reviewer disagreed with the characterization of the stressor of naturally occurring wildfires. The peer reviewer stated that wildfire should be considered “an
ecological disturbance that results in a potential long-term habitat enhancement rather than a short-term negative stressor.” The peer reviewer also disagreed with the Service’s discussion of wildfire suppression in the context of fisher habitat degradation (e.g., snag removal, fire breaks), stating it was more appropriate to view large-scale wildfire suppression as the removal of a naturally ecological process that creates fisher habitat over the long term.

Our Response: We appreciate and understand the peer reviewer’s perspective of short-term and long-term effects of wildfire to fisher habitat. Fire severity is one determinant of whether fire impacts are more likely to be short-term or long-term, as well as the potential for benefits to fisher habitat from fire. We assume that the peer reviewer, in stating that large-scale fire suppression removes fire as a naturally occurring ecological process, was really referring to decades of fire exclusion as removing a naturally occurring ecological process—that is, long-term (over the course of decades) suppression of fires to the degree that has changed forest structure and composition and has changed associated fire behaviors—not the direct effects of individual fire suppression actions that can remove fisher habitat. If this is a correct assessment of the peer reviewer’s comment, we concur with the peer reviewer and recognize that wildfire is part of a natural disturbance regime and that fishers evolved in forests subject to wildfires. Similarly, we understand that western forests are highly managed and decades of suppression activities have moved some forests away from historical fire return intervals and fire severities. We have expanded our discussion of the effects of wildfire in the final Species Report to ensure it is a balanced discussion of both the potential negative and positive effects of fire.

(104) Comment: One peer reviewer disagreed with the draft Species Report’s emphasis on wildfire as having a negative effect on fisher habitat, and believed that the report overemphasized the negative aspects of fire without discussing the benefits of fire. Additionally, the peer reviewer stated that ongoing wildfire suppression on public lands and limitation of controlled burns on private lands is likely to have the greatest negative impact to fisher habitat by prohibiting the creation of late-seral habitat elements (cavities, basal hollows, and structural deformities) on which the fisher and other species rely.

Our Response: The commenter is correct—our draft Species Report does place an emphasis on the negative aspects of wildfire as it pertains to fisher habitat. There are few studies on fisher use of burned landscapes (e.g., Hanson 2013, entire) and hypotheses by others (e.g., Powell and Zielinski 1994, p. 64) that timber management may replicate the effects of small stand-replacing fires on fisher. The lack of peer-reviewed information specific to this subject limits our ability to do more than speculate on potential benefits of wildfire to fisher. We do recognize, however, that wildfire can be beneficial to forested ecosystems that fisher inhabit. For example, low-severity fires may increase understory vegetative diversity and create coarse woody debris (Service 2014, pp. 59), which are beneficial to fisher prey species and provide a source for den and rest structures for fisher.

Wildfire suppression often includes the removal of snags or other large trees, but the scales at which this happens vary (Service 2014, p. 63). On the other hand, fire also creates many of the structural elements that are of concern to the commenter. While some of these elements may be removed by suppression activities, recruitment of these elements also occurs as a result of fire. We have expanded our discussion of the effects of wildfire in the final Species Report to ensure it is a balanced discussion of both the potential negative and positive effects of fire.

(105) Comment: One peer reviewer questioned the Service’s characterization in the draft Species Report that high-severity wildfire has the potential to “permanently remove suitable fisher habitat” and that wildfire is likely to remove habitat for a period of many decades. The peer reviewer disagreed with this characterization because fisher habitat should be viewed as dynamic, in part because wildfire has the potential to create ideal fisher habitat with a mosaic of older pockets of forest with ample opportunities for denning and resting, and young seral stages with an abundance of food for fishers.

Our Response: High-severity wildfire is more likely to remove forest cover from large blocks of habitat, which in the post-fire landscape, lack the canopy cover and structural elements needed by fisher (Jones and Garton 1994, pp. 380–382; Weir and Harestad 1997, pp. 257–258; Weir and Corbould 2008, p. 2). Several decades may be needed, depending upon forest type, to regrow forests that contain the canopy cover and structures associated with fisher habitat. We agree that fisher habitat is dynamic, but we recognize that there is not universal agreement regarding either the historical occurrence or potential impacts of high-severity fire with regard to fisher habitat. In our final Species Report, we have incorporated additional discussion of the various viewpoints from different researchers on this subject. For example, we note that in Sierra mixed-conifer forests, some researchers suggest that a historical fire regime characterized by mixed-severity fires, with high-severity fires occurring at moderate to long intervals, may have produced the heterogeneous forests with abundant, dense, late-successional habitat characteristics favored by fishers (Hanson 2013; Baker 2014; Cocking et al. 2014).

(106) Comment: One peer reviewer stated that there is no evidence in the literature that fishers need or can persist in large homogenous blocks of late-successional or old-growth coniferous forests. Thus, the peer reviewer believed that wildfire in the absence of or limitations on salvage should be viewed as natural disturbance events that may have some short-term impacts, but overall positive, long-term impacts that help maintain a dynamic landscape that meets all the necessary habitat needs for fishers.

Our Response: The draft Species Report does not state that fishers require large homogenous blocks of late-successional or old-growth forests, nor did we mean to imply this. We agree that wildfire is a natural disturbance that may have short-term and long-term impacts to fisher habitat, some of which are likely to be beneficial. Please also see our responses to Comments (103), (104), and (105), above.

(107) Comment: One peer reviewer suggested that the standard terminology for grading severity of fire is now low, high, and mixed severity, and referred us to Halofsky et al. (2011). The peer reviewer noted that the term “mixed severity” allows for patches of different severities, and subsumes the terms “moderate” and “medium.” Depending on the spatial scale of analysis, the peer reviewer believed it is possible that most fire in the regions of interest is of mixed severity. Finally, the peer reviewer stated that the distributions of patch sizes are important, given that large, high-severity patches may fragment habitat even if they are not the dominant severity.

Our Response: We thank the peer reviewer for this information, and have incorporated it into our final Species Report.

(108) Comment: One peer reviewer suggested that Tables 6 and 7 in the draft Species Report, which presented...
the estimated scope and severity of wildfire-related stressors, were faulty and overestimated the percent of available habitat likely to burn over the next 40- and 100-year time periods. They stated that this error is because the projections were based on extrapolations from past burns, which did not account for areas that may have burned more than once. The peer reviewer suggested that these projections could be corrected by using GIS to overlay the 27 years of available Monitoring Trends in Burn severity (MTBS) mapping data and adjusting for burned areas that might otherwise be counted twice, leading to inflated future estimates. The peer reviewer also suggested the Service consider Kolden et al. (2012) for information on accounting for the proportion of unburned area within fires.

*Our Response:* The draft Species Report explained that short fire-return intervals in the Sierra Nevada, NCSD population, Eastern Oregon Cascades, and Eastern Washington Cascades could lead to the overestimation (i.e., double counting) of scope for wildfire (Service 2014, p. 63). We also noted that the area burned per year is likely to increase, causing an underestimation of scope for wildfire (Service 2014, p. 63). While not stated in the draft Species Report, this observation implies that the overestimation and underestimation offset one another.

We appreciate the suggestions from the peer reviewer regarding how we may improve our assessment of scope and settlement, which may be done by extrapolations. As explained in the *Summary of Basis for This Withdrawal* and Determination sections of this document, in our final Species Report, we did not rely upon quantitative estimates of scope and severity, as we concluded they conveyed a false sense of precision. We have revised our assessment of the stressors in the final Species Report accordingly and considered the peer reviewer’s comments in our assessment. *(109) Comment:* One peer reviewer disagreed with the use of a study by Hanson (2013, entire) that discussed the fisher’s use of landscapes post-fire. The peer reviewer asserted that this study was unreliable and urged the Service to find other peer-reviewed literature on this subject to add to the final Species Report.

*Our Response:* Peer-reviewed literature on fisher use of burned landscapes is minimal. While the peer reviewer may not agree with Hanson (2013, entire), it is one of the only peer-reviewed research studies available documenting observations of fisher using burned areas. We received numerous pieces of information during the comment periods for the proposed rule, some of which included recent study results on fisher use of burned landscapes (both peer-reviewed and published and unpublished observations). The final Species Report has been updated to reflect this information as appropriate.

*(110) Comment:* One peer reviewer believed that the draft Species Report overemphasized the negative effects of fire while underemphasizing the benefits of fire. The peer reviewer recommended that the final Species Report provide a more thorough discussion of the benefits of fire, such as the creation of downed wood and other denning structures, the increase of prey abundance, and specific benefits of fire found in Oregon forests.

*Our Response:* We agree, and have attempted to provide a more balanced discussion of the effects of fire in the final Species Report, including both detrimental and beneficial effects with regard to suitable fisher habitat throughout the analysis area. Please also see our responses to Comments (103), (104), and (105), above.

**Other Comments Received (Federal, State, Local Government, Tribal, Public)**

**Adult Survival**

*(111) Comment:* One commenter presented new information that, although the overall population trend was stable to increasing in the Hoopa study (Higley et al. 2013), estimates were declining for male-only annual population estimates, male survival, and male-only lambda. The commenter suggested the primary reason for these declines could possibly be related to AR poisoning associated with illegal marijuana cultivation.

*Our Response:* We thank the commenter for pointing out this information about decreasing male population estimates, survival, and population growth rates on the Hoopa study area that had not been included in the draft Species Report. The final Species Report reflects this information but notes there is no direct evidence to support the suggestion that AR poisoning may be the cause.

**Climate Change**

*(112) Comment:* One Federal agency suggested that an explanation for the absence of fishers in the central and northern Sierra Nevada is likely due to a combination of differences in vegetation disturbance regimes (including state, flat topography in the north, and extreme temperatures in the north. The agency stated that: (1) Resting sites tend to be on steep slopes in canyons rather than ridges and close to water, as reported by Zielinski et al. (2004); and (2) denning sites are in heavily forested areas with dense canopy cover, on steep slopes, and in areas with low summer temperatures. The agency also stated that this information supports the fisher’s preference of areas with low heat loads and reduced temperature variability. The agency noted that the scope and severity of the potential threat of climate change is likely to be different as there are significant differences in vegetative ecology, topography, and climate from northern to southern Sierra Nevada. Additionally, the agency claimed that genetic evidence points to a 1,000-year or more genetic differentiation between fishers in the southern Cascade Range and those in the southern Sierra Nevada. Thus, the agency claimed that it is reasonable to assume that there were and continue to be some vegetative or climate-based causative factors for this separation and contraction of the fisher range.

*Our Response:* The Federal agency’s comment is contributing to the discussion in the draft and final Species Reports regarding the reason for the long-term separation between fishers in the SSN population and those in the southern Cascade Range in California. Researchers (e.g., Tucker et al. 2012, p. 12) found the reasons for this gap “perplexing,” but postulate that the clutter of fire in the southern Sierra Nevada, which discouraged human settlement, may be a factor. The Federal agency provides some speculation as to differences between the two areas that may contribute to the gap between the two fisher populations. However, based on our evaluation of the best scientific and commercial information available at this time, we are withdrawing the proposed rule to list the DPS (see Determination, above). If in the future we reconsider listing fishers in the west coast States, we will consider the potential relevance of these comments regarding the causes of the separation between fishers in the Cascade Range and the southern Sierra Nevada.

*(113) Comment:* The State of Oregon acknowledged that climate change is an issue of global significance, stating that it is not certain whether climate change will result in negative effects to the fisher. The State claimed that more focused research is needed on the effect of climate change on many species, including the fisher, to more accurately predict the specific effects of climate change on the west coast. Thus the State asserted that a Federal listing under the Act would not reduce the risk
to fisher from climate change. Alternatively, another public commenter requested that we specifically recognize climate change as a threat in the final rule.

Our Response: Section 4(a)(1) of the Act sets forth the factors used to evaluate whether a species meets the definition of an endangered species or a threatened species. The current and future effects of climate change were identified as a stressor to fisher (Service 2014, pp. 72–83; 149–151); in particular, changes in habitat due to wildfire are expected to be exacerbated by the effects of climate change (Service 2014, pp. 79–80). While we recognized the effects of climate change as an ongoing and future stressor, we did not in the proposed rule and currently do not identify climate change effects in and of themselves as a threat to the fisher (see Climate Change, above). We do not dispute the projected changes in climate as modeled by the IPCC report; however, the best available scientific and commercial information does not allow us to make specific predictions of the changes in climate and the future response of fishers or their habitat.

(114) Comment: Several commenters claimed that climate change impacts on fishers in the west coast States are real and likely profound, and should be considered by the Service as one of many factors impacting the survival of this already threatened species. Further, two of these commenters specifically spoke to climate change’s influence on wildfire, indicating that climate change will result in an increase in large, high-severity wildfires with longer and drier fire seasons.

Our Response: Please see our response to Comment (10) above. In addition, we have added discussion to our final Species Report of the potential synergistic effects of climate change and wildfire, and incorporated the results of new research provided to us as a consequence of peer reviewer and public comment.

Collision With Vehicles

(115) Comment: One commenter and one Federal agency expressed their concerns about fisher collisions with vehicles as a well-documented source of mortality and threat to fisher conservation, which is contrary to our conclusion in the draft Species Report and proposed rule. In cooperation with the Sierra Nevada Adaptive Management Project study area on the Sierra Nevada Adaptive Management Project, the public commenter, who participates on a Vehicle Collision subgroup of the Southern Sierra Fisher Workgroup, asserted that we did not provide sufficient information (Sweitzer et al. 2015b, p. 10). No other single road is known to result in this level of fisher mortality, and we do not foresee the construction of any significant number of similar high-speed, high-density roads within the Sierra Nevada Adaptive Management Project study area on the Sierra Nevada Forest, 10 in Yosemite National Park, and 2 in Sequoia-Kings Canyon National Parks (Spencer et al. 2015; Otto 2015, pers. comm.). The commenter also expressed concern that fisher collisions with vehicles will likely become more severe over time as the number and size of roads increase, thereby further limiting fisher dispersal among historically connected populations.

Our Response: We agree that fisher collisions with vehicles are a stressor that causes injury and mortality. This issue appears to be localized where fisher home ranges overlap highways that have high speed limits and traffic density. However, the issue appears to be localized (Sweitzer et al. 2015b, p. 10). No other single road is known to result in this level of fisher mortality, and we do not foresee the construction of any significant number of similar high-speed, high-density roads within the fisher’s range. As a result, the current magnitude of this stressor is not likely to have an overall significant impact at either the population or rangewide scales such that the stressor rises to the level of a threat to the proposed DPS. Please see our updated discussion in the “Collision With Vehicles” section of this document and the final Species Report.

Completeness and Accuracy

(116) Comment: The State of Oregon indicated that the draft Species Report did a good job of summarizing known fisher detections; however, it was not clear which areas were surveyed that did not result in fisher detections.

Our Response: Figure 6 in the draft Species Report included all opportunistic and systematic surveys, as well as trapping efforts and other reports since 1993. In comparing Figure 6 and Figure 7 (which presents all locality records from 1993 to present with reliability ratings 1 and 2), the difference between these two figures represents the areas where surveys or traplines have occurred, but fishers have not been detected since 1993. We have revised the legends to Figures 6 and 7 in the final Species Report to reflect this information.

(117) Comment: One commenter asserted that the Service’s review process was incomplete at the time of the proposed rule because the wealth of data and knowledge available on fishers in the California portion of the proposed DPS was not incorporated in the analysis. A second commenter described the draft Species Report as incomplete with an insufficient accounting of available data, and had omissions of information that was misleading to the public. Alternatively, another commenter stated that the Service provided sufficient information in the draft Species Report and proposed rule to demonstrate that the proposed West Coast DPS of fisher is in need of protections under the Act. One Federal agency also supported the accuracy and quality of the data used for the threats analysis (describing a sufficient description of the magnitude and overall immediacy of threats).

Our Response: Section 4(a)(1) of the Act requires the Service to use the best available scientific and commercial information in determining a species’ status under the Act. We developed the draft Species Report by synthesizing and analyzing the best available data. Due to internal review processes, there was a lag time between the completion of the draft Species Report and the publication of the Federal Register document. Since then, we have received and analyzed a significant amount of new information, including information obtained through the two comment periods, new literature publications, and some older publications published prior to the proposed listing rule of which we were not aware.

Consequently, our final Species Report represents a review and synthesis of all of the best available scientific and commercial information.

(118) Comment: Many commenters expressed concern that the Service has delayed listing the proposed West Coast DPS of fisher.

Our Response: We have not delayed listing the fisher. We have followed the statutory, regulatory, and policy requirements that govern adding species to the List of Endangered and Threatened Wildlife. In 2004, we determined the proposed West Coast DPS of fisher warranted listing (69 FR 18769, April 8, 2004), but immediate action to list the DPS was precluded by other higher priority listing actions at that time. The proposed DPS became a candidate for listing with a listing priority number (LPN) of 6 which reflected high magnitude but non-imminent threats. Each year after 2004,
the proposed DPS was reevaluated and candidate status reaffirmed with the same LPN. We continued to closely track the status of the proposed DPS, and if an emergency situation had developed, would have moved quickly to invoke protections of the Act as appropriate. As a result of the 2010 MDL agreements (Endangered Species Act Section 4 Deadline Litig., Misc. Action No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C.)), the proposed listing rule for the West Coast DPS of fisher was scheduled to be, and was, submitted to the Federal Register in fiscal year 2014, publishing on October 7, 2014 (79 FR 60419). As a result of the comments received on the proposed rule, we have evaluated all of the best scientific and commercial information available. We have determined that the proposed West Coast DPS of fisher is not in danger of extinction now nor is it likely to become in danger of extinction in the foreseeable future. Therefore, through this document, we withdraw the proposed rule to list the West Coast DPS of fisher.

Critical Habitat

(119) Comment: Several commenters requested that the Service finalize the proposed listing rule and also designate critical habitat (some noting specific areas they believe are critical for the taxon or factors that the Service should consider). Some of these commenters specifically requested that the Service designate critical habitat concurrent with the time of listing because they anticipate additional impacts to the fisher and its habitat associated with continued logging activities.

Our Response: On October 7, 2014, the Service published a proposed rule to list the fisher and made a finding that critical habitat was not determinable for the species (79 FR 60419). A not determinable finding allows us one additional year to either propose critical habitat or find critical habitat is not prudent. Since we are withdrawing the proposed rule rather than finalizing the listing of the West Coast DPS of fisher, we will not be designating critical habitat for the DPS.

(120) Comment: Two commenters agreed with the Service’s finding that a critical habitat designation was not determinable. One commenter stated that given substantial uncertainty concerning the proposed DPS application to west coast fisher populations (e.g., potentially excluding most of Oregon and Washington and distinguishing between California populations) it is not appropriate to propose critical habitat when taxonomic, genetic, functional, geographic, and conservation boundaries are uncertain. Alternatively, the second commenter urged the Service to reconsider its “not determinable” finding, stating that critical habitat should be designated at the very least in the southern Sierra Nevada and northwestern California.

Our Response: In the proposed rule to list the species, we stated that the information sufficient to perform a required analysis of the impacts of the critical habitat designation is lacking due to the considered DPS alternatives and our request to seek public and peer review input on these alternatives (79 FR 60419). In our evaluation of the best scientific and commercial information available at this time, described in the Determination section, above, we have determined the proposed West Coast DPS of fisher does not meet the definition of an endangered or a threatened species. Therefore, we are withdrawing the proposed rule to list the DPS and we will not be issuing a proposal to designate critical habitat.

Current Conservation Efforts

(121) Comment: One Federal agency urged the Service’s consideration of the Southern Sierra Nevada Conservation Strategy for the final Species Report and decision, including non-specific beneficial actions and fisher-specific conservation measures.

Our Response: We considered drafts of the Southern Sierra Nevada Fisher Conservation Strategy because the strategy was not finalized until shortly before our publication of this document. Unfortunately, the contents and recommendation in this strategy have not yet been adopted by the Forest Service.

(122) Comment: The State of Washington, one tribe, one Federal agency, and one other commenter declared that listing the proposed West Coast DPS of fisher in Washington is unlikely to significantly improve the recovery of the species and would instead hinder its recovery. For example, the State expressed concerns that its ongoing fisher recovery program, which is implemented with numerous conservation partners, could be hindered or slowed as a consequence of a Federal listing. The State of Washington articulated that the program is expected to recover the fisher in Washington, allow WDFW to remove the fisher from the State endangered species list, and also preclude the need to federally list the species under the ESA. The tribe and Federal agency highlighted the recovery work being conducted by WDFW, NPS, the Forest Service, and other partners, which includes addressing recovery needs associated with private timberlands and tribal governments that are willing to participate in fisher recovery. All commenters expressed concern that if a Federal listing is finalized, the current support of partners will wane or possibly fail because of the added risk of additional regulations for reintroduced fishers occupying their lands, or that future reintroductions of fishers from British Columbia (via the current strong partnership between Federal and State agencies with the British Columbia Ministry of Environment in Canada) could be affected. Further, the Federal agency emphasized the existing monitoring and management activities that benefit the fisher could be impacted by the additional regulatory burden associated with a Federal listing. The State requested that the Service delineate a DPS boundary that does not include the State of Washington. One public commenter also championed completion of the draft CCAA in Washington to ensure the conservation of fishers in the State.

Our Response: We fully support and encourage the development of a CCAA to ensure the conservation of fisher in the State of Washington; such an agreement will provide benefits to both the proposed DPS and our conservation partners, and may help to preclude any need for listing in the future. We recognize that our conservation partners may be less likely to cooperate with reintroduction efforts once a species is listed under the Act, given previous articulated concerns related to the potential for additional regulatory burden resulting from the presence of an endangered or threatened species. We cannot, however, take such a consideration into account in a listing decision, which is statutorily required to be made based solely on the basis of the best available scientific and commercial information (emphasis ours). In other words, we cannot consider the potential political, social, or economic ramifications of a listing in our final determination. We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast populations of fisher. At this time, our end decision is to use the original DPS configuration as presented in the proposed listing rule. Consistent with our statutory standard, based solely on our assessment of the best available scientific and commercial information, we have concluded that the proposed DPS is not currently in danger of extinction (endangered), or likely to...
become so within the foreseeable future throughout all or a significant portion of its range (threatened). Therefore, we are withdrawing the proposed rule to list the West Coast DPS of fisher (see Determination, above).

(123) Comment: The State of Washington explicitly requested recognition of the WDNR State Trust Lands HCP and its ecological benefits to the fisher in the final rulemaking process.

Our Response: The ecological benefits of the WDNR State Trust Lands HCP for fisher were recognized on pages 93, 103, and 132 of the draft Species Report and on page 60434 of the proposed listing rule (October 7, 2014; 79 FR 60419). They were fully considered in our evaluation of conservation efforts that may offset stressors to the West Coast DPS of fishers in our prior analysis, in the final Species Report, and this document.

(124) Comment: One commenter declared that listing the fisher as an endangered or threatened species would have little impact across the west coast States if wildfire and illegal marijuana cultivation on National Forest lands are not addressed. The commenter invited the Service to work with their organization to seek more funding to enhance forest management activities and increase the frequency of marijuana eradication efforts on National Forest lands.

Our Response: The proposed rule identified both wildfire and illegal marijuana cultivation as elements of the main threats to the fisher in the west coast States. Ongoing efforts to ameliorate the effects of both elements are currently being implemented on National Forest lands. Through a Section 6 Agreement, we are currently working with CDFW to fund research that investigates the effects (and conducts cleanup) of marijuana grow sites on National Forest lands. To date, this work has resulted in the remediation of 24 trespass marijuana grow sites on Hoopa Tribal Lands and the Six Rivers, Plumas, and Shasta-Trinity National Forests, including the Trinity Alps Wilderness (IERC 2015a, Appendix A; IERC 2015b, p. 1; IERC 2015c, p. 1). We welcome the opportunity to work with the commenter to continue and expand this effort and also recommend the commenter contact the Forest Service directly to discuss management of wildfire on National Forest lands.

(125) Comment: One commenter asserted that reliance on Federal lands for the conservation of the proposed West Coast DPS of fisher, as well as other late-seral-dependent species such as the northern spotted owl, has not been sufficient to date to curtail the decline of those forest species; thus, listing the fisher is warranted. The commenter stated that recent estimates (Stritcholt et al. 2006) show only about 36 percent of LSRs actually include late-successional forests, with the majority of the designated reserves expected to acquire such conditions over decades. For these reasons, the commenter believed that existing regulatory mechanisms are inadequate to conserve the proposed West Coast DPS of fisher.

Our Response: The final Species Report describes how State and Federal regulatory mechanisms have abated the large-scale loss of fishers to trapping and habitat loss, and how ingrowth of older forest habitat on Federal lands in the NWFP range (which has the LSR land allocations mentioned by the commenter) is increasing as predicted in the NWFP (Service 2016, pp. 164–167). Given the success of State and Federal regulatory mechanisms in reducing these threats, we determined in the proposed listing rule and reaffirm in this document that the inadequacy of existing regulatory mechanisms is not a threat to the proposed West Coast DPS of fisher (see Existing Regulatory Mechanisms, above).

(126) Comment: One commenter asserted that the past (i.e., the decade prior to 2014) likelihood of listing the fisher has had a positive effect on timberland owners voluntarily addressing numerous questions regarding the distribution and population status of fisher on their lands throughout California. The commenter claimed that if listing the fisher as a threatened species had occurred years ago, many of the voluntary research programs in existence today might be nonexistent, and those resources would have instead been channeled towards meeting the minimum regulatory guidance of a yet-to-be-determined incidental take standard. This commenter and a few other commenters declined their voluntary conservation efforts on private lands are both in response to the Service’s encouragement and their desire to address the conservation needs of fishers. Two of these commenters articulated that listing the proposed West Coast DPS of fisher would not only impede future conservation efforts (e.g., completion of HCPs, CCAAs) but also appear as a punishment for the beneficial conservation actions implemented to date for the fisher and its habitat.

Our Response: We do not have discretion not to list a species if listing is warranted, which means a species meets the definition of an endangered or a threatened species. In the case of the fisher populations on the west coast, in 2004, we determined the proposed West Coast DPS of fisher warranted listing (69 FR 18769; April 8, 2004), but immediate action to list the species was precluded by other higher priority listing actions at that time. See additional discussion on this history in our response to Comment (118), above.

With regard to this withdrawal of the proposed listing rule, there is an extensive amount of varied scientific, Service, other agency, and public opinion regarding the status of the proposed DPS both prior to, and following, the October 7, 2014 (79 FR 60419), proposed listing of the West Coast DPS of fisher. Given this variance and the extensive disparity in comments received (including peer reviewers) during the two open comment periods, we considered it necessary to re-evaluate all of this best available scientific and commercial information previously reviewed, and the new information we received, to formulate a final decision. Upon careful consideration and evaluation of all of the information before us, we have arrived at a different conclusion regarding the status of the proposed West Coast DPS of fishers. Specifically, we conclude that the stressors acting upon the proposed West Coast DPS of fisher are not of sufficient imminence, intensity, or magnitude to indicate that they are singly or cumulatively resulting in significant impacts at either the population or range-wide scale. Based on this current assessment, we find that the proposed West Coast DPS of fisher is not in danger of extinction currently, and is not likely to become endangered within the foreseeable future throughout all or a significant portion of its range. Therefore, the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species, and we are withdrawing the proposed rule to list the DPS as a threatened species (see Determination, above).

(127) Comment: Several commenters requested implementation of specific conservation or recovery actions (or a comprehensive strategy) for fishers in the west coast States, including management activities that would improve the overall landscape for fishers and other species. Many of these actions were recommended to the Service because the commenters believed they would ensure the long-term conservation of the fisher. Some of the recommendations were provided by commenters who believe the taxon would go extinct without them, or by
commenters who believe that the recommended actions would be sufficient to reduce the level of impact of a stressor(s) such that the associated impacts would not rise to the level of a threat.

Our Response: We appreciate the recommendations provided by commenters to continue the management and conservation of the fisher. Despite the withdrawal of the proposed rule to list the DPS (see Determination, above), the actions recommended by these commenters are still important to the conservation of fishers in the west coast States. We encourage ongoing monitoring and management for the benefit of fishers, although any actions undertaken will not be under a Federal regulatory context. Rather, we expect that the conservation efforts implemented by State, Federal, and private entities will continue into the future and the conservation recommendations provided by commenters may be adopted as voluntary actions by entities working to conserve the fisher in California, Oregon, and Washington.

Detection Probability

(128) Comment: One commenter suggested that the extremely low densities of fishers elude standard survey techniques on Mendocino Redwood Company’s lands in coastal Mendocino and Sonoma Counties. Additionally, the commenter specifically suggested that because fishers were “probably absent” from their lands, the Service should exclude their land from the proposed DPS boundaries.

Our Response: Although not clearly articulated, it appears the commenter was referring to the absence of fisher detections from 47 track plate station locations (surveyed between 2004 and 2008) within its holdings in Mendocino and Sonoma Counties. We agree with the commenter’s suggestion that fishers may be present in very small numbers, but were not detected due to the survey methods employed (i.e., Zielinski et al. 1995, pp. 67–89). Zielinski et al. (1995, p. 10) state clearly that their survey methods should be used to determine “presence” of fishers, but should not be used to conclude “absence” of fishers “until additional research is conducted on the probabilities of detecting individuals known to occur in an area.” Therefore, individual fishers may not be detected by Zielinski et al.’s 1995 survey methods if they occur in extremely low densities. We also acknowledge the commenter’s note that when survey methods were subsequently changed (mainly an increase in the survey period recommended by Slauson et al. [2009]), a fisher was detected at two survey stations in 2013, confirming the presence of fishers on its lands. The fisher’s range in the west coast States includes many areas with suitable habitat where fishers probably do not occur, including suitable habitat areas in coastal Mendocino and Sonoma Counties. Additionally, the best scientific and commercial information, which includes that presented by the commenter, does not support the commenter’s assertion that fishers are “probably absent” from their lands because: (1) A lack of detections using Zielinski et al.’s (1995) survey protocol between 2004 and 2008 does not confirm absence of fishers, and (2) fisher presence was confirmed in 2013 using newer survey methodology. Therefore, we disagree with the commenter’s assertion that because fishers were “probably absent” from its lands, that we should exclude their land from the proposed DPS boundary.

Development

(129) Comment: One commenter stated that road construction and maintenance removes and fragments fisher habitat, thus creating barriers to dispersal, causing collisions, creating loss of cover that increases vulnerability to predators, facilitating access to poachers, and indirectly leading to logging and firewood cutting. Additionally, the commenter stated that roads bisect the fisher’s habitat in the west coast States and create concerns about dispersal and mortality, which in turn lead to significant impacts to already small and isolated fisher populations.

Our Response: As described in both our draft and final Species Reports, we considered the potential effects (including fragmentation) of such activities on fishers and fisher habitat in our evaluation of stressors related to development, linear features (highways and other infrastructure), and fisher collisions with vehicles (see associated discussions under Summary of Factors Affecting the Species, above). Although the activities mentioned by the commenter can have a negative effect on fisher individuals, we found no evidence to suggest that such stressors are of sufficient imminent, intensity, or magnitude singly or cumulatively resulting in significant impacts at either the population or rangewide scales, currently or in the foreseeable future.

Disease or Predation

(130) Comment: One commenter stated that although they agree with the Service’s conclusion that disease or predation are important stressors on the West Coast DPS of fisher, more information is needed to better understand the relationship between these stressors and fisher viability. Specifically, the commenter found that the statement in the draft Species Report that predation and disease appear to be the most significant cause of mortality is not consistent with other statements regarding the uncertainty of the effects of disease on wild populations of fishers. For these reasons, the commenter concluded that disease and predation should not be significant threats that lead to listing the proposed West Coast DPS of fisher.
DPS, and that this factor should not alone, or in combination, lead to the listing of the proposed West Coast DPS of fisher.

Our Response: Consistent with our determination in the proposed listing rule, we do not consider disease or predation to be threats to the proposed West Coast DPS of fisher, now or in the future. Our finding in the draft Species Report that disease and predation are the most prevalent sources of direct mortality of fishers should not be construed to mean that these factors present significant threats to fishers in the west coast States. Thus, the proposed listing rule concluded that “although they are the most prevalent sources of direct mortality among individual fishers within the study areas for which we have information, it is unknown how disease and predation rates influence fisher population trends in general” (79 FR 60431). Disease and predation are naturally occurring sources of mortality, and we do not have data that indicate either of these stressors has increased beyond the levels in which fishers have evolved; we make this clarification in the “Disease or Predation” section of the final Species Report.

(132) Comment: One commenter noted that disease and predation are natural processes that affect all wildlife populations, and it is in those areas where populations are extremely low (such as the SSN population) that the risk of random disease events may be most significant.

Our Response: We agree with the commenter that in general, small populations are more susceptible to disease outbreaks that may result in population declines. The “Cumulative and Synergistic Effects of Stressors” sections of the draft and final Species Reports discuss the cumulative and synergistic effects of many stressors, including disease, acting on small, disjunct populations (Service 2014, pp. 144–172; Service 2016, pp. 128–132).

Our current analysis reveals that for individual fishers within the study areas for which we have information, it is unknown how disease and predation rates influence fisher population trends in general” (79 FR 60431). Disease and predation are naturally occurring sources of mortality, and we do not have data that indicate either of these stressors has increased beyond the levels in which fishers have evolved; we make this clarification in the “Disease or Predation” section of the final Species Report.

(133) Comment: Many commenters expressed support for the Service to list the entire range of fishers in the west coast States as a single DPS throughout its historical range (we also note that many others supported listing in general). Alternatively, numerous commenters supported either one of the potential alternative DPS configurations as presented in the proposed rule, or suggested additional potential DPS configurations for consideration as more appropriate for listing, for a variety of reasons. Others offered the opinion that the evidence presented does not support the need to list the proposed West Coast DPS of fisher under the Act.

Our Response: We appreciate the depth of thought and consideration given by many commenters to the question of which DPS configuration may be most appropriate for fishers in the west coast States. We may list as endangered or threatened any species, which includes, as defined by section 3(16) the Act, “any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.” In order to interpret this phrase in a clear and consistent fashion, the Service and NOAA issued a joint Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (61 FR 4722; February 7, 1996). The policy is clear that, in accordance with the statutory requirement to use the best available scientific data in determining the status of a species, our application of the DPS policy must follow sound biological principles (thus questions of whether or not a particular DPS may be politically acceptable, or other non-biological considerations, do not enter into our deliberations). The policy stipulates that in order to qualify as a DPS, the population in question must be both discrete and significant to the taxon to which it belongs. As demonstrated by the great variety of potential DPSs suggested by commenters here, the policy creates the possibility for any number of possible different varied configurations, and many of these could possibly be argued to meet these criteria. At the same time, Congress has instructed the Service and NOAA to utilize the authority to designate DPSs “sparingly and only when the biological evidence indicates that such action is warranted” (61 FR 4722; February 7, 1996). Taking all of these considerations into account, after thorough consideration and deliberation, at this time our end decision is to use the original DPS configuration as presented in the proposed listing rule.

(134) Comment: One commenter requested that the Service look more closely at fisher populations within and outside of the proposed West Coast DPS of fisher to see whether distinctions within the proposed DPS are equal to or stronger than distinctions between West Coast fishers and other North American fishers. The commenter theorized that there would be significant implications for fisher conservation if the Service lumped into a single DPS fisher populations and habitat that are naturally separated and which the commenter believes should not be combined.

Our Response: We appreciate the commenter’s concerns, and we received many comments on the degree of genetic separation between the different populations of fishers (both native and reintroduced) within the boundaries of the proposed West Coast DPS. Some commenters encouraged us to undertake actions that would aid connectivity and gene flow between some or all of these populations. Other commenters cautioned against the harm that might result from reconnecting populations that may potentially have remained naturally isolated from each other for hundreds if not thousands of years, and have thus diverged genetically (e.g., this argument was made in support of maintaining separation between the SSN and NCSO populations). Notwithstanding these arguments, we note that the potential delineation of a DPS that combines multiple subpopulations within a single administrative boundary does not preclude the separate management of those populations or habitats for different purposes or needs, as appropriate. In any case, we have concluded that the West Coast DPS of fisher as described in our proposed listing rule and in this document does not warrant listing; therefore, our proposed rule to list the DPS as a threatened species is withdrawn (see Determination, above).

(135) Comment: One commenter stated that the 2004 DPS was derived on the premise that fisher populations in Oregon and Washington are isolated remnants of a larger west coast fisher population that became contracted and isolated by human activity. The commenter stated that this premise is not consistent with Tucker et al. (2012), which suggests that the existing populations of west coast fishers are the result of natural and evolutionary isolation that was not caused by human activity and is not amenable to remedy by human management under the Act.
Additionally, because the Service found fishers extirpated in Washington and Oregon, and Tucker et al. (2012) suggests that extirpated fishers were naturally distinct from fisher populations currently residing in California, the commenter asserted that it may not be appropriate to list non-existent populations. Further, the commenter questioned whether existence of naturally isolated populations in California should serve as justification for listing of fishers in Oregon and Washington based on a false premise that reintroduced Oregon and Washington fishers are a stepping stone for reconnecting interbreeding populations in British Columbia and California that were naturally isolated long before anthropogenic influence. Multiple commenters questioned the inclusion of Oregon and Washington in the boundary for the West Coast DPS of fisher, given that native fishers are apparently absent from the majority of their former range in these two States, despite an abundance of moderate- and high-quality habitat available.

Our Response: The DPS as proposed was based on the overall historical distribution of fishers throughout Oregon, Washington, and California. We did not mean to imply that there is universal agreement regarding the historical distribution of fishers within across the west coast States. In our draft Species Report, we specifically noted the differences of opinion regarding the question of whether fisher distribution was formerly relatively continuous within across the west coast States, or naturally more disjunct (citing, for example, to differences between the view expressed by Grinnell et al. (1937), versus Knaus et al. (2011) or Tucker et al. (2012) [noting the work of Tucker et al. (2012) is specific to the California populations, and did not address the larger west coast population as suggested by the commenter]). Furthermore, the delineation of a single DPS boundary around multiple populations does not necessarily mean that we must manage toward the unification of populations into one single, continuous population. A DPS boundary is an administrative construct, within which we maintain the flexibility to manage populations separately, as appropriate and necessary for conservation.

We appreciate the depth of thought and consideration given by many commenters to the question of deriving a DPS configuration that may be most appropriate for West Coast fishers. Please see our response to Comment (133) for an explanation of our DPS policy and how it determines the DPSs we can develop. In applying our DPS policy, and after thorough consideration and deliberation, at this time our end decision is to use the original DPS configuration as presented in the proposed listing rule. Per section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding current and potential future threats to the West Coast DPS of the fisher and are withdrawing our proposal to list this DPS (see Determination, above). Although fishers are not located in large portions of Oregon and Washington, ongoing research and monitoring within the west coast States will inform how best to manage the various fisher populations given their different genetic compositions.

(136) Comment: Many commenters stated that there may be connectivity between the SSN and other populations of fishers in the western States, thus implying that the proposed DPS boundaries are appropriate. Alternatively, one Federal agency stated that the NCSO, SOC, and SSN populations of fisher are geographically separated and genetically distinct (reproductively and functionally isolated), and that there is no information regarding the contraction or extirpation of populations. Therefore, the agency suggested the Service reconsider its rationale for considering the aggregate of all three populations as a single DPS. A second Federal agency specifically suggested that, should the Service determine that the SSN population merits listing, it should be listed as a DPS in and of itself (and managed as such) because there is no functional relationship between these other populations and the SSN population that has been isolated for hundreds of years (Tucker et al. 2012). The second Federal agency also recommended extreme caution with respect to reconnecting the longstanding 261-mi (420-km) gap in the species’ historical range, which could result in unintended consequences from the mixing of genomes.

Our Response: We received many comments regarding the potential for connectivity between the SSN population and other fisher populations within the west coast States; some saw the “restoration” of connectivity as critical to the long-term viability of fishers, and some cautioned against trying to “reconnect” divergent populations when the evidence suggests they have been naturally separated for a very long period of time. In either case, we note that any final decision on managing fisher populations with regard to potential connectivity is neither precluded nor mandated by the identification of these populations as a DPS. We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast populations of fisher. However, at this time, our decision is to use the original DPS configuration as presented in the proposed listing rule. Please also see our responses to Comments (23) and (134).

(137) Comment: Assuming one or more populations of fishers in Oregon became listed under the Act, one Federal agency requested clarification regarding the management of fishers in Oregon based on genetic considerations, particularly those fishers that occur in the NCSO population. Specifically, the commenter inquired whether fishers in Oregon and Washington outside of the NCSO population should be managed separately from those in the NCSO population that may be genetically different. The Federal agency also stated that (from a regulated agency standpoint) there is little utility in attempting to manage the NCSO population separately from the SOC population, in part because current information indicates it is likely that interbreeding is occurring and there is not a practical way to separate the two populations for the section 7 consultation process.

Our Response: According to section 4 of the Act and its implementing regulations, we have assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of fisher and are withdrawing our proposal to list this DPS. Because there are conservation issues that, while of concern, do not rise to the level of meeting the standards for listing the proposed West Coast DPS of fisher under the Act, we will closely follow the management of fishers and their status within the west coast States. Ongoing research and monitoring within the west coast States will inform how best to manage the NCSO and SOC populations; the issue of appropriate management taking into account genetic considerations is independent of a DPS delineation under the Act. See also our response to Comment (135).

(138) Comment: The State of Oregon asserted that for multiple reasons listing the proposed West Coast DPS of fisher as threatened under the Act may not be appropriate at this time. However, if the Service does list fishers in the west coast States as threatened, the State encouraged the Service to consider DPS Alternative 2 as described in the proposed listing rule, which focused on
extant native populations with unique genetic characteristics and excludes reintroduced populations established with non-California/Oregon fishers. Among the alternative DPSs listed in the proposed listing rule, the State indicated that Alternative 2 appears to minimize the Federal regulatory "overlay" and recognizes the need (as much as possible) to develop and maintain positive working relationships among Federal and non-Federal landowners to achieve fisher conservation goals.

Our Response: Per section 4 of the Act and its implementing regulations, we have assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher and are withdrawing our proposal to list this DPS. We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for West Coast fishers. However, at this time, our decision is to use the original DPS configuration as presented in the proposed listing rule.

(139) Comment: The State of Washington supported conservation of fishers in the west coast States, although they suggested an alternative DPS configuration that included only populations within Oregon and California, with the Columbia River as the northern boundary. They stated that this DPS configuration is appropriate for conservation of fishers in California, where conservation has already been initiated, and Oregon, where the Act’s protections would likely assist in the development of an active fisher recovery program. The State indicated that providing the Act’s protections would significantly complicate the ongoing State conservation program being implemented for the reintroduced population in Washington. Further, the State argued that fishers in Washington are discrete from the other populations, and are not significant in the same way that the native California populations are. Specifically, the State argued that fishers in Washington should not be included in the proposed West Coast DPS of fisher.

Our Response: Please see our response to Comment (133), and our response to Comment (149) for an explanation of our DPS policy. We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast populations of fisher. However, at this time, our end decision is to use the original DPS configuration as presented in the proposed listing rule. We have determined that the proposed West Coast DPS of fisher, as previously defined, does not meet the Act’s definition of an endangered or threatened species throughout all or a significant portion of its range. Therefore, we are withdrawing the proposed rule to list the West Coast DPS of fisher (see Determination, above), and the question of whether the DPS should include Washington State or not is moot.

(140) Comment: One Federal agency stated that any DPS listed by the Service that includes the NCSO population and also excludes the SOC population would be counter to the Alsea Valley Association v. Evans court ruling (Alsea Valley Alliance v. Evans, 161 F. Supp. 2d 1154 (D. Or. 2001), appeal dismissed, 358 F.3d 1191 (9th Cir. 2004). The Federal agency asserted that movement of fishers occurs between the NCSO population and the SOC population (supported by data), demonstrating that these two populations cannot meet the Service’s discreteness policy as two separate DPSs. They stated that mature individuals within the NCSO and SOC populations can interbreed and interbreeding should be expected in the future.

Our Response: Please see our response to Comment (133). We have chosen to retain the DPS configuration as published in our proposed rule for our evaluation (79 FR 60419). At this time, we are withdrawing the proposed rule to list the West Coast DPS of fisher under the Act (see Determination, above). If in the future we consider listing of an alternative DPS that includes the NCSO population and excludes the SOC population, we will thoroughly evaluate the Alsea Valley Association v. Evans court ruling and other considerations raised in this comment. However, we note that we did not propose to list the SOC population as a separate DPS.

(141) Comment: One Federal agency suggested that fisher populations in the State of Washington are not at risk, relative to populations in other portions of the three-State range under consideration, implying that the population in Washington should not be included in any DPS, should fishers in the west coast States be listed under the Act. They pointed out that based on WDFW’s evaluation of fisher habitat in the State of Washington, the primary factors attributed to extirpation of the species from that State (e.g., loss and fragmentation of forested habitats, overtrapping) were no longer operative, citing to Lewis and Hayes (2004). Further, they pointed out the following regarding other potential threats:

- With regard to the more recently identified stressor of ARs, the NPS does not administer rodenticides in the Olympic, North Cascades, or Mount Rainer National Parks and works with cooperators and concessions to preclude the use of these agents (although the level of potential illegal use in park areas is unknown). In addition, the Federal agency noted that only one of five of the recent fisher mortalities recovered in the Olympic peninsula recovery area (2013–2014) showed AR exposure, and as that individual was recovered just outside the city limits of Port Angeles, they surmise it most likely was exposed at a residential setting. The Federal agency suggested that more recent data indicate the key risk factor of AR exposures for fisher in California may not be as relevant in Washington.
- The high-quality fisher habitat in Washington’s national parks and adjacent national forests is minimally threatened by wildfire due to the hyper-oceanic climate with relatively high rainfall, as compared to the more arid eastern slope of the Cascade Mountains and south into portions of Oregon and California.
- The reintroduced Washington population does not share the unique genetic characteristics of the California populations.

Our Response: See our responses to Comment (133) regarding our consideration of a final DPS. In addition, we thoroughly discussed and considered the regional variability in stressors to fisher populations and habitat in the west coast States in both our draft and final Species Reports and this document. This evaluation has led us to the conclusion that the proposed West Coast DPS of fisher is not in danger of extinction throughout all or a significant portion of its range, nor is it likely to become so within the foreseeable future. Therefore, we are withdrawing our proposed rule to list the West Coast DPS of fisher.

(142) Comment: One Federal agency disagreed with the Service that the SSN population of fishers may warrant consideration for listing because that population is small and isolated from other fisher populations. They questioned whether the SSN population is actually imperiled, for the following reasons:

(1) There is no evidence that the distribution of the SSN population has contracted from historical levels, and there is no reason to believe that there has been any change in abundance of this population. The locality records presented in the draft Species Report indicated a stable distribution over the last century, and the findings of Tucker
et al. (2012) indicated that the SSN population has been isolated from other fisher populations since well before European settlement. The weight of evidence suggested that either: (a) The SSN population responds to stressors differently than other fisher populations that have experienced range contractions, or (b) stressors within this population are less severe than they are elsewhere in the species’ range.

(2) There is no evidence that fishers have declined in abundance in contemporary times. Current estimates of abundance are similar to estimates of carrying capacity, suggesting that the current distribution and abundance of the SSN population remain similar to historical levels. Recent estimates of population growth in the SSN population from the Sierra Nevada Adaptive Management Project suggest it has ranged from stable to positive; there have been no studies indicating negative growth.

(3) There is no evidence that the potential stressors identified in the listing proposal have negatively impacted population dynamics of the SSN population. Without at least correlative evidence of an association between stressors and population decline, it is difficult to argue that the stressors are indeed operative threats that act on the species. As an example, it is acknowledged in the draft Species Report that the impact of AR exposure on vital rates at the population level is unknown. Therefore, although there may be an underlying cause and effect relationship, it is premature to rely on the existing evidence to support a listing.

Our Response: We have included consideration of the Federal agency’s comments and other information suggesting that the SSN population may or may not be imperiled, as outlined in the three points above. Many of the considerations pointed out by the agency played a role in our final decision; ultimately, we have concluded that the stressors acting on fishers in the West Coast DPS are resulting in population level or rangewide declines, such that fishers in the DPS are in danger of extinction or likely to become so within the foreseeable future. Therefore, at this time, we are withdrawing the proposed rule to list the West Coast DPS of fisher under the Act (see Determination, above).

(143) Comment: One tribe questioned and disagreed with the Service’s inclusion of Washington as part of the proposed West Coast DPS of fisher. Specifically, the tribe suggested DPS Alternatives 1 or 2 (as described in the proposed listing rule) to provide a more reasonable basis for the species listing because the Washington population of fishers is discrete based on distance and the barrier of the Columbia River, both of which provide a low likelihood of genetic interchange, as shown by genetic research. Further, the tribe asserted that the historical Washington fisher population is more related to fishers from central British Columbia, as reported by Lewis and Hayes (2004).

Our Response: See our response to Comment (133).

(144) Comment: One local government stated that lands within Lincoln County (Oregon) should be removed from the proposed DPS boundary because fishers have never been seen in the county historically or currently.

Our Response: There is a recorded observation of a fisher in Lincoln County, Oregon, from the 1990s. There are also observations of fishers in adjacent Tillamook County to the north and coastal Clackamas County to the south. Although none of these records provide verifiable evidence (i.e., no evidence that can be subject to independent review such as photos, tracks, genetic material), they were recorded by observers estimated to be of fair or good reliability in the Oregon Biodiversity Information Center database. Given the historical habitat in the coast range of Oregon, the current distribution of fishers based on verifiable records, and the existing unverifiable observations scattered through the central and northern coastal counties, it is reasonable to conclude that fishers were likely historically present in the northern Oregon Coast Range, which includes Lincoln and Tillamook Counties, and the western end of Lane County. While there may not be any verifiable records that fishers occurred in Lincoln County, we must make conclusions based on the best available information, which in our view, indicates that fishers were likely historically present in the northern Oregon Coast Range. Because our proposed DPS boundary was derived in part based on the historical range of fishers in the west coast, we consider it appropriate to include Lincoln County within the DPS boundary. At any rate, based upon our assessment of the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher, we are withdrawing our proposal to list this DPS (see Determination, above); therefore, the point is moot.

(145) Comment: One commenter stated that the proposed DPS boundary for the listable entity should be solely within California (i.e., native populations only that include a DPS for the SSN population, and a DPS for the remainder of California that excludes all lands and nonnative fisher populations that may occur in Oregon).

Additionally, this commenter asserted that listing should not be warranted for both of their suggested DPSs (with another commenter supporting a not warranted finding for the SSN population area) based on the health of the suggested DPSs, lack of threats to each DPS, and the conservation measures in place for these populations.

Our Response: Regarding potential DPS delineations, please see our response to Comment (133). We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast populations of fisher, and considered many potential variations. However, at this time, our end decision is to use the original DPS configuration as presented in the proposed listing rule. Furthermore, based on our evaluation of the best scientific and commercial data available, we have concluded that the proposed DPS does not meet the definition of an endangered or threatened species under the Act (see Determination, above).

(146) Comment: Two commenters stated that fishers are extirpated in Washington and Oregon, and that reintroduced fishers in these two States are genetically distinct from native fishers in California, which argues against combining all native fishers into a single DPS.

Our Response: See our response to Comment (133).

(147) Comment: Two commenters asserted that a DPS including native fisher populations in Oregon and California should not be expanded to include lands within the remainder of Oregon and Washington that are inhabited by reintroduced fishers. The commenter stated that genetic research demonstrates that reintroduced fishers in Oregon and Washington are not closely related to native fishers in California. A third commenter stated that these genetic differences explain why NCSO should be managed separately between these two regions (i.e., Washington and Oregon populations managed separately than the NCSO population), also citing Aubry and Lewis (2003) as support for two disjunct, genetically isolated populations in the southwest portion of Oregon and the southern Cascades portion of Oregon (the latter of which is reintroduced). Additionally, one of these commenters specified that the State of Washington considers fishers
likely extirpated (Lewis and Stinson 1998). Therefore, with the exception of native fishers in southwestern Oregon (i.e., south of the Rogue River and west of Interstate 5), the Service should exclude most of Oregon and all of Washington from any DPS.

Additionally, one commenter articulated that if fishers in the west coast States and other fisher populations are genetically divergent, morphologically distinct, or specially adapted to diverse habitats for prehistoric, natural, or evolutionary reasons, then it is logical and scientifically consistent for the Service to reconsider whether the fishers in the west coast States actually contain (within its geographic range and populations) the same natural, prehistoric, and evolutionary separation that the Service relies on to distinguish the proposed West Coast DPS from other fishers.

Our Response: Regarding the delineation of DPSs, please see our response to Comment (133). We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast populations of fishers. However, at this time, our decision is to use the original DPS configuration as presented in the proposed listing rule and based on our assessment of the best scientific and commercial data available we have withdrawn our proposal to list this DPS (see Determination, above). Although fishers are not located in large portions of Oregon and Washington, ongoing research and monitoring within the west coast States will inform best management practices for the various fisher populations given their different genetic compositions. See also our responses to Comments (135) and (137).

(148) Comment: Two commenters asserted that the lack of fisher in Oregon and Washington (other than the reintroduced populations) supports the premise that fishers are extirpated from the majority of their former range in these two States, despite an abundance of moderate- and high-quality habitat, and it also supports an argument that fishers were likely not well distributed historically within the Service’s analysis area. Additionally, the commenter stressed that the contiguous population that occurs in northern California and the extreme southwestern portion of Oregon should not be included with the remainder of coastal Oregon, the Oregon Cascades, or the State of Washington as a DPS. Further, the commenter believed this assertion is supported by Knaus et al. (2011), which indicates that genetic distinction exists between the two California fisher groups and all other groups in their study.

Our Response: We disagree that the current lack of fishers in large parts of Oregon and Washington supports an argument that fishers were likely not well distributed historically within the proposed West Coast DPS. Present-day distributions are not necessarily a reflection of historical distributions, particularly given the tremendous trapping pressures fishers underwent in the early 1900s. These effects, combined with additional mortality from predation control efforts, followed by subsequent habitat loss in the mid to late 1900s, have substantially reduced the numbers and distribution of fishers. Although the record is not sufficient to fully describe the specific historical distribution, given the past distribution of forest conditions that likely supported fishers, and the well-established record of fisher population and distribution declines through trapping records and other sources, we conclude fishers were historically distributed throughout much of the proposed DPS, although populations may not have been fully contiguous.

We solicited comments from peer reviewers and the public regarding the possibility of different DPS configurations for the West Coast population of fishers. We recognize and appreciate that there are many possible approaches to delineating potential DPSs, and that there may be valid arguments in support of (or against) aspects of each (see our response to Comment (133)). However, at this time, our decision is to use the original DPS configuration as presented in the proposed listing rule. Although fishers are not located in large portions of Oregon and Washington, ongoing research and monitoring within the west coast States will inform how best to manage the various fisher populations given their different genetic compositions.

(149) Comment: One commenter contended there is little evidence that an extant population of fisher remains in Oregon and Washington, and that there is little hope that any fishers found or reintroduced into Oregon and Washington would reconnect with the NCPSO population of fishers. Therefore, the commenter believed the Service should evaluate an alternative DPS as the listable entity.

Our Response: The commenter is incorrect in stating that there are no extant fishers in Oregon. On the contrary, fishers in the NCPSO population occupy southwestern Oregon. In addition, a reintroduced population (SOC population) has persisted in the southern Oregon Cascades for well over 30 years. With respect to Washington, fishers from a recent reintroduction on the Olympic Peninsula are reproducing, and though it is too early to say whether this population will persist, results from monitoring are encouraging. Additionally, fisher reintroductions are both ongoing and planned in the Washington Cascades.

The commenter did not provide any support for their statement that fishers in Oregon, at least, would not reconnect with the NCPSO population. Recent data shows spatial overlap of individuals from the NCPSO and SOC populations, suggesting that these two populations are beginning to intersect. There has been limited monitoring of fishers in Oregon to robustly describe their distribution, but recent and ongoing surveys in the Cascades will better inform our understanding of the distribution of the reintroduced SOC population and its relationship with the NCPSO population. Given our current understanding of suitable fisher habitat, it appears that there may be adequate habitat to support fishers in the northern Cascades of Oregon and allow connectivity with extant fishers in the reintroduced SOC population and south to the NCPSO population.

We acknowledge the commenter’s point that Washington fishers are not likely to reconnect with the NCPSO population. The Columbia River is almost certainly a considerable barrier to fisher movement in the proposed DPS. While it may restrict populations from substantially intermingling, it is likely not impenetrable, allowing some genetic mixing of fisher populations over the long term. Please see our response to Comment (133).

At this time, our decision is to use the original DPS configuration as presented in the proposed listing rule. Per section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher and are withdrawing our proposal to list this DPS (see Determination, above).

Distribution

(150) Comment: One Federal commenter stated that the NCPSO and SOC populations of the proposed West Coast DPS of fisher are interconnected, suggesting an increased probability of genetic exchange between the two populations into the foreseeable future. The commenter provided information to the Service in response to our request for information (as outlined in the proposed rule) as to whether the...
Klamath River, the Rogue River, and Interstate 5 may act as filters or barriers to fisher movement between the NCSO and SOC populations.

Our Response: The commenter provided information that was previously considered and incorporated in the draft Species Report (Farber and Schwartz 2007 in Service 2014, p. 100). Recent information from ongoing survey and monitoring efforts in the native NCSO and reintroduced SOC populations indicates that two native fishers were documented within the area of reintroduced fishers. One of these native fishers was part of a radio telemetry study initiated within the NCSO population; data collected from this animal indicate that it crossed Interstate 5 and continued into areas occupied by the reintroduced SOC population. The second native fisher detection in the reintroduced SOC population occurred through a hair snare and remote camera study initiated within the SOC population. It is unknown if the second native fisher dispersed from the NCSO population or if it is part of an unknown remnant native population that historically occupied the area now considered the reintroduced SOC population. While there is evidence that fishers may cross Interstate 5, we do not have information on how often this activity may or may not occur. We also do not have information about the likelihood of increased genetic exchange between the two populations into the foreseeable future, although these observations demonstrate that it is certainly possible, or about the relative success fishers have when attempting to cross features such as interstates or rivers.

(151) Comment: One commenter stated that although surveys for the presence or absence of fishers in the proposed West Coast DPS have not been completed for its entire range, they believe that the best available data indicate that the proposed DPS is in danger of extinction. The commenter stated that a lack of survey information should not prevent the Service from making a listing decision, particularly given the proposed DPS is “struggling to survive” and “is considered likely to be extirpated throughout a significant portion of its historic range.” Additionally, if more survey information becomes available, the commenter indicated that the Service should closely analyze that new information and any potential bias from the submitters of that new information.

Our Response: Section 4 of the Act requires that we assess factors that may contribute to a species meeting the definition of an endangered or threatened species. In our evaluation of all the best scientific and commercial information available, we find no evidence of significant impacts at either the population or rangewide scales for fishers in the proposed DPS (see Determination, above). We have not based our decision on a lack of survey information. A compilation and analysis of survey records alone would not likely be sufficient to evaluate the response of populations to biological stressors that act upon the populations. We welcome any new information regarding the biological status of fishers in the west coast States, including any new survey information that may come available.

(152) Comment: One commenter stated there is ambiguity when comparing historical and contemporary localities of fisher detections and states that, compared to the historical distribution of fishers, there does not appear to be any contemporary range contraction in California. The commenter requested clarification of whether Figure 4 in the draft Species Report represents all reliability ratings. Further, based on a comparison of Figure 7 and Figure 8 in the draft Species Report, the commenter stated that fishers are currently distributed over a larger geographical area in California and with a far greater number of locality records on the northern California coast in recent times (after 1993).

Our Response: We agree with the commenter’s assertions that there has not been any range contraction in the contemporary time period in California. For clarification, Figure 4 in the draft Species Report depicts locality information from reports of the species in the analysis area from 1896 to the present (Service 2014, pp. 22, 26) and therefore, represents all reliability ratings from high reliability to unreliable records. We included all records in this figure because it provides the best picture of all of the data informing us as to the likely historical distribution of fisher within the west coast States; we have clarified this in the Figure 4 legend. Regarding comparisons of Figures 7 (high-reliability recent records) and 8 (all historical records) from the draft Species Report, records prior to 1993 indicate a wider historical distribution to the east in the NCSO population. While the furthest extent of the north-south distribution in California is similar to the historical distribution, there are more records of fishers throughout the length of the Cascade and Sierra Nevada Ranges of California than there are in the historical distribution. Therefore, the current distribution of fishers is not described as being greater than it was historically. We agree that there are a greater number of locality records from the California coast in recent times than there are in the historical record. These recent records reflect the significant amount of research that has been conducted along the California coast in recent times.

(153) Comment: One commenter stated that data for the proposed West Coast DPS of fishers indicate stable occupancy in the coastal redwoods and Sierra Nevada areas with no statistical support for population declines. The commenter stated that while the draft Species Report acknowledged these studies undertaken on the northern California coast, and should take note of new information in Sweitzer et al. (2015a, entire) and the CDFW fisher status review, there is little discussion of the implications of fisher use of managed forests or how that information can be used to predict suitable reintroduction sites in Oregon and Washington.

Our Response: There is an extensive discussion in the Habitat Associations section of the draft Species Report (see especially pages 17 and 18) of fisher use of managed lands, and this discussion has been further expanded in the final Species Report (Service 2016, pp. 15–21) in response to comments and new information received during the comment periods. The commenter acknowledges the discussion in the draft Species Report summarizing the results of research on the status (Service 2014, pp. 37–46) of fisher populations; this section has also been revised and expanded to reflect new information received since the draft Species Report was released (Service 2016, pp. 42–53). Reintroductions are currently under way in the Washington Cascades, but only Forest Service and NPS lands were considered for reintroduction sites. While our draft and final Species Reports do not specifically address how fisher use of managed lands can be used to determine suitable reintroduction sites in Oregon and Washington, such an evaluation is beyond the scope of our listing determination. However, the information summarized in the final Species Report, our experience with the Northern Sierra Nevada Reintroduced Population in California, and the information provided by the commenter will all be considered as future reintroductions onto managed lands are planned.

In addition, the lack of evidence for fisher population declines in the west coast States, in conjunction with our assessment of the stressors to the species, was an important consideration.
in our final determination that the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act (see Determination, above).

(154) Comment: One commenter stated that the fisher populations in the proposed West Coast DPS have expanded effectively by almost a half million acres in the past 20 years (since 1990), including fisher presence now documented in places such as east of Interstate 5, around the perimeter of Shasta Lake, and south of the Fountain fire area on private lands. The commenter asserted this information supports not listing the proposed West Coast DPS of fishers as an endangered or threatened species.

Our Response: Section 4(a)(1) of the Act directs us to determine whether any species is an endangered species or a threatened species because of factors affecting its continued existence. The presence of fishers in locations not previously documented in recent years is not necessarily indicative of increasing fisher populations and population expansion; for example, an increase in fisher detections may be indicative of increased survey effort in recent years.

The commenter does not present data indicating what methods were used to determine that the fisher population area across the proposed West Coast DPS has expanded by a half million acres since 1990, nor are any negative survey data for prior years presented. We have no evidence to suggest that any range expansion has occurred such as described by the commenter. Finally, no new data are presented that indicate that fishers are evenly distributed throughout this expansion area. The comment does not present evidence sufficient to support a listing determination. However, based on our assessment of the best scientific and commercial data available, we have concluded that the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act, and we are withdrawing the proposed rule to list the DPS.

(155) Comment: One commenter stated that there is no indication that the range of the proposed West Coast DPS of fisher east of Interstate 5 has contracted (as indicated in the draft Species Report and proposed rule), and suggests that it may even be expanding. The commenter concluded that recent survey results suggest the present range is contracted from the Interstate 5/Sacramento River corridor and Shasta Lake east through the Pit River area, the Fountain River area, and further south into eastern Tehama County.

Our Response: Please see responses to Comments 152 and 154.

(156) Comment: One commenter stated that the proposed West Coast DPS of fisher does not occur in the coastal region of Mendocino County. The commenter provided negative survey information from multiple survey efforts that included extensive, systematic survey efforts across much of the Mendocino coastal redwood region, resulting in only one detection on the easternmost border of the dominant coastal zone in Mendocino County. The commenter suggested their lands should not be included in the proposed DPS due to the absence of fishers.

Our Response: We disagree that fisher do not occur in the coastal region of Mendocino County and that the proposed DPS’s range should not include the commenter’s lands in coastal Mendocino County due to the apparent absence of fishers. Our position aligns with the information provided by the commenter and in our files, specifically: (1) The internal report that included a verified fisher detection on their lands, and (2) positive survey results from CDFW surveys conducted within coastal redwood habitat in Mendocino County immediately adjacent to their lands. Figure 1 of the proposed rule (79 FR 60419) and Figure 7 of the draft and final Species Reports (Service 2014, p. 31; Service 2016, p. 34) show verifiable fisher detection locations in northern coastal Mendocino County. These two [identical] maps were created using highly reliable fisher detection records from 1993 to present. We do agree, however, that based on the lack of suitable fisher habitat within the commenter’s lands (due to extensive timber harvest over the past 100 years), fishers probably occur in very small numbers on their lands. Our DPS policy does not exclude lands from a DPS’s range based solely on the current rarity or perceived absence of the target species. In addition, portions of coastal Mendocino County are under Federal ownership and contain relatively large amounts of suitable fisher habitat. Therefore, excluding all of coastal Mendocino County from the proposed DPS’s range boundary would exclude large tracts of suitable habitat (some occupied and some unoccupied) that occur outside of private timber company holdings.

(157) Comment: One commenter both agreed and disagreed with the best available information presented regarding distribution of the proposed West Coast DPS of fishers on their lands. The commenter stated that their managed timberlands in northern California are inhabited by a large, healthy population of fishers, and that managed timberlands in Oregon and Washington are not inhabited by native populations of fishers. A second commenter also articulated that fishers are well documented on their timber lands in California (i.e., lands that are managed for commercial timber harvest), asserting that the population (based on wording in the comment letter, we assume the commenter is referring to the population as a whole in California and not just the fisher population on their lands) is stable or expanding.

Our Response: We agree there is direct physical evidence that fishers occur on the first commenter’s lands in north coastal California (Hamm et al. 2003, p. 203), but disagree that sufficient scientific or commercial information exists that suggests fishers occur on their lands as a “large, healthy population.” Regarding whether the fisher population on their lands is “large,” the commenter provided a single fisher density estimate from a 77-mi² (200-km²) portion of their lands in north coastal California, which if extrapolated across their entire holdings would suggest a relatively large population. However, the commenter did not provide a fisher population size estimate for their lands in north coastal California, possibly because of the difficulty of extrapolating a density estimate of a rare forest carnivore from a relatively small study area to an entire extant population area. Several fisher studies have been conducted since the early 1980s within the NCSO population. However, as we stated in the draft and the final Species Reports (Service 2014, p. 37; Service 2016, p. 42), no published population or density estimates are available for the entire [emphasis added] NCSO population, especially as currently defined. The lack of such estimates suggest the researchers do not believe valid population size estimates can be generated by extrapolating density estimates from relatively small study areas to the much larger NCSO population area. The same commenter also did not present data on demographic parameters (e.g., sex ratio, age structure) or vital rates (e.g., birth and death rates) that would support a conclusion that the population is currently “healthy.” Therefore, the commenter’s assertion that the fisher population on their lands is large and healthy is not supported by the best scientific or commercial information available.
While we agree with the second commenter’s assertion that fishers may be “well documented” on the commenter’s lands, the lack of abundance estimates over time, which are required for a population trend analysis, make it impossible at this time to conclude that the fisher population is stable. However, using the survey methods employed by the commenter, we do agree it is possible to detect a relative “expansion” of a fisher population on their lands; that is, an expansion that may suggest an increase in fisher distribution.

**Economics**

(158) **Comment:** One local government asserted that listing the proposed West Coast DPS of fisher would result in significant socioeconomic and cumulative impacts, and that conservation actions for endangered or threatened species should be balanced with potential impacts to humans. Two additional public comments stated that a listing would significantly impact rural communities, with one commenter specifically addressing Southern Oregon’s rural communities, timber producers, family farmers, and other natural resources industries.

**Our Response:** Section 4(a)(1) of the Act lists the factors we use to determine whether or not a species is endangered or threatened; such a determination is to be based solely on the best scientific and commercial data available. While the Act provides for the consideration of potential economic impacts in the course of designating critical habitat, it does not provide for any such consideration when determining whether a species meets the statutory definitions of an endangered or a threatened species. Per section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher and are withdrawing our proposal to list this DPS (see Determination, above). Consequently, no Federal protections under the Act will be put in place for the proposed DPS, and, therefore, no real or perceived socioeconomic or cumulative impacts referred to by the commenter will be realized. We note that extensive conservation actions for fishers in the west coast States have been implemented and will continue to be implemented at the Federal, State, and local levels in the future. We are continuing to monitor the biological status of fishers in the west coast States, and will continue to do so in the future.

(159) **Comment:** Two commenters stated that for this listing evaluation for the proposed West Coast DPS of fisher, the listing process should not be rushed, and the Service should allow the public and affected stakeholders additional time to review given that a potential listing of the fisher will have significant, adverse impacts to forest management activities on both Federal and private timberlands in California. A second commenter stated that a slow Federal listing process would assist the State of California to complete their final decision on whether the fisher should be State-listed in California.

**Our Response:** We opened a 90-day comment period with the publication of the proposed listing rule, and prior to the close of the comment period, we extended the comment period for an additional 30 days (79 FR 76950). Additionally, we held one public hearing and seven information meetings between November 17, 2014, and December 4, 2014. On April 15, 2015 (80 FR 19953), concurrent with our announcement of an additional 30-day comment period, we invoked a 6-month extension of the due date of our final decision due to the substantial disagreement regarding available information related to toxics and rodenticides (including law enforcement information and trend data) and related to surveyed versus unsurveyed areas (including data on negative survey results) to help assess distribution and population trends and in our notice, we specifically sought information relating to these issues. In all, the public had a total of 120 days to provide comment on the proposed listing rule and with the 6-month extension of our final decision, we have used the maximum time allowed by the Act to complete this listing process. With regard to the listing process undertaken by the State of California, they implemented their decision-making process (which resulted in listing of the SSN ESU under ESA), and we have not (and, by law, could not) slowed our process to accommodate the State’s decision-making process. Our evaluation and that of the State are separate, independent processes governed by separate regulatory processes and timeframes.

(160) **Comment:** One commenter asserted that listing the proposed West Coast DPS of fisher would likely adversely affect their organization’s members’ supply of public timber. Additionally, the commenter was concerned about spread of insect, disease, and wildfire from poorly managed public lands to their member’s lands, and there would be a potential “take” liability that would constrain private land management.

**Our Response:** Section 4(a)(1) of the Act lists the factors we use to determine whether or not a species is endangered or threatened; such a determination is to be based solely on the best scientific and commercial data available. The consideration of the potential economic implications of listing a species is not a consideration when determining whether a species meets the statutory definitions of an endangered or a threatened species (although the Act does allow for the consideration of such impacts when designating critical habitat). It is also not clear to us how the commenter’s concern regarding the potential spread of insect, disease, and wildfire would result from listing. Following our assessment of the best scientific and commercial data available, we have withdrawn our proposal to list this DPS (see Determination, above). Therefore, no Federal protections under the Act will be implemented for the species. However, we noted that TRP programs in place that are actively engaged in conservation of fishers in the west coast States.

**Existing Regulatory Mechanisms**

(161) **Comment:** The State of Washington argued that there are many existing regulatory mechanisms that provide a benefit to fishers and their habitat. For example, the State stressed that trapping regulations have substantially reduced fisher mortality in the analysis area, although they argue that incidental captures may still have a meaningful influence on fisher populations, and the Service should not underestimate the severity of this threat (i.e., trapping).

**Our Response:** We evaluated the existing regulatory mechanisms in Washington State for fisher in both our draft and final Species Reports, including trapping regulations. We also evaluated trapping as a stressor for fisher (Service 2016, pp. 125–127). Trapping for fishers is not legal in Washington, and most uses of body-gripping or leg-hold traps, which are largely responsible for injury or mortality as a result of incidental capture, are also prohibited. Based on our analysis, we agree that existing trapping regulations have led to a substantial reduction in fisher mortality. However, we found no evidence to suggest that incidental captures are having a meaningful influence on fisher populations in Washington State, and that maintenance of the absence of data, any inference in this regard would be speculative. Therefore, based on our
analysis of the best available scientific and commercial information, we conclude that the severity of trapping as a stressor for fisher populations in Washington State has not been underestimated, and that all existing regulatory mechanisms have been given appropriate consideration (see Trapping and Incidental Capture and Existing Regulatory Mechanisms, above).

(162) Comment: The State of Washington stated that, with regards to regulatory mechanisms, they expect to restrict the use of pesticides in Washington State if pesticide poses a threat to the environment. The State asserted that they are willing to use their authority to address illegal use or minimize off-target impacts of pesticides through administration of a Pesticide Management Strategy and annual cooperative agreements with the U.S. Environmental Protection Agency. If it is found that illegal or off-target use of rodenticides is negatively impacting fishers, the State asserted that their implementation of the Pesticide Regulatory Program and Natural Resource Assessment Section would prevent pesticide use from remaining a threat to the fisher in Washington.

Our Response: We discussed the known effects of illegal and off-target rodenticides on fishers in the State of Washington in the draft Species Report (Service 2014, pp. 152–169) and in our final Species Report (Service 2016, pp. 141–159). As described in our final Species Report, the best information we have about rodenticide exposure in Washington comes from 13 dead fishers from the reintroduced ONP population whose carcasses were recovered and tested. Three of the 13 had been exposed to ARs, and were either born on the Peninsula or had resided there for longer than the persistence time for the ARs detected (given that the original reintroduced individuals came from British Columbia and exposure to toxicants could have occurred at that location); the sample size was too small to extrapolate. However, these three were found in or near residential areas, suggesting that exposure may have resulted from legal use of rodenticides. We appreciate the State’s commitment to contribute to the conservation of fishers in Washington, but at this time we do not have evidence to suggest that pesticide use poses a threat to fishers in Washington (see the “Toxicants” sections of this document and the final Species Report for additional discussion).

(163) Comment: The State of Oregon asserted that listing the fisher would do little to protect the taxon, and that a Federal listing would likely result in unintended consequences or disincentives for private landowners to engage in voluntary actions that may promote the conservation of the proposed DPS, including habitat protections. Additionally, the State indicated that they are already implementing conservation actions that address many of the threats described in the draft Species Report and proposed rule (e.g., managing to reduce the risk of high-intensity wildfire, identifying key wildlife crossing points on roads to reduce mortalities from vehicle collisions). Finally, the State indicated that listing would not address impacts from climate change, disease, or predation, the latter two of which are natural processes that affects all wildlife populations.

Our Response: Listing a species under the Act takes into consideration specific factors listed in section 4(a)(1) of the Act which may, singly or in combination, contribute to a species meeting the definition of an endangered or a threatened species. This determination is to be made solely on the basis of the best scientific and commercial data available; whether or not listing the species will have a beneficial effect in terms of reducing or eliminating identified threat factors is not a lawful consideration in this determination. We described conservation measures that are currently being implemented to ameliorate the stressors to the species in both our final Species Report and in this document, including important conservation contributions by the State of Oregon.

(164) Comment: The State of Oregon, plus one other commenter, asserted that the draft Species Report misrepresented the requirements of the Oregon Forest Practices Act. The commenter stated that while the report acknowledged no-cut buffers, it failed to account for Oregon’s basal area and tree count requirements in riparian areas ranging from 50 to 100 ft (15 to 30 m) on each side of the stream. The State of Oregon also provided descriptions for additional protections afforded by the Oregon Forest Practices Act for wildlife sites and other protected resources.

Our Response: As described by the commenter, we have included the Oregon Forest Practices Act riparian regulations and other information in the Existing Regulatory Mechanisms section of the final Species Report.

(165) Comment: The State of Oregon stated that listing the fisher may do little to address threats such as loss of fisher habitat given existing management on Federal lands. Specifically, they stated that declines in late-successional forests in western Oregon occurred largely during 1880–1990. They reiterated from the NWFP that: (a) A primary goal is the restoration and maintenance of late-successional and old-growth forests and old-growth dependent species; and (b) that the NWFP projected that, over a time horizon of 100 years, the area of late-successional and old-growth forest that was depleted by timber harvest could be restored and maintained at or near historic levels.

Our Response: Section 4(a)(1) of the Act sets forth the factors used to evaluate whether a species meets the definition of an endangered species or a threatened species. Listing a species under the Act requires the identification of factors affecting the species such that it meets the definition of an endangered or threatened species. The analysis is strictly a biological analysis; whether the Act can make a difference in ameliorating specific threats is not a consideration in a listing determination. We acknowledge the commenter’s statement that habitat on Federal land may recover through management under the NWFP, and indeed in our final Species Report we were able to incorporate ingrowth that has occurred within the NWFP area over the past 20 years, based on the recent NWFP 20-year late-successional old-growth monitoring report (Davis et al. 20XX, entire). Ultimately, we have determined that habitat loss through vegetation management, though historically contributing to fisher declines, does not currently threaten the proposed West Coast DPS of fisher, nor is it likely to do so in the future (see Vegetation Management, above). According to section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher and are withdrawing our proposal to list this DPS (see Determination, above).

(166) Comment: Several commenters stated that existing regulatory mechanisms are adequate for the long-term protection of fishers in the west coast States; thus, listing the proposed DPS is not warranted. One of these commenters specified that existing Forest Service and BLM “sensitive status” protections and CDFW’s “candidate status” protections are sufficient, and that additional ESA protections would only result in added administrative costs and delays in operating and management activities. Two other commenters stated that existing regulatory mechanisms are adequate based on the beneficial management prescribed through the NWFP (reserves, LSRs, and the survey
and management standards and guidelines for matrix lands) and the Sierra Nevada Forest Plan Amendment (SNFPA), both of which reduce areas available for timber management and halted the significant impacts associated with destruction/loss of late-successional forests, as well as other protective land use designations that benefit fishers and their habitat (e.g., Sierra Fisher Conservation Area, Giant Sequoia National Monument, and other National Park Service lands). Another commenter highlighted the Forest Service and BLM’s extensive planning efforts to consider sensitive species for every project, which contributes substantially to fisher conservation.

In contrast, four commenters asserted that the existing regulatory mechanisms are inadequate because federally protected lands do not provide sufficient suitable habitat (or protection of essential habitat elements) for fishers. One of these commenters argued that significant timber harvest acreage in California occurs via clearcutting or similar alternative methods, with other acreage also planned for sanitation-salvage logging operations and group-selection silviculture (Haines 2014), none of which (the commenter asserts) benefits the fisher. The second commenter stated that an ESA-listing would help address the lack of adequate pesticide (specifically rodenticide) regulatory mechanisms in Oregon and Washington. The third commenter asserted that reliance on the Federal lands LSR system, which provides conservation targeted at northern spotted owls and other late-seral-dependent species, is not sufficient to ensure conservation and recovery of the fisher because current LSR restrictions allow significant alteration and degradation of fisher habitat.

Our Response: We have thoroughly considered all existing regulatory and other mechanisms in place that are relevant to stressors identified for the proposed West Coast DPS of fisher, as described in our final Species Report and in this document. Our evaluation of all best scientific and commercial data available leads us to conclude that the stressors acting upon the proposed West Coast DPS of fisher are not of sufficient imminence, intensity, or magnitude to indicate that they are singly or cumulatively resulting in significant impacts at either the population or rangewide scales. As this finding leads us to conclude that the stressors acting on the species are not functioning as operative threats on the fisher’s habitat, populations, or the proposed DPS as a whole, we cannot further conclude that existing regulatory mechanisms are inadequate. Furthermore, our assessment of fisher habitat throughout the analysis area indicates that there are large areas of currently unoccupied habitat that are of moderate to high suitability for fishers; this is particularly true on Federal lands.

(167) Comment: One commenter proclaimed that reliance on the Federal lands LSR system to provide for conservation of the northern spotted owl and other late, seral-dependent species has not been sufficient to curtail the decline of the owl, and will not be sufficient to ensure conservation and recovery of the fisher. The commenter also alleged that recent estimates show only about 36 percent of LSRs include late-successional forests, with the majority of the designated reserves expected to acquire such conditions over decades (Strittholt et al. 2006). Finally, the commenter claimed that current LSR restrictions still allow significant alteration of fisher habitat and do not provide protection of elements essential to fisher habitat, such as large trees, downed wood, and high canopy closure, and that the lack of direction to protect these habitat elements results in degradation and destruction of late-successional habitat utilized by the fisher.

Our Response: Please see responses to Comments (125) and (166).

(168) Comment: One commenter stressed that existing regulatory mechanisms are inadequate for addressing illegal and egregious trespass marijuana agriculture and associated use of ARs. The commenter noted that State and Federal wildlife officials (law enforcement) currently have few legal or regulatory mechanisms to ensure best management practices for both trespass and cottage industry marijuana growing operations.

Our Response: We agree with the commenter that some existing regulatory mechanisms are not effective in addressing illegal trespass marijuana agriculture and associated use of ARs. By definition, illegal activities are not compliant with regulations. While the draft Species Report indicates that Federal law enforcement agencies have been very successful in eradicating (see for example Figure 19 (Service 2014, p. 156)), and in some cases, remediating illegal marijuana trespass grow sites, the draft Species Report (Service 2014, p. 142) stated that “[t]he primary regulatory issue for rodenticides and fishers is the availability of large quantities of rodenticides that can be purchased under the guise of legal uses, which can then be used illegally in marijuana grows within fisher habitat.” In addition, we do not know how well existing regulatory mechanisms protect fishers from exposure to legal uses of rodenticides (Service 2014, p. 144). However, since we do not have evidence to suggest that fisher populations within the west coast States are exhibiting any significant impacts at either the population or rangewide scales as a consequence of exposure to ARs, we cannot conclude that the inadequacy of regulatory mechanisms to control illegal marijuana grow operations poses a threat to the proposed DPS. In addition, please see our response to Comment (166).

(169) Comment: One commenter requested that the Service strongly consider CDFW’s comments, information, and recommendations in the final decision given that approximately 95 percent of the extant fisher populations are located in California.

Our Response: We have reviewed and considered all comments and information provided, including the information provided by CDFW and we have incorporated relevant information in this document and the final Species Report, where applicable. Our final determination is based upon our thorough consideration of all of the best scientific and commercial information available to us, including the information provided by CDFW.

(170) Comment: One commenter requested that the Service urge the Forest Service and BLM to create and implement forest plan standards for fishers, under section 7(a)(1) of the Act.

Our Response: Section 7(a)(1) of the Act states, in part: “All other Federal agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this Act by carrying out programs for the conservation of endangered species and threatened species listed pursuant to section 4 of this Act.” Section 7(a)(1) applies only to listed species, and we have determined that listing the proposed West Coast DPS of fisher is not warranted (see Determination, above). Therefore, the Act does not require that conservation programs for fishers be implemented. However, we will continue to monitor the status of the fisher in the west coast States through monitoring associated with the various forest and management plans and other conservation efforts that occur within the fisher populations or other unoccupied, suitable habitat areas and provide recommendations to the Forest Service and BLM, as appropriate.

(171) Comment: One commenter stated that the Service should recognize the Oregon Forest Practices Act in the existing regulatory mechanisms section
of the proposed rule but mischaracterized the regulation description and the State’s associated program in the Species Report. Specifically, the commenter asserted that although the Oregon FPA provides for the retention of habitat components that may not be explicitly designed to protect fishers, the protected habitat is the type of late-successional habitat that the Species Report asserts the fisher requires. The commenter also added that the draft Species Report included a “myopic view toward old-growth habitat” by ignoring a large body of science recognizing that fisher thrive in a mosaic of habitat conditions. Finally, the commenter contended that the Oregon FPA is a sophisticated statute that drives a robust and dynamic regulatory environment in Oregon that consistently produces high-quality wildlife habitat on private lands, including habitat suitable to fisher success, and that the draft Species Report’s assertion to the contrary is in error.

Our Response: We disagree with the commenter’s assertion that the Oregon FPA protects the type of late-successional habitat characteristics that fishers require. At the structure-specific scale, the retention of trees and snags as required by the Oregon FPA will not meet the needs of denning fishers based on our understanding of their use of these structures. As an example, minimum diameters for retained snags and green trees under the Oregon FPA are smaller than the inside diameter of hollow trees used by denning females. Furthermore, the smaller green trees that are retained will not have the decay that is required for use by denning females, and there is no requirement to retain these trees on the landscape for the time needed to develop the appropriate size, nor to retain them through multiple harvest rotations to allow sufficient time to develop the degree of rot necessary to form a hollow stem that provides a den site. Thus, while the Oregon FPA requires retention of green trees and snags in harvest areas, these retained trees and snags most likely will not meet the needs of denning females given the minimum size allowed for retention, and the likely loss of these remnants during the next harvest rotation.

While fishers may use a mosaic of habitat conditions for which some level of younger industrial forests may be sufficient at the landscape scale, the Oregon FPA requirements for retaining older forest stands are limited to specific conditions such as no-cut retention buffers around streams and protection of specific wildlife sites.

These retention areas may or may not be late-successional, depending on what forest stand exists at the time they are put in effect. Even if these stands are late-successional, they occur on a substantially small part of the non-Federally managed landscape compared to the heavily managed portion of industrial forest where little structure is likely to occur.

We have stated in the draft Species Report and in the final Species Report that fishers use and even reproduce in managed forest landscapes if there are sufficient amounts and an adequate distribution of key habitat and structural components important to fishers, noting that younger and mid-seral forests may be suitable for fishers if they retain the necessary structural complexity and features. While this habitat could be provided by timber managers on a discretionary basis, as noted above, the minimum size requirements and lack of long-term retention under the Oregon FPA will not necessarily result in meeting the structural habitat needs of fishers.

Our Response: One commenter declared that the draft Species Report is too dismissive of NEPA benefits to fishers. The commenter asserted that NEPA, along with other existing regulatory mechanisms, significantly contributes to the conservation of fisher, which further supports that listing is not warranted. The commenter acknowledged that NEPA does not have substantive requirements, but stated that its procedural requirements often result in carefully designed, agency actions that minimize or mitigate project effects to specific species and resources, including fisher. Further, the commenter asserted that combining the Forest Service’s policy with NEPA requirements makes NEPA an action-forcing statute that guides the agency’s analysis and implementation of all projects that could affect fishers. The commenter referenced the Bybee Vegetation Management project on the Rogue River-Siskiyou National Forest as an example that provides substantial conservation benefit to fishers.

Our Response: We consider NEPA to be an important environmental disclosure statute. Our discussion of NEPA in the draft Species Report, the proposed rule, and this document (see “Existing Regulatory Mechanisms” sections) clearly states that the evaluation of projects under NEPA does not regulate or protect fisher nor does it require or guide potential mitigation for projects. The individual actions analyzed under NEPA are the projects that may or may not benefit species.

Foreseeable Future

Our Response: One commenter noted that in the proposed rule we stated, “we considered 40 years to be a reasonable estimate of the foreseeable future for fisher because it falls within the spectrum of predictions into the future and is supported by habitat model and climate model predictability.” However, the commenter noted that the Service, in both the draft Species Report and the proposed rule, declined to use such models to support conclusions, speculating that the Service’s conclusion was too uncertain to substantially inform the threats evaluation. Similarly, the commenter noted that the draft Species Report acknowledged that habitat ingrowth will occur, but concludes, “While we attempt to quantify habitat loss, we were unable to quantify habitat recruitment or silvicultural treatments that may offset some habitat loss over our 40-year analysis window.” The commenter stated that the draft Species Report made numerous other references to uncertainty in modeling and prediction of ingrowth and basically refuses to account for ingrowth due to this uncertainty. The commenter asserted that the speculative nature and inconsistent treatment of the “foreseeable future” has ramifications throughout the draft Species Report and proposed rule, and suggested that the Service acknowledge the degree of
uncertainty in projecting all stressors across the foreseeable future. Finally, the commenter requested that the Service revise the definition of "foreseeable future" for its final determination to one that is supportable by substantial predictive information.

Our Response: The concept of the "foreseeable future" comes into play under section 3 of the Act in the definition of a threatened species. The Act defines a "threatened species" as any species (or subspecies or, for vertebrates, distinct population segment) that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act does not, however, define the term "foreseeable future." Furthermore, the concept of the foreseeable future is an inherently nebulous construct; there is no mathematical formula capable of providing a quantitative solution to identifying a precise moment in time when the status of the species would transition from threatened status to endangered status.

We interpret foreseeable future as that extent of time over which the Secretary can reasonably rely on predictions about the future in making determinations about the future conservation status of the species. In the context of the definition of a threatened species, the foreseeable future is the period of time over which events can reasonably be anticipated. Our references to "reliable predictions" are not meant to refer to reliability in a statistical sense of confidence or significance; rather, the words "rely" and "reliable" are intended to be used according to their common, non-technical meanings in ordinary usage. In other words, we consider a prediction to be reliable if it is reasonable to depend upon it in making decisions, and if that prediction does not extend past the support of scientific data or reason so as to venture into the realm of speculation. Our approach to defining the general period of time that may be considered to constitute the foreseeable future is in accord with the Department of the Interior Solicitor's opinion on foreseeable future (M-37021, January 16, 2009; p. 9), available on the Internet at https://solicitor.doi.gov/opinions/M-37021.pdf.

As suggested in the Solicitor's opinion for our analysis of the stressors to the proposed West Coast DPS of fisher, we are relying on an evaluation of the foreseeable impacts of those stressors and the foreseeability of the effect of those stressors on the proposed DPS, extending this time period out only so far as we can rely on the data to formulate reliable predictions about the status of the proposed DPS, and not extending so far as to venture into the realm of speculation. In this case, many of the stressors fell into a foreseeable future timeframe within which we concluded the effects of stressors on the proposed DPS could be reliably projected out over a time period of approximately 40 years. For the stressor of climate change, for example, many different models project changes in temperature, precipitation, or other climatic variables over a period of at least 100 years (see "Climate Change" sections of this document and the final Species Report). As described in the final Species Report, the predicted changes in climatic conditions are generally in agreement under the variety of different emissions scenarios considered until mid-century; after that point, the trajectory of projected changes begin to diverge. For this reason, we conclude that we can reasonably rely on predictions regarding future climate changes over a period of roughly 40 years, up to that mid-century point. Similarly, we conclude it is reasonable to predict changes in forest conditions as a result of vegetation management over approximately the same period of time, based on forest planning horizons and time needed to observe changes in forest conditions (see "Vegetation Management" sections of this document and the final Species Report). For these reasons, we conclude 40 years constitutes a reasonable approximation of that period of time over which we can reliably predict the effects of several of the stressors acting on the proposed West Coast DPS or fisher.

We agree that for some stressors we do not have sufficient data to reliably predict effects on fisher populations and that the timeframe of 40 years is the only large-scale vegetation trend analysis available that classified vegetation loss to type of disturbance (i.e., vegetation management activities versus wildfire or some other disturbance type). Our Response: The draft Species Report discusses the timeframe of the overall impact that appears demonstrable, and more carefully analyze the trend in timber harvest into the future, noting the accompanying uncertainty when applicable.

Our Response: The draft Species Report discusses the timeframe of the projected management activity that we were aware of at that time, and because habitat loss has both an immediate and ongoing effect on fisher populations and public and private land management regimes are planned on a multi-decade to 100-year (e.g., Sustained Yield Plans
under the California Forest Practice Rules timescale (Service 2014, p. 50). This 40-year period of time was what we could reasonably rely on for predictions about the future in making determinations about future conservation status of the proposed DPS. We continue to use this timeframe for vegetation management in our final Species Report. For the final Species Report we have changed the approach to reporting scope and severity to qualitative terms (whereas our uncertainty in the draft Species Report was represented as a range of values), our vegetation management analysis in the final Species Report continues to identify areas of uncertainty. Representing scope and severity as qualitative values is a further acknowledgement of this uncertainty. Please also see our responses to Comments (43), (58), (99), (181), and (215).

(176) Comment: Six commenters asserted listing is warranted primarily due to mismanaged forested areas. Three commented stated that logging activities in the Sierra Nevada have stripped large portions of the landscape, large trees, downed logs, and multi-layered canopies that shelter animals, including the fisher, all of which have led to a steep fisher decline. Further, commenters proclaimed that logging has destroyed specific fisher habitats while favoring generalist species such as grey fox and striped skunk, which compete with fishers. One of the commenters proclaimed that habitat is not managed to benefit fishers (especially in the interspersed “checkerboard” areas of Forest Service and private lands) and the Forest Service is over-thinning (as opposed to light thinning from below of smaller trees, which appears to have no effect on fisher). Two of the four commenters also asserted that listing is warranted because fisher sightings are fewer than normal, with one of the commenters further articulating that well-documented studies (no citations) indicate that the logging of late-successional forests on private and Federal lands (referred habitat of fishers) is the chief culprit behind the species’ steep decline, and that managing fisher habitat as if it were spotted owl or wolverine habitat would be good for fishers.

Our Response: Many fisher researchers have suggested that the magnitude and intensity of past timber harvest is one of the primary causes for historical fisher declines across the United States (Douglas and Strickland 1987, p. 132; Powell 1993, pp. 77-80; Powell and Zielinski 1994, p. 41) and is one of the main reasons fishers have not recovered in Washington, Oregon, and portions of California (Aubry and Houston 1992, p. 75; Powell 1993, p. 80; Powell and Zielinski 1994, pp. 39, 64; Lewis and Stinson 1998, p. 27; Truex et al. 1998, p. 59). We note in the final Species Report and in this document (see Vegetation Management above), however, that timber harvest volume has sharply declined throughout the west coast States since 1990, with rates substantially less than that described by most of the above-cited researchers. In the Sierra Nevada there has been a net gain of potentially suitable fisher habitat in recent years (Service 2016, p. 108). Vegetation management is not always detrimental to fisher due to many factors including differences in forest types and land ownership, silvicultural practices, project-specific objectives, and regulatory mechanisms, which vary by State and by Federal agencies. For example, private forests typically are not managed for features of fisher habitat, whereas the loss of intermediate- and high-quality fisher habitat on Federal lands due to management actions has declined substantially (at least within the NWFP area since its implementation) (Kennedy et al. 2012, p. 128). Habitat loss and fragmentation may be compounded by a number of factors, which may include competition for prey and suitable den and rest sites as suggested by the commenter.

We disagree that habitat for fisher should be managed as if it were spotted owl or wolverine habitat. While northern spotted owl and fisher habitat may be similar in some respects, how they use the habitat is different. For example, fisher travel widely within their home ranges while spotted owls are central place foragers (i.e., foraging is restricted to a narrow area associated with a nest or roost structure). Wolverines occupy higher elevation, sub-alpine habitats than fisher; therefore, we do not find the comparison between fisher and wolverine habitat as valid.

Finally, several of the commenters point to the “steep decline” in fishers as evidence of the negative impacts of forest mismanagement. We agree that fishers have been lost throughout much of their historical range, but indications are that these past losses were largely due to threats that are no longer functioning as operative threats on the landscape. In our evaluation of all best scientific and commercial data available to us, we do not have evidence that fishers in the proposed West Coast DPS, although reduced from their past abundance and range, are currently experiencing declines.

(177) Comment: One commenter stated that fishers are not threatened by habitat loss. This commenter spoke of substantial areas of unused habitat throughout its range, which will continue to increase through Federal management, private conservation plans, and forest practice rules. The commenter also stated that not listing the fisher as threatened is further supported by continued presence of fishers in commercial forests. Similarly, another commenter stated that fishers continue to be found in areas that have a long history of timber harvest and road building (and no old-growth).

Our Response: As discussed in our response to Comment (182), past habitat loss is clearly implicated in the historical range contraction of fishers. In addition, any ongoing loss of suitable fisher habitat will act as a stressor on remaining fisher populations. Fishers require forests that provide high canopy cover and complex structure, and forest management actions to provide denning, resting, and foraging opportunities; the continued loss or fragmentation of these forest types is therefore expected to have a negative effect on fisher reproduction and survival. Although the commenters are correct that fishers have on occasion been observed in areas with a long history of timber harvest, our understanding of how fishers respond to forest management is limited given the wide variety of forest treatments that occur, the scales at which fisher response is measured (e.g., at the landscape level versus a den site), and the specific fisher activity being observed (e.g., denning, foraging, travel). Furthermore, there are no data indicating how specific forest management activities may affect demography and long-term persistence of fishers in a given area. Our final Species Report has been updated to incorporate available information with regard to fisher use of managed or commercial forests.

As described in our draft Species Report, a significant amount of moderate- and high-quality habitat remains available but unoccupied by fishers within the analysis area, for example, within the NCSO population (Service 2014, p. 39). According to the results of our habitat model (presented in Appendix A in the draft Species Report), roughly 16 million acres of intermediate- to high-quality fisher habitat is present in the analysis area, and approximately 11 million acres of land are currently under some form of protection (NWFP reserves, National Parks, Southern Sierra Fisher
Conservation Area, etc.; Service 2014, pp. 122–126). Recent information from the NWFP 20-year late-successional and old-growth monitoring report (Davis et al. 20XX, entire) demonstrates that loss of suitable habitat in recent decades (as represented by OGSI–80 forests) has slowed dramatically, particularly on Federal lands, compared to pre-1990 levels (Service 2016, pp. 101–105). As projected, ingrowth is occurring and the NWFP appears to be on track to meet its targets for maintaining or increasing forests in late-successional condition in its reserve areas (Service 2016, pp. 100–102). Suitable habitat in the area of the SSN population has increased (Spencer et al. 2016, pp. 42–44). In addition, Federal, State, and private actions are expected to further contribute to the preservation and management of suitable fisher habitat in the west coast States, although several agreements are still in the preliminary stages, and we have not relied upon them in making our final determination here.

Although some ongoing level of habitat loss and fragmentation is anticipated through vegetation management activities, we have no information to suggest that it will be so great as to result in likely significant impacts to fisher habitat at either the population or rangewide scales. Based upon our evaluation of all the best scientific and commercial data available, in this final determination we have concluded that although past habitat loss was undoubtedly a key factor in the historical declines in range and abundance of the fisher throughout the proposed DPS, it is not currently an operative threat on the proposed West Coast DPS of fisher, nor do we have information to indicate that it is likely to become so within the foreseeable future.

(178) Comment: One commenter stated that when considering the combined amount of private commercial timberlands, NWFP lands, and other public lands with suitable fisher habitat, these areas provide more than enough suitable habitat for the fisher. Furthermore, the commenter stated that the Service’s decision to use northern spotted owl habitat as a surrogate for evaluating stressors to fisher habitat is arbitrary, capricious, and not based on the best available science.

Our Response: Please see our response to Comment (176) regarding our evaluation of habitat loss as a potential threat to the proposed West Coast DPS of fisher. In reaching our conclusion that the proposed West Coast DPS of fisher does not meet the definition of a threatened species, we found that the amount of suitable habitat for fisher is sufficient to maintain viable fisher populations now and in the foreseeable future.

In our final Species Report, additional data were available that allowed us to evaluate the stressor of vegetation management without using northern spotted owl habitat as a surrogate. Our final analysis relies instead on the recently released NWFP 20-year late-successional old-growth monitoring report (Davis et al. 20XX, entire) within the analysis area covered by the NWFP (most of the proposed DPS except the Sierra Nevada and eastern portions of the Oregon and Washington Cascades) and GNN vegetation trend analysis for the remainder of the analysis area.

(179) Comment: Two commenters (including one local government) stated that the Service did not address the adverse effects of mechanical thinning on fishers, when considered at the forest-stand scale. One of these commenters specifically stated that the draft Species Report neglected to show research that demonstrates adverse effects of mechanical thinning on fishers, and that fishers actively avoid thinned areas, citing to the dissertation of Garner (2013). Another commenter cited Truex and Zielinski (2013, entire) as an example of how fisher react negatively to mechanical treatments.

Our Response: We agree with the commenters that the draft Species Report did not specifically address the adverse effects of mechanical thinning in the discussion of forest management techniques that adversely affect fishers. We appreciate receiving the references, as this is new information for us. Although the draft Species Report discussed the possible negative effects of understory treatments in general on fishers, we have updated the final Species Report to specifically address the issue of mechanical thinning and its effect on fishers.

(180) Comment: One commenter asserted that the Forest Service overestimates their managed forests, which causes conditions that are counter to the heavily forested habitat that fishers prefer. Therefore, the commenter asserted that the fisher is most harmed by logging. In addition, the commenter observed that understory thinning does not affect fishers. However, the commenter did not present any new data to support either of these observations.

Our Response: Both our draft and final Species Reports provide a comprehensive discussion of forest management impacts to fishers on public and private lands. We have no evidence, nor did the commenter provide any evidence to support their generalization that the Forest Service thins too heavily to maintain fisher habitat. Our final Species Report discusses the fact that timber harvests focused on restoration are more likely to retain and develop habitat structures important to fishers, and tend to be more prevalent on Federal lands and some other public (e.g., State) lands because of agency missions and regulations (Service 2016, p. 119). Regarding the effects of understory thinning, such effects to fishers can vary greatly by the ecosystem type, the intensity and scale of treatments (Naney et al. 2012, pp. 29–37), and the response of the prey communities being affected by the treatments” (Service 2016, p. 107). Therefore, in general, we do not agree that the commenter’s assertions can be supported as a broad generalization.

(181) Comment: Several commenters stated that ongoing forestry practices on private lands are resulting in conservation for the taxon, especially through fisher habitat improvement, which supports the likelihood that the proposed DPS does not need Federal protection as a threatened species. One commenter articulated that studies in northern California have found fishers using landscapes managed primarily for timber harvest as opposed to fishers exclusively using late-successional forests. Another commenter asserted that landowners can and are managing for fisher habitat without significant economic harm, such as by using forest conservation easements and establishing stream protection zones. Another commenter highlighted Mendocino Redwood Company’s continued work with the Service on an 80-year joint Federal/State multi-species HCP/NCCP as demonstration for private industry conservation efforts. One commenter specifically stated that forest management in Siskiyou County is beneficial, as demonstrated by fishers from this area being used for reintroductions to other areas. Another commenter specifically stated that multiple pieces of evidence exist (e.g., Weaverville study, Green Diamond’s two study areas, SPI Stirling translocation area, and Michigan-California EKSA study) that demonstrate how managed industrial timberlands provide habitat for stable fisher populations. Finally, one commenter stated that, in general, fishers extensively use managed landscapes, and the importance of continuing retention under sustainable forests initiatives/councils contributes to keeping important habitat elements on the landscape.
In contrast, several commenters asserted that private lands forestry practices are having a negative effect on fisher habitat, including the perspective that these forestry practices (primarily clearcutting) are the primary issue impacting fisher habitat. Two of these commenters specifically highlighted impacts in the Sierra Nevada, including one that presented photographs of habitat loss adjacent to Forest Service lands in the central Sierra Nevada area, and two others who discussed clearcutting concerns near Castle Crags State Park/Dunsmuir in California. Another commenter specifically stated that the practice of clearcutting is occurring on some private lands, and combined with herbicide application to prevent understory competition, is causing a lack of diversity with very few animals present in these areas.

**Our Response:** We agree with the commenters from both opposing viewpoints that some ongoing private forestry practices across the proposed West Coast DPS are consistent with fisher conservation, and some are detrimental. Forest conservation easements, multi-species HCPs/NCCPs, sustainable forest initiatives, and working with Federal and State agencies across the proposed West Coast DPS to fund research projects and reintroduction efforts all contribute to fisher conservation on private lands. However, forestry practices such as clearcutting and broad-scale herbicide application remove understory shrubs required by fisher prey species and degrade fisher habitat. Though we are withdrawing our proposal to list the West Coast DPS of fisher as threatened (see Determination, above), we will continue to monitor stressors and work with private landowners to develop management strategies that will allow us to work toward the conservation of fisher throughout the west coast States. See also our responses to Comments (174) and (176).

**Comment:** One tribe asserted that the draft Species Report overemphasizes the importance of late-successional forest to fishers, while a separate commenter stated that fishers are not as reliant on late-successional old-growth forests as the draft Species Report indicates (further stating that fishers use a wider range of habitat than recognized by the Service), suggesting that fishers are not “habitat limited.” The tribe stated that they recognize the importance of older forest stands for rest and den sites (which were found to be important for female fishers in Washington (Lewis 2014)); however, numerous studies have found fishers to use a variety of forest stands including managed forests (citing Klug 1997, Thompson 2008, Sel and Kerns 2001, Aubrey and Raley 2006, Clayton 2013, Lewis 2014 as examples for this comment).

**Our Response:** We agree that fishers in the west coast States rely on a variety of forest types and we have clarified discussion in the final Species Report regarding the fisher’s dependence/needs regarding late-successional forests and managed forests (Service 2016, pp. 15–25). Please see our responses to Comments (28), (37), (39), and (57).

(183) **Comment:** Regarding overall forest management, one commenter requested that the Service address herbicide application as a potential threat to the fisher. The commenter stated that broad (aerial) application can render entire patches of forest unsuitable for fisher and their prey. Additionally, on private lands, removal of deciduous trees and shrubs that favor conifers is likely a larger stressor on fisher habitat than the species report recognizes.

**Our Response:** The draft Species Report addressed herbicide application as an example of a silvicultural or fuels reduction treatment that may reduce the overall complexity of forest understory (Service 2014, p. 109). The effects of understory treatment to fishers can vary greatly by the ecosystem type, the intensity and scale of treatments (Naney et al. 2012, pp. 29–37), and the response of the prey communities being affected by the treatments. We recognize that herbicide application, on a broad scale, may alter the ways in which fishers use landscapes. The final Species Report includes additional discussion on herbicide application and the effects to fisher and their prey.

(184) **Comment:** One commenter, citing Raley et al. (2012), stated that the lack of overarching patterns of selection by fishers for particular forest types or seral stages may be due to differences in management histories among locales and subsequent influences on forest structure. The commenter asserted that the draft Species Report views these differences in management histories as static and fails to consider associated temporal dynamics, particularly with regard to downed large trees and residual trees left post-harvest following early 20th century forest management practices. These remnant woody structures are no longer provided under current management operations, and the commenter suggests that the Service’s analysis failed to take into account the fact that denning areas are no longer provided for fishers under modern even-aged management practices.

**Our Response:** We understand that forest management is not a static process; please see the response to Comment (75) for further discussion in this regard. We do not deny that some legacy structures used by fishers for denning or other activities may be lost in some areas due to timber harvest or other activities. However, there are safeguards in place on many lands to conserve these structures, as described below. In addition, the cavities and other important forest structures used by fishers are not only remnants of earlier forest management, but are also a result of wildfire and other natural disturbances such as forest-related insect and disease outbreaks. These natural events continue to occur within the west coast States. Federal lands are managed for natural resources and sustained yield of forest products under land and resource management plans. The majority of Federal lands within the fisher’s range in the west coast States are within the NWFP boundary and include a network of reserved land use allocations. In addition, both the Federal resource management plans and the NWFP contain standards and guidelines for snag and coarse woody debris retention. Even-aged forest management practices, as mentioned by the commenter, are more common on non-Federal lands. State regulations provide for the retention of some snag and down woody debris as well as other retention areas associated with riparian features, for example (Service 2014, pp. 131–141). While the State regulations do not all specifically address fisher, structurally important elements of fisher habitat will be present, at least minimally, on non-Federal lands. In other words, FPPRs in all three west coast States do not specifically address fishers and their habitat requirements, although some management practices will benefit fisher habitat, particularly in the SSN population area given the state of California’s recent listing of this population as an ESU. Future recruitment of cavities and forest structures used by fisher will occur through natural and non-natural processes within the fisher’s range in the west coast States, though land ownership will likely determine their rate of recruitment and overall abundance.

(185) **Comment:** One commenter requested more information regarding the Service’s assertions that fisher conservation requires extensive late-successional forest conditions and that logging practices generally pose a threat to fishers. The commenter stated that while this may be true for historical
logging practices and at large scale of analysis, a current and accurate status review requires that the Service evaluate all current forest practices, which are vastly improved over historical timber harvest activities.

Our Response: We recognize that fishers use a variety of habitat types and are not limited to late-seral forest types. Please see our response to Comment (57) for additional discussion in this regard. Regarding the potential impacts of past, ongoing, and projected future impacts of vegetation management on the proposed West Coast DPS of fisher, we received a substantial amount of new information in this regard, which is incorporated into our final Species Report. Please see our responses to Comments (176) and (177) regarding our updated assessment of all of the best scientific and commercial data available regarding vegetation management, including logging practices, as a stressor to fisher in the proposed West Coast DPS.

(186) Comment: One commenter stated that it is evident that fisher have expanded their range or become more abundant in the coastal redwood and Douglas-fir forests, noting that much of this area is in managed private timberlands. The commenter referred to recent information from north coastal California collected by their company—Green Diamond Resource Company (Diller et al. 2015, Hamm 2013), which indicates that fisher detection rates or occupancy appear to be stable on their lands. The commenter also referred to data from the Klamath Forest Reservation, which indicates generally stable trends in the population on those tribal lands (Higley et al. 2013). The commenter noted that the draft Species Report acknowledges these studies, and also stated that there is little discussion of the implications of fisher use on managed forests in California and how that information may be useful in predicting suitable sites for reintroduction.

Our Response: We agree that fishers do use managed timberlands, but whether populations can persist long-term (i.e., for several decades) on managed lands is currently unknown. The commenter’s lands (i.e., Green Diamond Resource Company in north coastal California) are surrounded by Federal lands that contain large patches of occupied, high-quality fisher habitat. Therefore, these private lands may contain more fishers than expected for many managed industrial timberlands because the surrounding Federal lands could be a constant source of fishers that may or may not persist on the commenter’s land. The commenter did not present information that suggests fishers can persist over the long term on their lands, nor information on the overall health of the fisher populations that occupy their lands. However, from 2009 to late 2011, fishers were translocated from the NCSS population to unoccupied habitat within the fisher’s historical range in the northern Sierra Nevada and Southern CascadeMountains, within industrial timberlands, and have successfully reproduced (Powell et al. 2014, entire). Population modelling, however, showed that short-term population stability cannot be confirmed before year-10 of the project, or 2020 (Powell et al. 2014, abstract).

(187) Comment: One commenter stated that fishers are abundant on their managed forest lands in north coastal California, based in large part on camera sightings and incidental sightings reported by employees and contractors, the validity of which are determined through conversations between the person that sights the fisher and commenter’s biological staff. The commenter stated that this approach lends credibility and increases the confidence level of the incidental sighting information, although they recognize obvious limitations to the use of incidental sightings. Regardless, the commenter believed the incidental sighting data should be considered because they corroborate the results from rigorous survey methods used throughout the same sighting areas during the same time periods, and further supported that fishers appear to be abundant and thriving within the commenter’s managed timberlands (which are not characterized as late-seral forests).

Our Response: The commenter asserts that fishers are abundant on their lands in north coastal California based in part on incidental sightings by employees and contractors. Incidental fisher sighting data can be used for simple, coarse-scale comparisons made between geographic areas, to guide systematic survey efforts, or for coarse mapping of fisher distribution for internal use by the commenter. Incidental sighting information generally is not used by scientists for mapping species distribution for peer-reviewed literature, and is not used to estimate species abundance. The scientific standard for estimating fisher relative abundance and distribution excludes anecdotal sighting data and only uses verifiable detection data such as physical specimens, photographs, video, tracks, or captures by researchers or trappers. Therefore, we have not used incidental sightings in our evaluation of abundance estimates. Figure 7 in the draft Species Report (Service 2014, p. 31) and final Species Report (Service 2016, p. 34) illustrates fisher occurrence on the commenter’s lands in north coastal California, based on fisher detections of high reliability using the types of verifiable detection information listed above. We have updated our final Species Report, however, to note credible observations reported to us of fishers in forests managed for timber harvest.

(188) Comment: One commenter stated that private industrial and managed State forest lands represent 33 percent of forest land area in the State of Washington. The commenter asserted that much of the State’s forest land within the historical range of the fisher is managed. The commenter also stated that State FPRs govern harvest and include provisions for retention and riparian buffers in Washington, Oregon, and California. However, the commenter questioned why the draft Species Report and proposed rule offered no consideration of habitat recruitment from riparian buffers and leave trees, which are expected to promote habitat connectivity and develop necessary habitat features over time.

Our Response: We did consider the protections offered by the FPRs (and HCP) in Washington, Oregon, and California (Service 2014, pp.103–105, 132–137). We agree that some areas of privately managed forests may provide habitat for at least a portion of the fisher’s life-history needs (i.e., foraging, and possibly denning where legacy trees persist) now or in the future. However, habitat recruitment on private forest lands per the FPRs in Washington does not protect the specific structures associated with late-successional habitat that fishers require, and is unlikely to support an area equivalent to the entire home range of a successfully denning female fisher. At the structure-specific scale, the retention of trees and snags as required by the Washington FPRs will not meet the needs of fishers based on our understanding of fisher use of these structures. As an example, minimum diameters for retained snags and green trees under the Washington FPRs are smaller than the inside diameter of hollow trees used by denning females. Furthermore, the smaller green trees that are retained likely will not have the decay that is required for use by denning females, and there is no requirement to retain these trees on the landscape for the time needed to develop the appropriate size and to allow for the development of rot to the degree that a hollow stem occurs. Thus, while Washington FPRs require the retention of green trees and snags in harvested areas, they most likely will
not meet the needs of denning females given the minimum size allowed for retention.

While fishers may use a mosaic of habitat conditions that some level of younger industrial forests may provide at the landscape scale, the Washington FPR requirements for retaining older forest stands is limited to specific conditions such as no-cut retention buffers around streams and protection of specific wildlife sites. These retention areas may or may not be late-successional, depending on what forest stand exists at the time they are put in effect. Even if these stands are late-successional, or are allowed enough time to become late-successional, they occur on a substantially small part of the landscape compared to the heavily managed portion of industrial forest where little structure is likely to occur. Please see Comment (171) above regarding Oregon FPRs. In addition, the draft Species Report states that the broad objectives of the California FPRs leave uncertainty as to the adequacy of habitat protection for fisher denning, resting, and reproduction (Service 2014, p. 139). Based on these considerations, we could not anticipate a significant amount of habitat recruitment for fishers from riparian buffers and leave trees under State FPRs.

(189) Comment: One commenter asserted that most of the non-Federal forest landscape will likely never regain suitable habitat conditions for fisher, and that logging will reduce stand density, and reduce dead wood abundance and complexity, thus degrading fisher habitat. Additionally, the commenter pointed to recent literature (Aubry et al. 2013) that documents how fishers specifically focus on dead wood for resting sites, which is counter to Federal land’s aggressive prescriptions (“widespread fuel reduction logging” and “shifts from thinning young stands to logging in mature native forests and/or regeneration harvest”) that reduce dead wood recruitment. Therefore, the commenter stressed that listing the fisher under the Act will aid in the appropriate, critical management of Federal lands, especially given the Federal agencies’ recent “push toward more regeneration harvest.”

Our Response: We appreciate the commenter’s views, however, we respectfully disagree that non-Federal lands will never be suitable for fisher in the future. Our final Species Report provides an evaluation of conservation methods and existing regulatory mechanisms on Federal and non-Federal lands (Service 2016, pp. 115–122, 162–189). While there is clearly more potential impact to fisher habitat from timber management practices on non-Federal land, HCPs, CCAAs, and interagency conservation strategies (to the extent these are in effect), for example, include measures that provide for important aspects of fisher life history and habitat needs. We recognize that objectives for timber management on non-Federal lands generally provide fewer protections for fishers. However, management on State and private lands for older-forest or for retention of habitat blocks for other species may facilitate fisher movements across the landscape or provide future habitat as some areas are allowed to develop into older stands.

We do not have information that indicates Federal agencies are implementing more regeneration harvest, and the commenter does not provide references or other sources to support this claim. To the contrary, and as noted in the final Species Report (Service 2016, pp. 60–62), timber harvest levels on Federal lands have dropped substantially over the past two and one half decades (Gale et al. 2012, pp. 4, 10, 11, 17; Kennedy et al. 2012, p. 128; Charnley and Long 2014, pp. 631–632; WDNR 2016, entire). Federal land managers operate under land and resource management plans that guide and set standards for natural resource management including protections for sensitive species such as the fisher. With regard to concerns about the recruitment of dead wood on Federal lands, please see our response to Comment (190) above.

(190) Comment: One commenter disagreed with our statement in the draft Species Report (Service 2014, p. 87) that the fisher analysis area habitat model was used “as a reference point from which to evaluate current habitat conditions across the analysis area and estimate the future losses due to ongoing vegetation management activities.” The commenter asserted that this is only partially true and that the backbone of the analysis is based on using “several other sources of information” in the evaluation of the scope and severity of vegetation management because there are no available data sources tracking changes specific to fisher habitat across the analysis area.

Our Response: The commenter is correct. The habitat model was used as a reference point from which to evaluate current habitat conditions across the analysis area; however, it was not used in our analysis of habitat loss from vegetation management. The final Species Report has been corrected to reflect this point.
One commenter asserted that such relocations could result in the permanent removal of fisher denning habitat, increased fragmentation, and increased mortality risk from vehicle collisions.

**Our Response:** The commenter appears to be referring to the Last Chance Grade project proposed by the California Department of Transportation (Caltrans), which would reroute U.S. Route 101 from the coastline into more interior areas within State and National redwood parks that contain habitat suitable for resting and denning fishers. The Service agrees with the commenter that the Last Chance Grade project would result in the permanent loss of suitable fisher habitat and, like all roads, would increase habitat fragmentation and potentially increase fisher mortality rates from vehicle collisions. Notably, all of the Last Chance Grade bypass routes are primarily 2-lane road segments unlike the existing 4-lane Prairie Creek Bypass to the south on U.S. Route 101 (referred to by the commenter). Therefore, the amount of suitable fisher habitat removed would be reduced and the probability of roadkill mortality would likely be lower on the relocated sections compared to the existing 4-lane Prairie Creek Bypass. We will be working with Caltrans to avoid and minimize potential impacts to the fisher and suitable fisher habitat from the Last Chance Grade project, regardless of the fisher’s Federal status.

(194) **Comment:** One commenter stated that the proposed rule significantly overstates the contribution of logging to forest fragmentation. The commenter explained that fishers frequently use managed landscapes, and the draft Species Report’s assertion that fragmentation due to timber harvest can last more than 80 years is in error and is not supported by literature (citing Lewis and Stinson 1998, and Klug 1997). The commenter also stated that even if logging creates a short time-window during which fisher prefer other lands, individual harvest units are not so large as to negatively affect fisher, in part because (a) Fisher female and male home ranges are approximately 38 times and 108 times the maximum legal clear-cut size in Oregon, respectively; and (b) fishers are highly mobile, and fragmentation created by logging in compliance with modern forest practice rules is unlikely to have a material effect on the species’ continued survival. The commenter stressed that this assumption is substantiated by Lewis and Stinson (1998) and Klug (1997).

**Our Response:** We agree that fishers use managed landscapes; we discussed this fact in the draft Species Report (Service 2014, pp. 15, 17, 56, 88), and provide an expanded discussion based on new information received in this regard in our final Species Report (Service 2016, pp. 19–21). We evaluated all of this new information, in addition to all information already in our files (including Lewis and Stinson 1998 and Klug 1997), in our final determination for the proposed West Coast DPS of fisher. As stated in the draft Species Report (Service 2014, p. 55), fragmentation from timber harvest or fire (depending on harvest method, fire intensity, and site potential) ranges in time, from one fisher lifetime (about 10 years) after low-intensity disturbances in forested systems that regenerate quickly, to more than 80 years in the drier areas of California and southern Oregon (Agee 1991, p. 32; Franklin and Spies 1991b, p. 108). While we understand the points made by the commenter, the types of forest and spatial arrangement of clear cut units plays a large role in how fishers may use fragmented landscapes. In the redwood region, growing conditions are more conducive to quicker vegetative ingrowth than conditions in drier forests. Similarly, the topography and spatial arrangement of an area may influence the degree to which fragmentation affects fisher. For example, there may be fewer clear cuts in steeper topography, resulting in less overall fragmentation and lesser impacts to fisher movement. Our 80-year estimate is derived from the literature, and refers to the transition age from young to mature forest (Franklin and Spies 1991b, pp. 91, 108; Davis et al. 2015, p. 16) and as an estimate of the time it takes forests to exhibit important structural features for fisher habitat following fire or other natural disturbances. However, neither of these time frames can be applied ubiquitously across the entire fisher’s range in the western conterminous fisher habitat regeneration time after clear cutting. Therefore, we disagree with the commenter that a definitive statement can be made about the length of time it takes to regenerate fisher habitat across the entire proposed West Coast DPS of fisher’s range. Furthermore, we disagree that a definitive statement can be made that negative effects caused by fragmentation are ameliorated by fishers’ mobility and home range size. See additional discussion on this topic in our response to Comments (59), (176), and (177), above.

(195) **Comment:** One commenter asserted that we should rely on the Zielinski et al. (2010) model to ensure correct classification of fisher habitat as opposed to the Carroll et al. (1999) model, which they believe overstates the level of habitat fragmentation and isolation that the fisher may be experiencing.

**Our Response:** We appreciate this comment and suggestion. We received numerous comments on habitat modeling. Please see our responses to Comments (60) through (73), above, and (219) through (227), below, for more information in this regard. The analysis of habitat fragmentation and isolation within the proposed West Coast DPS of fisher is based on numerous pieces of literature (e.g., Service 2016, pp. 58–62) and is not limited to those specific to habitat models. We have reviewed the references suggested by the commenter and taken that information into consideration in our final analysis.

(196) **Comment:** One commenter stated that fisher habitat has been fragmented due to logging, highways, and urban/industrial development. The commenter reasoned that this, in combination with a high male mortality rate due to rodenticide toxicosis, will make it difficult for fishers to find mates and reproduce.

**Our Response:** We agree with the commenter that some fisher habitat has been fragmented by roadways, logging, and urban or industrial development. We also agree that there has been mortality associated with ARs. However, our analysis of the best available scientific and commercial information does not indicate that there is a decline in the populations of fisher across the landscape as a result of these stressors such that they meet the definition of an endangered or threatened species pursuant to the Act (see Determination, above). The best available information does not support the assertion that fishers are having difficulty finding mates to reproduce because of habitat fragmentation or the toxic effects of rodenticides.
Fuels Treatments

(197) Comment: One Federal commenter and one local government noted that fuels treatments on public lands were not examined in the draft Species Report. Further, they articulated that strategic fuels treatments are necessary to return stands to their historical condition, which will benefit the conservation of fisher habitat within California, particularly in high fire hazard areas on Forest Service lands, or other lands that are currently overstocked with trees and consequently drawing too much groundwater.

Our Response: We briefly discussed fuels treatments under the “Current Vegetation Management” stressor and “Summary of Effects of Habitat Stressors” in the draft Species Report (Service 2014, pp. 85–96, 108–110), and have added a section specific to Fuels Reduction Treatments in the final Species Report. As we note in these sections, vegetation management is a broad term that encompasses many types of activities that impact fisher habitat. Fuels treatments are an example of vegetation management. We did not differentiate fuel treatments by land ownership for the same reason that we did not differentiate the different types of vegetation management activities, because data were not available to differentiate acres of those specific treatment types across the proposed DPS.

We recognize that fuels treatments, when appropriately applied, may reduce habitat quality at the local scale in the short term to facilitate reducing the scale and severity of future fires in the landscape. We have added a section to our final Species Report titled Conservation Measures That May Reduce Impacts of Fire Effects that discusses some of the key fuels reduction programs being implemented on public lands within the analysis area.

An analysis of impacts to groundwater from fuels treatments is outside the scope of this action.

(198) Comment: Many commenters opposed a final rule that weakens the Endangered Species Act protections for the fisher in favor of “fisher-friendly forestry.” One commenter stated that not listing the fisher would result in the Service lessening the obligation of the ESA upon industries that degrade habitat in pursuit of a greater profit margin.

Our Response: Section 4 of the Act requires that we make a decision as to whether a species warrants listing based solely on the basis of the best available scientific and commercial data information (emphasis ours). We cannot consider the potential political, social, or economic ramifications of a listing in our final determination. Consistent with our statutory standard, based solely on our assessment of the best scientific and commercial data available, we have concluded that the proposed DPS does not meet the definition of an endangered or threatened species throughout all or a significant portion of its range; therefore, we are withdrawing the proposed rule to list the West Coast DPS of fisher (see Determination, above). Our decision should not be construed as lessening the need to conserve fishers in the west coast States and their habitat. We intend to continue monitoring fisher populations and managing for their conservation, in partnership with other Federal, State, and private entities in the States of Washington, Oregon, and California.

(199) Comment: Two commenters emphasized the benefits of fuels treatments (one commenter provided research information showing that fishers can tolerate some level of fuel treatment activity). One of these commenters specified that the benefits of fuels treatments in reducing the risk of destructive wildfire outweighs the short-term negative effects to habitat of reductions in canopy cover and numbers of downed logs and snags. A third commenter stated that logging has been stemmed, fires have been suppressed, and lawsuits have prevented implementation of necessary fuel treatments. One of these commenters also voiced that fuel treatments should be addressed “first, before focusing on any particular species.” Should the Service list the proposed West Coast DPS of fisher, one of the commenters expressed trepidation that associated regulations would impose new restrictions on the Forest Service’s ability to carry out fuel treatments on ridgetops.

Our Response: We understand the concerns and frustrations of the commenters and recognize that fuels treatments may have beneficial effects to fishers (see our responses to Comments (44), (45), and (197), above). We are not entirely certain what the commenter means by focusing on fuels treatments prior to any particular species. If the commenter is suggesting that we need to remedy the situation between logging, wildfire suppression, and litigation prior to evaluating a species for listing, then that is outside the scope of the current action and the process by which the Service reviews species for listing under the Act.

Genetics

(200) Comment: One public commenter and one Federal agency indicated that reconnecting the SSN and NCSO populations may not be important, as suggested by recent research that says these two populations are genetically distinct. The Federal agency also suggested that the two populations could be managed separately as long as the SSN population is independently viable.

Our Response: We appreciate the concerns expressed by the commenter and Federal agency; however, the question of whether or not to try to connect the SSN population to the NCSO population is a management issue beyond the scope of this listing determination.

(201) Comment: One commenter asserted that the Service should describe the NCSO and SSN population size and isolation separately because there is no information in the draft Species Report to support the NCSO population being genetically isolated or contracting.

Our Response: We are unsure as to what further distinction the commenter is asking for, as we discuss the NCSO and SSN populations separately throughout the entirety of the draft Species Report, as well as in our final Species Report. See also our response to Comment (242).

(202) Comment: Two commenters disagreed with our characterization of the SOC population as being reintroduced because the source population was not west coast fishers. The commenters asserted that this population comprises fishers that are descendants of fishers introduced from Minnesota and British Columbia and, therefore, have genetic stock that is not native to Oregon or California. To further the conservation and ensure recovery of fishers in the west coast States, the commenters suggested that a recovery team evaluate and propose how to contend with this subpopulation, with a recognition that further genetic research may be necessary.

Our Response: Per section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher, and we have determined that the threats we identified in the proposed rule are not now, and will not in the foreseeable future, act on the species in such a way that the fisher meets the definition of an endangered or a threatened species. Consequently, we
are withdrawing our proposal to list this DPS (see Determination, above). We understand the point made by the commenter. The genetic distinctions between the SOC and NCSO populations will continue to be considered as we move forward with their management, regardless of Federal listing status.

(203) Comment: One commenter expressed concern regarding the idea that the Klamath River or the Klamath River Highway could potentially serve as a barrier to dispersal. The commenter noted that Farber and Schwartz (2007) did not find that fishers north of the Klamath River were genetically different from fishers to the south.

Our Response: We stated in the draft Species Report that there is information from one study in northern California indicating that fishers have crossed both the Klamath River and a two-line paved highway to interact with fishers on the other side of these features, thus maintaining genetically homogenous populations on either side of these features (Farber and Schwartz 2007, Tab 6)" (Service 2014, p. 100). We presume that the commenter misinterpreted information in the draft Species Report, which indicates the Klamath River and Klamath River Highway do not serve as barriers to dispersal.

(204) Comment: One commenter stated that the Olympic Peninsula is not a unique population, and suggested that this population does not meet the criterion for significance in the Service’s 1996 DPS policy. Specifically, the commenter asserted that the genetic stock was not unique on the Olympic Peninsula when it was introduced to the area and that the stock exists from the fisher’s origin in Canada.

Our Response: We did not assess whether the fisher population on the Olympic Peninsula, if analyzed alone, would or would not be significant as defined in our 1996 DPS policy. The subject of the present evaluation is the proposed West Coast fisher DPS, as delineated in 2004 (April 8, 2004; 69 FR 18770). The reintroduced Olympic Peninsula population falls within the boundaries of this proposed DPS, and we do not disagree that the Olympic Peninsula fisher population has a genetic origin from British Columbia. However, this fact has no bearing on our conclusion that the proposed West Coast DPS of fisher does not meet the Act’s definition of an endangered or threatened species throughout all or a significant portion of its range (see Determination and Significant Portion of the Range, above).

Habitat

(205) Comment: One Federal agency commented that our characterization of available habitat for the SSN population was incorrect. Specifically, the agency stated that habitat amount and distribution are not a limiting factor because there is unoccupied habitat north of the Merced River and that demographic factors are likely preventing fishers from expanding into that available habitat.

Our Response: Sampling and modeling efforts have not detected significant increasing or decreasing trends for fisher in the SSN population (Sweitzer et al. 2015a, p. 785). The fisher in the SSN population appears to be limited by available habitat throughout a majority of its range. The exception is the region north of the Merced River, which at present is unoccupied (Service 2016, pp. 40, 48–50). It is not known why fisher have not colonized into their former range north of the Merced River in Yosemite National Park. Lack of sufficient recruitment (demography) for the population to expand may be a factor (Sweitzer et al. 2015a, p. 785). The short juvenile dispersal distances documented for the species may also be a factor (Service 2016, pp. 13–14). A s noted in our final Species Report, new information suggests that potential suitable habitat is increasing in the SSN population area (Sweitzer et al. 2016, pp. 42–44). Based upon our evaluation of all of the best scientific and commercial data available, we have concluded that the availability of suitable habitat is not a limiting factor for the proposed West Coast DPS of fisher (see Summary of Factors Affecting the Species, above).

(206) Comment: The State of Washington agreed that there are significant portions of the fisher’s historical range in Washington that contain large areas of contiguous high-quality habitat, most notably the National Forests and National Parks on the Olympic Peninsula and in the Cascade Mountain Range. While these areas are only part of the fisher’s historical range, the State considered these areas as adequate to support self-sustaining fisher populations in Washington, and suggested that restoring fishers to these areas would constitute substantial recovery of the species. The State mentioned that there are other areas that were part of the historical range (much of the Puget Sound) that could no longer support fisher populations and portions of the historical range (southwest Washington, south of Grays Harbor and the Chehalis River, and west of Interstate 5) where fisher populations could be restored if forest management targeted the development of habitats that support reproductive females (see Lewis 2014). The State also articulated that the maintenance of southwest Washington as managed timberland (as opposed to urban or agricultural areas, for example) allows for land management actions (e.g., longer rotations, increased production of large snags and down logs, protection cavity trees, designation and protection of reserve areas and habitat corridors of older forests) that can improve habitat conditions for fishers and support fisher population expansion into these areas.

Our Response: As noted in our evaluation of habitat-related stressors in this document (see Summary of Factors Affecting the Species, above), based upon our evaluation of all of the best scientific and commercial data available, we have concluded that the availability of suitable habitat is not a limiting factor for the proposed West Coast DPS of fisher.

(207) Comment: One commenter stated that the draft Species Report implies that retained vegetation is not valuable unless it is retained in perpetuity, which is a position not supported in the literature. The commenter continued by stating that the report acknowledges protection requirements for northern spotted owls, bald eagles, and great blue herons, but discounts their contribution to fisher success with the statement, “[W]ith the exception of the no-cut riparian buffer, these are not intended to be retained long-term. Furthermore, these areas, at best, would only provide individual structures and small pockets of habitat in a landscape that is otherwise typically managed for industrial timber harvest with short rotations and limited opportunity to grow into suitable fisher habitat.” The commenter asserted that the Service’s statement mischaracterizes both the magnitude of the retained habitat and its importance to fisher. Finally, the commenter explained that landowners must retain a 70-ac (28.3-ha) core of habitat in a buffer around northern spotted owl nests, a 330-ft (100.6-m) buffer around bald eagle nests, and a 300-ft (91-m) buffer around great blue heron nests, all of which remain in place for the length of time the nests are being used by the protected species and coincidentally provide potential fisher habitat.

Our Response: We respectfully disagree with the commenter’s perception that we mischaracterized the importance of habitat to fisher. When any of the nests of the species mentioned are no longer active,
there are no longer protections for that habitat under the FPRs (e.g., Oregon FPRs, OAR 629–665–0010). Therefore, these areas may be subject to future vegetation management, including harvest and removal of habitat suitable for fishers. Further, while we recognize that forests are dynamic, the current management regimen on much of the industrial forest land base precludes the likely development of these types of patches once they are lost. Finally, given that a female fisher’s home range averages 18.8 km² (7.3 mi²), the size of these patches of potential fisher habitat are clearly not sufficient on their own to sustain fisher life-history needs (Service 2014, pp. 11, 135). Therefore, we maintain our position that such small areas protected for the benefit of these other species would result in little benefit to fishers in terms of protecting the structures and large areas of habitat they require, although, depending on the surrounding landscape and the configuration of these patches, they may facilitate movement of fishers between more suitable habitat patches.

Our Response: We assume the commenter’s statement about “high canopy” refers to the height to live crown distance, and not that the actual percent canopy cover was high. Generally speaking, fisher avoid non-forested habitats as they are more susceptible to predation when there is a lack of hiding cover; this is not to say, however, that fisher may not be observed in such areas on occasion. An abundance of coarse woody debris, boulders, shrub cover, or subterranean lava tubes sometimes provide suitable overhead cover in non-forested or otherwise open areas for daily movements, seasonal movements by males, and juvenile dispersal (Buskirk and Powell 1994, p. 293; Powell et al. 2003, p. 641). We received many comments regarding our perceived overemphasis on fisher use of late-successional forests; please also see our response to Comment (57), above regarding fisher use of multiple forest types.

(209) Comment: One commenter asserted that their observations of fisher have not been in “classic old-growth of late-successional reserves,” and noted that canopy closure is important but other factors are at play.

Our Response: We acknowledge that fisher are known to use a variety of forest types if they are structurally complex and have relatively high canopy cover. As described in our final Species Report, multiple studies have independently and consistently identified high canopy cover as one of the most important variables associated with fisher occupancy (Service 2016, pp. 65, 68, 77, 86, 89). The commenter did not articulate what the “other factors at play” are so we are not able to provide further response in that regard. Please also see our response to Comment (57), above.

(209) Comment: One commenter asserted that fisher have been detected at open sites (i.e., water holes with no trees in sight, or areas that burned 40–50 years ago with high canopy) as opposed to just heavily forested areas. Relatedly, two additional commenters stated that the Service overemphasized the importance of the late-seral stage of forested areas when describing fisher habitat in the draft Species Report and proposed rule. A fourth commenter stated they detected fishers in areas with little late-successional habitat but complex structures and a variety of seral stages, thus highlighting why the Service should emphasize that fisher use a wide variety of habitats when complex forest structures are present.

Our Response: Our draft Species Report identified habitat loss as the result of one or more stressors to fisher, and acknowledged that the scope and severity of habitat-related stressors differ across the analysis area, as noted by the commenters. Habitat loss and fragmentation may be compounded by a number of factors, which may include competition for prey and suitable den and rest sites. Habitat components important to a fisher’s use of stands and the landscape can be identified broadly as structural elements (for example, snags, down wood, live trees with cavities, and mistletoe brooms), overstory cover (dominant, co-dominant, and intermediate trees), understory cover (vertical and horizontal diversity), and vegetation diversity (floristic species) (Lofroth et al. 2010, pp. 119–121). Both the draft and final Species Reports provide an appropriate emphasis on the importance of structural elements of fisher habitat in our discussions of fisher biology and our assessment of stressors.

While both the draft and final Species Reports document past and ongoing activities that contribute to habitat loss for fisher, we agree that there are large areas of apparently suitable but unoccupied habitat for fisher across
most of the proposed West Coast DPS, although to a greater extent in the northern portion of the proposed DPS’s range. The current distribution of fisher, based on the best available scientific and commercial information, is noticeably less than its historical distribution (Service 2014, p. 25, Figure 5). However, evidence suggests that a number of factors, not limited to relative habitat abundance, may explain why fisher are not known to fully occupy its historical range (e.g., other historical stressors such as past trapping and intentional poisoning) (Service 2014, pp. 39–40; please also see our response to Comment (40) regarding historical trapping and distribution of fisher and fisher habitat, as well as our responses to Comments (176) and (177).

Regarding reduced timber activity since implementation of the NWFP, we note in our final Species Report the overall decline in timber harvest throughout the proposed DPS, not just the NWFP area, since 1990, acknowledging that the high rates of timber harvests that historically affected fishers has dramatically declined. However, we wish to clarify timber management is not limited to Matrix land use allocations under the NWFP. Timber management may occur within Riparian Reserves and late-successional reserves when it is consistent with Aquatic Conservation Strategy objectives and for the development and conservation of late-successional conditions, respectively.

We received multiple comments on fisher use of managed forests and have addressed this in our final Species Report (see our response to Comments (57) and (217)). We also received multiple comments on the recruitment of fisher habitat on Federal and non-Federal lands, and the extent to which regulatory mechanisms may provide for fisher habitat. We agree that many of the current management plans in place (e.g., NWFP, SNFPA) will contribute to the protection and further recruitment of additional suitable habitat for fisher within the west coast States, and have expanded this discussion in the “Vegetation Management” section of our final Species Report. Please see our responses to Comments (38), (42), (75), and (229). We have ultimately determined that stressors resulting in habitat loss do not pose a threat to the proposed DPS.

(211) Comment: One commenter requested that we address the need for field verification of snag retention in the final rule because “structural habitat components are likely missing or at a lower density than required within habitats that are part of greater planning efforts.”

Our Response: Snags, in addition to other structural elements, are key components of fisher habitat that are used for denning and resting. The final Species Report cites multiple references demonstrating the importance of these features. Field verification of snag retention could be important to determining the potential for denning or resting areas by fisher, but certainly should not be the only factor used to determine habitat suitability. That being said, it is important to understand that we cannot require Federal land management agencies or non-Federal land managers to field verify whether their own regulations are or are not being met.

(212) Comment: One commenter expressed concern that the Service did not adequately discuss the quality of fisher habitat on NPS lands. The commenter stated that the Service should more carefully evaluate the potential suitability of NPS lands as fisher habitat to better understand the severity (or lack thereof) of habitat as a stressor given NPS’s focus on conservation and preservation.

Our Response: NPS lands account for a relatively small portion of the proposed West Coast DPS, approximately 4.53 percent of the area (Service 2014, p. 239). Of the NPS lands within the proposed DPS, approximately 36.5 percent were modeled as intermediate- and high-quality habitat (Service 2014, p. 239). While this may appear to be a relatively low percentage given their natural resource management objectives, much of the National Park Service ownership in the analysis area is classified as alpine and above the elevations expected to provide habitat for fishers. The draft Species Report discussed the contribution of NPS lands to fisher habitat and stressors potentially present on those lands (see Service 2014, pp. 125–126, 239, and Appendix A). Similarly, our discussion of stressors potentially acting on fisher by subregion considers all lands within that subregion, including NPS lands.

(213) Comment: One commenter asserted that the Service’s analysis of habitat-related stressors was significantly overestimated. The commenter stated that the analysis: (1) Did not use a habitat layer representing the total amount of fisher suitable habitat (as described in the “Habitat Association” section of the draft Species Report (Service 2014, pp. 13–18)); (2) used spotted owl habitat as a surrogate for fisher habitat; and (3) overstated the amount of fisher habitat that would be lost or rendered significantly less suitable for fisher use due to the habitat-related stressors; and (4) arbitrarily assigned a 60–80 percent severity index to current management activities on Federal lands.

Our Response: In response to the commenter’s first point, we used the best available scientific and commercial information to develop a seamless habitat model to approximate habitat conditions within the proposed West Coast DPS of fisher. We encourage the commenter to read the white paper describing how the habitat model was developed (Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, which is available as Appendix B in the final Species Report). Additionally, please see our other responses to habitat model Comments (60) through (73), and (219) through (227).

We received numerous comments regarding our use of northern spotted owl habitat as a surrogate for fisher habitat and our assessment of the habitat loss stressor. We were able to utilize other datasets for our analysis in the final Species Report, and did not use northern spotted owl habitat as a surrogate; please see our responses to comments related to northern spotted owl habitat as a surrogate (Comments (79), (80), (233) through (235)).

We received numerous comments on our quantitative calculations of scope and severity of stressors potentially impacting the proposed West Coast DPS of fisher (see explanation in Summary of Basis for This Withdrawal and Determination sections, above). In response to those comments, we no longer rely on quantifying stressors in our final Species Report, as in many cases they required extrapolations where specific data were not available, and may have implied a false sense of precision in our assessment. In our final Species Report, we instead provide a qualitative categorization of stressors to better explain the degree of impact a stressor may have on fishers or their habitat (Service 2016, pp. 57–58). Our assessment of the severity and scope of stressors from the draft Species Report is preserved in Appendix C of the final Species Report.

(214) Comment: Two commenters asserted that fishers have been detected in areas consisting of ponderosa pine plantations, scattered pine Douglas-fir and white fir remnants, and scarce hardwood habitat areas. A second commenter also stated that fishers have been detected in 15–20-year-old plantations. The commenters concluded that fishers use a wider variety of...
habitats than those described in the Species Report.

Our Response: The draft Species Report reported fisher use of a wide variety of habitat types including managed landscapes and stands that are not mature or late-successional (Service 2014, pp. 13–18). We did receive additional information in this regard, however, and have revised and expanded our discussion of this topic in the final Species Report (Service 2016, pp. 15–21).

(215) Comment: One commenter stated that the draft Species Report and proposed rule assessment of the potential impacts of vegetation management is flawed in several ways, including failure to clearly describe and incorporate the results of habitat modeling, failure to discriminate between effects in occupied versus unoccupied portions of the analysis area, failure to evaluate potential ingrowth of habitat, and failure to rigorously assess the potential amount of vegetation management in the future.

Our Response: The draft Species Report (Service 2014, pp. 18–19) provides an overview of habitat models we reviewed, and how and why we developed our own habitat model. We developed a white paper to provide additional information on the development of the model (see Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, available as Appendix B in the final Species Report). Please also see our responses to comments related to the Habitat Model.

We based our assessment of future vegetation management upon the best available scientific and commercial information. As described in the draft Species Report, we considered habitat information completed by others and we used harvest rates over the past 10 years to provide reasonable projections of ongoing and future vegetation management (Service 2014, pp. 85–96). We also acknowledged that there is much variation in harvest rates by landowner and forest type, which lead to assumptions about the scope and severity of future vegetation management (Service 2014, pp. 92–95).

In our final Species Report, in response to peer review, public comment, and new information received during the comment period, we have again evaluated the potential impacts of vegetation management throughout the proposed West Coast DPS of fisher. New data that became available to us allowed us to estimate habitat recruitment throughout the analysis area, and address many of the concerns expressed by the commenter. Please also see our responses to Comments (75), (229), and (230). Finally, we received numerous comments on our quantitative calculations of scope and severity of stressors potentially impacting the proposed West Coast DPS of fisher in our draft Species Report. In response to those comments, we no longer rely on such quantitative assessments in our final Species Report as they implied a false sense of precision in our assessment. For this reason, in our final Species Report we provide a qualitative assessment of stressors to better explain the degree of impact a stressor may have on fishers and/or their habitat.

(216) Comment: One commenter asserted that fisher recovery depends on protection of habitat connectivity to facilitate genetic exchange. The commenter stated that there is a lack of exchange between Oregon’s Siskiyou Mountains and the introduced populations in the southern Oregon Cascades, suggesting there is not enough suitable habitat to facilitate dispersal. Likewise, the commenter stated that there is no exchange between the northern California population and SSN population. The commenter provided several suggestions for areas in need of habitat connectivity/corridors to facilitate genetic exchange, both within populations (e.g., Southern Sierra Nevada) and between populations (Southern Cascades up to the introduced population in the Olympics).

Our Response: Contrary to the commenter’s statement, there is evidence of individuals from the NCSO population occurring in the same geographic area as SOC individuals. Recent and ongoing camera surveys have and are informing our understanding of the distribution of these two populations. There is mixed opinion on the degree to which genetic exchange should occur between the NCSO population and either the SSN or the SOC populations, both of which are genetically distinct and have been separated from the NCSO population. We will be considering the value and risks of genetic exchange and genetic isolation among these populations as we move forward with their management. See also our response to Comment (136).

(217) Comment: One commenter stated that the scope and severity analysis for habitat significantly overstated the past and future effects of habitat destruction, modification, or curtailment. The commenter asserted that the common thread for fisher habitat association is diversity; fishers need diversity of successional stages and forest structures to provide for varied life functions, whereas the draft Species Report and proposed rule overemphasized fisher reliance on older forests. The commenter acknowledged that fishers need some older forest stages for den sites, but a full range of successional stages and forest structures for their prey base, and that these varied habitat structures should be arranged in a mosaic across the landscape in areas sufficient to support fisher home ranges. In a similar vein, one Federal agency offered the Ashland watershed study area of the Rogue River-Siskiyou National Forest as an example of an area where fishers use a wide variety of habitats, although denning activity is constricted to where denning habitat, characterized by the presence of suitable denning structures (snags, hardwoods), occurs. The Federal agency suggested that this denning habitat is one of the key limiting factors for fisher.

Our Response: Please see our responses to Comments (28) and (57). We have ultimately determined that stressors resulting in habitat loss do not pose a threat to the proposed DPS. Per section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of fisher and are withdrawing our proposal to list this DPS (see Determination, above).

Habitat Conservation Plans (HCPs)

(218) Comment: One commenter stated that the Service must make it a priority for the conservation of fishers in the west coast States to provide resources and action to assist Green Diamond in completing the Forest HCP in a timeframe that rewards Green Diamond for more than 20 years of investments in conservation, making it one of the best private land conservation partners in the history of implementing the Act. The commenter also stated that not supporting Green Diamond (either intentionally or by neglect) would appear as a punishment given their management of timberlands to provide a healthy population of fishers. The commenter stated that without a Forest HCP in place, it will become a liability if the fisher is listed and Green Diamond has no incidental take permit coverage for fishers.

Our Response: We commend the dedication of Green Diamond for the conservation of fisher and other natural resources on its land holdings. While we are withdrawing the proposed rule to list the DPS under the Act (see Determination, above), this decision does not mean that no conservation actions are needed for fisher and its habitat within the west coast States. Rather, we acknowledge stressors acting
on fisher and its habitat will continue now and into the future, and will still require management by all interested parties, including Federal, State, and private entities. We will continue to work with Green Diamond and other landowners and managers for the conservation of fisher.

Habitat Model

(219) Comment: One Federal agency stated that the habitat model did not accurately identify a substantial amount of suitable habitat available in Crater Lake National Park that could be important for the recovery of the fisher, particularly in light of concerns related to climate change that may reduce fisher habitat into the future. Although the map included in the draft Species Report suggests that nearly 90 percent of the Park is not considered fisher habitat, the Federal agency (National Park Service) claimed that they have information (from both observations and collared fishers) indicating the presence of fishers in areas the model describes as “selected against.” In addition, the Federal commenter stated that two of three fisher sightings in the Park were in winter, suggesting fisher utilize habitat in the park year-round.

Our Response: Fisher use of areas that receive high amounts of annual snowfall, such as Crater Lake National Park, is variable across the range of the species (Service 2014, p. 14). The two fishers detected in the Park in winter represent a small sample size and do not provide a statistically viable dataset. While the detections may demonstrate use of an area that often receives high snowfall, the best available scientific and commercial information does not provide sufficient information to determine if these observations are typical or are anomalies. We also note that relatively few of the fisher detection locations provided to us were in areas classified as “selected against.” The habitat model for Crater Lake National Park was fitted using reliable fisher detection locations collected within and near the park, as well as other reliable fisher detection locations from the Klamath and Southern Cascades regions. However, much of the area of the park was classified as habitat that, at the landscape scale, fishers would be likely to select against. If this classification is correct, it does not mean that fishers would never travel through such a landscape, but rather that fishers would generally use landscapes like these at a much lower rate than would be expected if fishers used all types of landscapes in proportion to the availability of each type of landscape. It is also possible that any future revisions of the model might benefit from a refinement of the modeling regions so that fisher habitat use in the Southern Cascades might be examined separately. However, given the small number of fishers known to use landscapes categorized as “selected against” by the habitat model, we do not anticipate that any such refinement would alter our conclusions about the status of the proposed West Coast DPS of fisher.

(220) Comment: The State of Washington claimed that the habitat model used by the Service overestimates the amount and extent of high-quality habitat in southwestern Washington (south of State Highways 8 and 12 and west of Interstate 5), and the western coastal portion of the Olympic Peninsula. The State articulated that these landscapes are dominated by early-seral and young mid-seral stands, and are unlikely to provide sufficient high-quality habitat to support reproductive females. The State also asserted that the habitat model used for the fisher analysis underrepresents the extent of high-quality or moderate-quality habitat in the Washington Cascades, in particular at higher elevations and on the east side. The State declared that these comments regarding the accurate representation of the Service’s model are based on the findings of the habitat analysis provided by Lewis and Hayes (2004), and the resource selection findings presented by Lewis (2014, chapter 3). If the model is used for the final rule, the State requested that more details are provided for readers that describe how the model was developed and what measures were used.

Our Response: For information about the development of the habitat models used in the Species Report, we encourage the commenter to read the white paper describing how the habitat model was developed (Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, available as Appendix B in the final Species Report). The development of habitat models for Washington was a challenge, given that we were unable to gain access to location data from the fishers reintroduced to the ONP, and there are no other recent, reliable fisher location data for Washington. Therefore, for southwestern Washington and coastal areas of the Olympic Peninsula, we used a projection of a model developed for the Northern California and Southern Oregon coast, and for the Washington Cascades and Olympic Mountains, we developed expert models.

We agree with the State’s characterization of the lands in southwestern Washington and the western coastal portions of the Olympic Peninsula, and we also agree that the habitat model likely overestimated the suitability of these landscapes for fishers. Although there was high environmental similarity, in terms of the variables used in the model, between this region and the region for which the model was developed, the relationship between the model variables and the landscape suitability for fishers apparently differs between the two regions (see also our responses to Comments (63) and (68)). However, a reevaluation of the quantity and quality of suitable fisher habitat in this area of Washington, where fishers are generally rare or absent, would be very unlikely to change the determination to withdraw the proposed rule. Therefore, we have not revised the habitat model for this area.

Regarding differences between the habitat model used in the draft Species Report and the model presented by Lewis and Hayes (2004), as we noted in our response to Comment (69), it appears to us that the differences between the two models are relatively minor. We agree that there are some differences between the two models in the quantity of habitat shown at high elevations and on the east side of the Cascades. Since both models are expert models, and fishers are only now being reintroduced to the Washington Cascades, it is impossible to know at this time whether one model is more correct than the other.

Regarding the use of resource selection functions derived from reintroduced fishers on the Olympic Peninsula, please see our response to Comment (68).

(221) Comment: Two commenters expressed concerns regarding the habitat variables used for the model that defined the three habitat categories (low, intermediate, and high), and they requested more explanation/detail from the Service as to the number of acres associated with each of the three categories by the different subregions, and (in general) more clarity and explanation of the methods to better understand the modeling process, definitions, assumptions, validation, and applicability of the results.

Our Response: The explanation/detail requested by the commenters is outlined in the updated white paper describing how the habitat model was developed (Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, included Appendix B of the final Species Report).
(222) Comment: One commenter stated that it was unclear how the habitat model could be used to determine habitat selection and suitability given that it appears the model is based on presence-only data. The commenter asserted that habitat selection analysis typically requires an assessment of habitat use versus availability, and it does not appear that the Service collected information on unused/available habitat.

Our Response: Presence-only data are commonly used to fit models of habitat suitability and habitat selection. Maxent, which we used to fit models for the modeling regions within California and Southern Oregon, is a particularly widely used presence-only habitat suitability modeling platform that is well-accepted in the scientific community. Both Maxent modeling and strength-of-selection evaluation rely on comparisons between used and available habitat. “Available habitat” refers to all areas within the modeling region, whether they are used, unused, or unsurveyed. Data describing available habitat come directly from the environmental data layers used in the model, and no additional data are required to identify “available” habitat. In contrast, presence-absence habitat suitability and selection models require input data identifying locations where the species is absent. Although we did have data on locations with negative survey results for fishers, these could not be used as model input in the presence-only Maxent models. However, after the models were developed we did compare the negative survey results with the model results. This comparison is described in the final Species Report.

(223) Comment: One commenter requested more clarity and explanation of methods to better understand the modeling process, definitions, assumptions, validation, and applicability of results. The commenter stated that given the large uncertainty with the model, it is difficult to assess the validity of assertions used in the report. Additionally, the commenter stated that there is no description of model assumptions or how they may affect model projections, and the uncertainty over the model also limits evaluation of the scope and severity of effects of many of the fisher habitat stressors.

Our Response: We encourage the commenter to read the updated white paper describing how the habitat model was developed (Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, included as Appendix B of the final Species Report). In addition, we recommend the commenter to review the other responses to comments on the habitat model in this section.

With regard to the evaluation of scope and severity of stressors, the habitat model was used only in the evaluation of habitat stressors related to wildfire and linear features. Furthermore, the final Species Report has been revised to emphasize qualitative analyses of these stressors, and the quantitative analyses that relied on the habitat model have been moved to Appendix C. Because the habitat model played such a limited role in the evaluation of stressors, especially in the final Species Report, any uncertainties inherent in the model results had little influence on our conclusions about the effects of the stressors.

(224) Comment: One commenter stated that the Service did not tie together the analysis completed to create the fisher habitat model with the analysis process used for a northern spotted owl consultation, which they believe is necessary to do given the Service’s use of northern spotted owl habitat as a surrogate for fisher habitat (denning and nesting sites), and because of the fisher’s use of a mosaic of habitat types. The commenter also stated that the Service’s claim that the removal or modification of northern spotted owl nesting-roosting-foraging habitat is equivalent to tracking the removal or modification of fisher habitat is unsupportable by the best available science.

Our Response: The commenter may have misinterpreted our use of northern spotted owl consultation data, which was used as a rough index to estimate the scope of fisher habitat loss to vegetation management activities on Federal lands throughout the analysis area in the absence of quantitative data specific to fisher habitat trends across the proposed DPS. In any case, in our final Species Report, we did not rely upon documented section 7 consultations on northern spotted owl suitable habitat as a surrogate for evaluating the effects of vegetation management on fisher habitat. The NWFP 20-year late-successional old-growth monitoring report (Davis et al. 20XX, entire) provided us with an excellent source of information specific to changes in forests with old-forest structural characteristics throughout the majority of the analysis area, this report, in conjunction with other data specific to the region formed the foundation of our final evaluation of fisher habitat in the final Species Report. Please also see our response to Comment (79).

(225) Comment: One commenter stated that the Service’s habitat analysis model provided an important foundation for several of the analyses in the draft Species Report. However, while the methodology for the habitat model itself was made available for public input in advance of the proposed listing rule, the commenter stated that important portions of the results were not provided. Thus, the reviewer questioned what the characteristics were for forests of high- and intermediate-quality habitat, how the definitions were derived, and how habitat definitions and quantities and fisher use compare to the other habitat quantification method used for the northern spotted owl.

Our Response: We encourage the commenter to read the updated white paper describing how the habitat model was developed (Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, included as Appendix B of the final Species Report). Additional information is now included in the white paper regarding the variables used to generate the model in regions where Maxent modeling was used. (Information regarding the variables used to generate the expert models was included in the earlier version, and is still included.)

We are unable to answer the commenter’s question about comparisons between our fisher habitat model and the northern spotted owl habitat surrogate. The quantification of northern spotted owl habitat was derived from a non-spatial database, so the locations of these areas of downgraded and removed habitat cannot be precisely identified in relation to the fisher habitat map. Furthermore, a variety of methods were initially used to identify the northern spotted owl habitat, including professional judgment by local biologists working in the area of each action. It is likely that most of these designations were made at the scale of a single forested stand or treatment unit, whereas our fisher habitat model was developed at the landscape scale. Even if we knew all of the methods used to designate northern spotted owl habitat and had all of the maps depicting the locations of the now-removed habitat, it would be inappropriate to compare the two directly, because of the difference in scales.

However, we have now developed other methods to determine how much fisher habitat has been altered by
vegetation management on Federal land (see the “Vegetation Management” section of the final Species Report (Service 2016, pp. 98–111)), and we are no longer relying on the northern spotted owl habitat surrogate. Therefore, it would no longer be relevant to attempt such a comparison between fisher habitat and the northern spotted owl habitat surrogate, even if it were possible to do so. Please also see our responses to Comments (79) and (224).

(226) Comment: One commenter stated that the habitat model would be inappropriate for use in describing habitat and species distribution of forestlands with moderate to open canopies where complex forest structures are present. This commenter claimed that both habitat fragmentation and isolation were overstated by the Carroll et al. (1999) model, and found the Zielinski et al. (2010) model to have a correct classification of fisher habitat. The commenter was concerned that the habitat model used for the proposed rule appears to rely on forest canopy closure and would not be able to predict forest structures needed by fisher.

Our Response: Although previous research has repeatedly shown that fishers are associated with landscapes with a high proportion of dense forest cover, there have been fewer studies of fisher habitat use in drier regions where canopy cover and closure are relatively low, such as the Eastern Cascades or the Kern Plateau, and we acknowledge that canopy cover or closure may not be associated with fisher habitat use in the same way as in those regions where fisher habitat use has been more thoroughly studied.

We disagree with the commenter’s characterization of our habitat model as “relying on canopy closure.” Although canopy cover was one component of the fisher habitat model used in the draft Species Report, it was not the only component, and it was only used in some of the modeling regions. In the expert models used for the Washington and Oregon Cascades, canopy cover was handled differently on the eastern and western sides of the Cascade Crest, in light of the more open forest conditions that prevail on the east side. The expert models also included a measure that was related to the likely presence of structures that fishers could use for denning and resting, and was not related to canopy cover.

The commenter is correct that the model does not, and is not intended to, predict the specific locations of forest structures needed by fishers, especially given that it is useful on the landscape scale and not on the scale of individual trees. However, at least in regions where the expert model was used, it does incorporate the likely presence of these structures on the landscape into the assessment of fisher habitat suitability.

For more information, we encourage the commenter to read the updated white paper describing how the habitat model was developed (Habitat Modeling Methods for the Fisher West Coast Distinct Population Segment Species Assessment, included as Appendix B of the final Species Report).

(227) Comment: One commenter asserted that habitat quality (as shown in the legend label in Figure 2 of the draft Species Report) is typically based on an association with a demographic parameter, and it is not evident that the Service used demographic information in their analysis. Therefore, the commenter suggested that the Service avoid any conclusions regarding habitat quality.

Our Response: There is no single, standardized definition of the phrase “habitat quality.” We acknowledge that some scientific researchers and authors prefer a definition that refers to demographic or fitness effects associated with habitat characteristics, but this usage is not universal. Our use of the term was meant in a more generic way, and we did not intend to imply any conclusions regarding the effects of the habitat categories on the demographic parameters of fishers that might be present.

Habitat Recruitment

(228) Comment: One commenter stated that although the draft Species Report includes several statements acknowledging that habitat ingrowth could be a factor offsetting habitat loss, the Service declined to provide any quantitative or qualitative analysis of this effect, citing the “high degree of uncertainty.” Further, the commenter stated that despite the Service not considering habitat ingrowth, the Service proceeded to extrapolate the scope and severity of vegetation management by applying a speculative extrapolation of harvest rates on non-Federal lands from the most recent decade to the entire 40-year period. The commenter asserted that this approach creates a one-sided analysis of the stressor, and believes this was an important factor in designation of vegetation as a threat in the proposed rule. The commenter stated that the 40-year period is long enough to accrue a substantial estimated impact from a hypothetical degree of habitat removal, but not accounting for habitat ingrowth over the same period eliminates any balancing of effects. The commenter articulated that several available sources indicate that ingrowth could be substantial over the course of a 40-year foreseeable future (e.g., Spies et al. (2007a, Fig. 3), USDA Forest Service and USDI BLM (1994)). Also, the commenter stated that there are numerous timber growth and yield models that have been extensively tested within the analysis area. In summary, the commenter proclaimed that the analysis leading to designation of vegetation management as a threat to the fisher in the proposed rule (Factor A) is imbalanced and indefensible due to the unsupported selection of the 40-year foreseeable future and the refusal to account for ingrowth.

Our Response: We understand the concerns of the commenter and have addressed many of these in our responses to peer review comments regarding habitat recruitment (see our responses to Comments (42) and (75)). We appreciate the references for ingrowth over the course of a 40-year foreseeable future (please see our response to Comment (174) for an explanation of how we derived our foreseeable future timeframe, as well as our expanded discussion in our final Species Report (Service 2016, pp. 100–110). The commenter indicated that there are numerous timber growth and yield models that have been extensively tested within the analysis area; however, the commenter did not provide any further information on the models for us to consider or evaluate further. In the end we chose to use the NWFP 20-year monitoring report tracking changes in old-growth and late-successional forests (Davis et al. 20XX, entire). This information tracked changes by disturbance type over a 20-year period. We also tracked vegetation changes outside of the NWFP area using a GNN dataset. Both of these tools accounted for ingrowth. See also our response to Comment (75).

(229) Comment: Several commenters expressed concern that the draft Species Report and proposed rule did not adequately address the potential for regrowth (i.e., ingrowth or recruitment) of fisher habitat, particularly on NWFP and other Federal lands as a result of various regulatory measures, to better understand the relationship of habitat recruitment to fisher viability. One commenter specifically stated that vegetation management is not a threat, noting that the Service’s analysis only considered losses of vegetation/habitat. Two other commenters asserted that forest growth has exceeded forest harvest in the prior 2 decades, and it may continue over the 40-year analysis period considered in the draft Species Report. Finally, one commenter claimed...
that it is a reasonable assumption that harvest on privately managed lands exceeds that of harvest on Federal- and State-managed lands given different objectives for each of those landowners. This commenter also stressed a concern that the Service’s analysis of habitat stressors related to vegetation management resulted in only negative effects to fisher habitat given that private forest landowners are required to demonstrate a balance of harvest and growth.

**Our Response:** We understand the concerns of the commenters and have addressed many of these in our responses to Comments (38), (39), (42), and (75). We agree with the commenter that it is reasonable to assume harvest on non-Federal lands will exceed harvest on Federal- and State-managed lands and noted that in the draft and final Species Reports. The NWFP 20-year old-growth and late-successional monitoring report that we used to assess habitat recruitment and habitat loss due to vegetation management also confirmed that harvest rates on Federal lands are substantially less than on non-Federal lands (Davis et al. 20XX, p. 24). We also used Davis et al. (20XX, entire) to track net vegetation change in the NWFP area, and GNN data (LEMA 2016) to track net vegetation change outside of the NWFP area. Based on these data, the commenter is correct in that, in some portions of the NWFP area, forest ingrowth has exceeded timber harvest over the past two decades. We have used all of this information in our assessment of vegetation management as a stressor to fishers.

**Comment:** One commenter asserted that recent protocol-compliant surveys following wildfires (specifically referencing the 1992 Fountain Fire in California) have shown significant detections of fishers, indicating that habitat regrowth/ingrowth following fires has occurred. The commenter believes that taking this type of information into account when considering habitat recruitment is critical given that fire is likely the most significant stressor facing the fisher.

**Our Response:** Fires can cause reductions to or removal of important elements of fisher habitat, including vegetative diversity, overstory canopy cover, understory cover, and key structural elements (large hollow trees, large down logs, large live trees) (Service 2014, p. 59). The effects to fisher habitat are related to fire severity. For example, low-severity fire may reduce some habitat elements while increasing others; however, high-severity fire is more likely to remove forest cover from large blocks of habitat. (Service 2014, p. 59). The recovery of the forest understory after low-severity fire, especially on productive sites, can occur within one fisher lifetime (Naney et al. 2012, p. 6). Research specific to the degree to which fishers use post-fire landscapes is extremely limited, but we have updated the final Species Report to reflect all of the best scientific and commercial data available to us on the topic, including the observations of fishers following the Fountain Fire (Service 2016, pp. 66–67). We thank the commenter for providing the data associated with their study so that we may continue to better understand the use of post-fire landscapes by fisher.

**Maps/Sightings**

**Comment:** One commenter requested that data in Figures 6 through 9 of the proposed rule be more clearly stated, also recommending that the Service follow the example provided by Aubry and Lewis (2003; Figure 2), using data (reliability 1 and 2) for the last 20 years. The commenter stated that although they have concerns about incorrect interpretations that can be drawn from sighting data that include points with reliability ratings of 3 and 4, they are also concerned with conclusions that can be drawn from specific points in Washington with reliability ratings of 1 and 2. For example, two of the most recent reliability 2 observations were likely to be of two fishers that escaped from Northwest Trek Wildlife Park (observations #53 and 54 in Appendix A of Lewis and Stinson [1998]) and, therefore, they do not indicate native Washington fishers, or the existence of a small population or the remnants of one. In addition, the commenter noted an incorrect interpretation that could be made from the observation of a fisher reintroduced (and radio-collared) in Montana that dispersed to Washington and was recovered in Stevens County in 1994 (observation #55 in Appendix A of Lewis and Stinson 1998). The commenter stated that the most recent reliability 1 observation of a fisher that could be native to Washington was collected near Lilliwaup Swamp in the eastern portion of the Olympic Peninsula in 1969 (Observation #52).

**Our Response:** We have revised the legends in Figures 6–9 of the final Species Report to more clearly describe the data presented in each (Service 2016, pp. 33–36). We agree that fishers were likely extirpated from Washington prior to reintroductions starting in 2008, and acknowledge that this comment represents the best available and most supportive conclusion regarding the history of fisher extirpation in Washington. Accordingly, we included the commenter’s description of recent fisher detections in Washington into our description of past and current distribution in the final Species Report. However, Figures 8 and 9 were included in the Species Report to show the approximate historical distribution of fishers, and are not meant to display a temporal or spatial history of likely fisher extirpation in Washington, especially since the range of reliability ratings in each of these figures is different. Figure 8 presents fisher detection locations with all reliability ratings (1–6) to illustrate the probable historical distribution of fishers. Figure 9 illustrates that fishers still occurred at various locations throughout their historical distribution during the period of 1953 to 1993. In this figure, reliability ratings of 5 and 6 are not depicted due to their low reliability.

**Comment:** One local government stated that the map included in the proposed rule was confusing and unclear about how the fisher’s listing may impact Inyo County, and specifically requested that the Service provide a better map to gauge the potential effects of the listing action. Another local government stated that the maps were at too broad a scale to be helpful, also requesting the basis for the boundary in a final listing document. Finally, another commenter stated that they question the validity and accuracy of maps in Figures 8 and 9 (believes data are missing between the two maps) of the draft Species Report.

**Our Response:** We understand the concerns about needing to clearly identify which areas were included in our proposed listing rule. In this final finding, however, we are withdrawing our proposal to list the West Coast DPS of fisher (see Determination, above). Therefore, we will not be providing additional maps in this final finding that would provide the requested clarification.

We assume that one commenter misunderstood the content contained within Figures 8 and 9 of the draft Species Report. Figure 8 depicts all locality records (reliability ratings 1 through 6) prior to 1993. Figure 9 depicts a subset of these records for the time period between 1953 and 1993 for reliability ratings 1 through 4. Figure 9 is a subset of the data contained in Figure 8 and, therefore, contains fewer points than Figure 8. In our review, the data in these maps are valid and accurate.
Northern Spotted Owl (NSO) Habitat Surrogate

(233) Comment: One tribe in the State of Washington stated that northern spotted owl habitat is not a good surrogate for fisher habitat because fisher may use younger forests in Washington that have resting and denning structural elements. Additionally, the tribe mentioned that tribal lands in western Washington impose riparian protection where logging occurs and in some instances employ a reserve system that protects significant stands of late-successional forest. The tribe further articulated that the draft Species Report ignored these contributions to fishers in terms of current habitat conditions and recruitment of habitat for the future, thus likely inflating the risks to fishers in Washington from habitat loss.

Our Response: The tribe may have misunderstood our use of northern spotted owl habitat as a surrogate. We did not use any northern spotted owl habitat surrogate to calculate the amount of habitat for fishers in Washington now or in the future. The loss or degradation of northern spotted owl suitable habitat as documented through section 7 consultation was used only as a proxy to estimate the potential threat from loss of fisher habitat on Federal lands (see also our response to Comment (79)). Regardless, in our final Species Report, we did not need to rely on northern spotted owl habitat as a surrogate for fisher habitat loss or degradation, as the results of the NWFP Monitoring Report (Davis et al. 20XX, entire), and other data, became available to us, providing superior datasets for this analysis.

The conservation value of some tribal lands for fisher, including the Makah Reservation, was described in the draft Species Report (Service 2014, pp. 127–128). Although recruitment of habitat (ingrowth) on non-Federal lands was not explicitly considered in our draft Species Report, the availability of the NWFP Monitoring Report mentioned above provided us with the data to estimate ingrowth over the past 20 years within that portion of the analysis area that overlaps with the NWFP (which covers most of the proposed West Coast DPS, with the exception of the Sierra Nevada and east of the Cascades). Also see our response to Comment (188) for a discussion of the value of managed forests to fisher; we have broadened our discussion of this topic in our final Species Report.

Comment: One Federal commenter asserted that the northern spotted owl habitat is a useful proxy for fisher habitat in some parts of fisher range, but is inappropriate in California and not useful in the NWFP area. The Federal commenter stated that fishers use habitat types that northern spotted owls do not, especially because northern spotted owls are not present in the southern portion of the fisher’s range. Additionally, the Federal commenter noted that northern spotted owl critical habitat does not include wilderness, Jeffrey pine, or serpentine soil areas and, therefore, leaves out some fisher habitat. Another Federal commenter also cautioned the Service in using northern spotted owl habitat as a surrogate for fisher habitat because while northern spotted owl nesting/roosting habitat is likely fisher habitat, not all fisher habitat is northern spotted owl nesting/roosting habitat, particularly in areas where hardwoods (e.g., oak) are a component and may provide cavities suitable for fisher denning. Additionally, this second Federal commenter stated that in the drier forests in southwest Oregon, some areas not considered northern spotted owl habitat (especially with important fisher habitat characteristics such as hardwoods and cavities) may function as denning habitat.

Our Response: At least one of the commenters may have misunderstood our use of section 7 consultations on northern spotted owl suitable habitat on Federal lands within the NWFP area (see our response to Comment (233)), and confused northern spotted owl suitable habitat (which we did use to estimate the scope of fisher habitat loss to management activities) with northern spotted owl critical habitat (which we did not use; see our response to Comment (80)). In any case, as described in our response to Comment (79), in our final Species Report, we did not use northern spotted owl habitat as a surrogate to evaluate the effects of management activities on fisher habitat in the analysis area, as better data became available to us for this purpose.

(235) Comment: One commenter suggested that the Service use spatial data, other land cover data, and herbicide application rates to understand change within the same timeframe as the northern spotted owl habitat data to obtain a more complete picture of fisher habitat loss.

Our Response: We appreciate the suggestion. However, we used the most relevant data coverages of which we are aware for our analysis, and the commenter did not provide us with any specific information with regard to other sources of data that we may have overlooked.

Policy

(236) Comment: One local government entity criticized the “single species” focus of the listing proposal, stating that the CEQA and NEPA require consideration of impacts of the proposed rulemaking to humans. The commenter requested that the Service take the following into consideration in the final listing determination: (1) Impacts to the human environment such as management to reduce insect and disease damage and catastrophic fire risk, as well as the promotion of watershed health; (2) benefits of post-fire salvage logging (we presume the commenter means benefits to the human environment, not to fishers); and (3) timber targets and their relationship to jobs in mills.

Our Response: The CEQA and NEPA regulations referenced by the commenter do not require proposed listings under the Endangered Species Act to consider effects on the human environment, nor can we, by law, consider potential economic impacts of a Federal listing in our determination. On the contrary, the Endangered Species Act lists the specific factors we must use to determine whether or not a species meets the definition of an endangered or threatened species, and Section 4 of the Act requires that we base this decision solely on the best scientific and commercial data available (see also responses to Comments (122) and (158)).

(237) Comment: One commenter expressed concerns that a final listing determination could disrupt the collaborative work on fisher conservation that has been ongoing in the SSN population, particularly if listing leads to closure of the last remaining timber mill, which would make it more difficult to carry out fuels treatments.

Our Response: Please see our responses to Comments (122), (158), and (236) for a description of the factors that we may consider in making a listing determination under section 4 of the Endangered Species Act, which does not include concerns such as those noted by the commenter here. In any case, as noted previously, we are withdrawing the proposed rule to list the fisher under the ESA (see Determination, above).

(238) Comment: One commenter asserted that listing the fisher will lead the Forest Service to manage for one species at a time rather than managing for “the whole ecology of the forest.” For example, the commenter stated that the Federal listing of the northern spotted owl has restricted logging in the
Sierra Nevada and prevented appropriate fuels treatments and prescribed burning, leading to an unhealthy forest more susceptible to catastrophic wildfire. The commenter proclaimed that listing of the fisher or any other additional regulation will be counter-productive to fisher conservation and cause all the species of the forest to be “doomed.”

Our Response: Please see our responses to Comments (122), (158), and (236) for a description of the factors that we may consider in making a listing determination under section 4 of the Endangered Species Act, which do not include concerns such as those noted by the commenter here. In any case, we are withdrawing the proposed rule to list the fisher under the ESA (see Determination, above). We recognize the authorities and independent missions of Federal agencies to manage their resources and support their efforts in management of ecosystems and species alike. While we have determined that the fisher does not meet the definition of an endangered or threatened species under the Act, we will continue to work cooperatively with Federal agencies to conserve fisher and its habitat in the west coast States for the continuing benefit of the American people.

(239) Comment: One commenter expressed concern that the proposed designation of critical habitat was not published concurrently with the proposed listing rule. Furthermore, the commenter is opposed to the development of a section 4(d) rule that would promote fisher-friendly forestry and weaken protections for the fisher under the Act.

Our Response: In the proposed rule to list the DPS, we stated that critical habitat was not determinable; a not determinable finding regarding critical habitat provides additional time (1 year) under our implementing regulations at 50 CFR 424.17(b)(2). However, as we have now determined the proposed West Coast DPS of fisher does not meet the definition of an endangered or a threatened species, we are withdrawing the proposed rule to list the DPS (see Determination, above), and we will not be issuing a proposal to designate critical habitat. Neither will we be considering a section 4(d) rule for the proposed DPS since 4(d) rules can only be promulgated for species listed as threatened under the Act.

(240) Comment: One commenter asserted that although surveys for fishers are not complete for all regions of its range, the best available information indicates that the fisher is in danger of extinction. The commenter also stated that the Service’s failure to conduct surveys for fisher “does not give the Service a free pass to deny listing to a species that is struggling to survive and is considered likely to be extirpated throughout a significant portion of its historic range,” and that the Service “must rely on the available data to make a scientific determination.” Finally, the commenter declared that the lack of scientific certainty regarding the population trends of fishers in Oregon and Washington due to the Service’s own failure to complete population surveys should not support a not warranted determination, and that the courts have declared that the Service must provide benefit of the doubt to the species.

Our Response: We do not agree with the commenter’s assessment. Section 4 of the Act requires that we make a determination with regard to whether any species is an endangered species or a threatened species solely on the basis of the best scientific and commercial data available after conducting a review of the status of the species. Here we have conducted a thorough status review, received extensive peer review and public comment, and considered all of the best scientific and commercial information available regarding the status of the fisher, including new information received during our open comment periods. We agree it would be preferable to have more extensive survey data throughout the fisher’s range in the west coast States; however, we must make our decision based on the best data available to us at the time of our determination. Furthermore, we wish to point out that there is no requirement for the Service to conduct surveys for fisher, as implied by the commenter. The best available data do not indicate significant impacts at either the population or rangewide scales, currently or in the future. As a consequence, we cannot conclude that fishers in the proposed DPS are in danger of extinction throughout all or a significant portion of their range, or likely to become so within the foreseeable future (see Determination, above). The commenter additionally suggests that fishers have been extirpated from a significant portion of their historical range; this concept does not enter into our consideration, however, as fishers cannot be in danger of extinction or likely to become so in a portion of their range where they no longer occur. As explicitly stated in our final SPR policy, we do not base a determination to list a species on the status (extirpated) of the species in its lost historical range (July 1, 2014; 79 FR 37577, p. 37583).

The lack of scientific certainty regarding a species’ range, status, or population trend is not a basis for listing a species under the Act. Although absolute certainty is not required, there must be sound scientific support for a listing decision. Per section 4 of the Act and its implementing regulations, we have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher, and we have determined that the threats we identified in the proposed rule are not now, and will not in the foreseeable future, act on the species in such a way that the fisher meets the definition of an endangered or threatened species. Consequently, we are withdrawing our proposal to list this DPS (see Determination, above).

(241) Comment: One commenter asserted that the Service’s proposed rule to list the West Coast fisher DPS as threatened is a direct acquiescence to the demands of extreme environmental groups as opposed to the use of best available science.

Our Response: As required by section 4 of the Act, we base all decisions regarding the potential listing of a species solely on the basis of the best scientific and commercial data available; see also our responses to Comments (122), (158), and (236), and (240). The 2004 decision that listing was warranted but precluded, the 2014 proposed rule to list the species, and this withdrawal of the proposed listing rule are not exceptions. Despite our final determination that the protections of the Act are not warranted for the fisher at this time, we will continue to work cooperatively with all interested parties in the conservation of fishers in the west coast States and their habitat.

Population Estimates

(242) Comment: Several commenters expressed their general support of the proposed rule to list the West Coast DPS of fisher as threatened due to declines in the NCSO and SSN populations. Alternatively, several other commenters stated or cited information that indicates the overall populations are not declining, including some areas particularly in the NCSO population that are stable or increasing. One commenter asserted that despite potential threats to the NCSO and SSN populations, they are not declining (citing support for this with Higley and Matthews (2009), Swiers (2013), and Zielinski et al. (2013)), and another commenter specifically noted that some subpopulations in small portions of the NCSO population that may show a decline are not indicative of the entire NCSO...
population. Another commenter stated that the Service should describe the NCSO and SSN population sizes and isolation separately, claiming that there was no information in the draft Species Report to support NCSO as genetically isolated or contracting (and citing Service (2008)), thus indicating that the NCSO population range has been consistent for 75 years. 

Our Response: We appreciate the various opinions expressed by commenters related to whether the NCSO and SSN populations have declined. Our draft Species Report identifies the uncertainties associated with relative population stability for the NCSO (Service 2014, p. 38) and SSN (Service 2014, p. 42) populations. We reviewed numerous pieces of information provided during the open comment period, as well as information in our files, and have considered and incorporated the new information, where appropriate, into our final Species Report. To clarify for the reader, Service (2008) states: “Because there is no apparent significant decrease in the extent of geographic distribution in NCAL [northern California-southwestern Oregon regional population], we infer some level of regional stability over the last 75 years, and conclude that the NCAL population meets the assumption of stability for the VORTEX modeling exercise.” Our understanding of the extent of the NCSO population has not changed since this 2008 reference, except for the expansion of the population as a result of the NSN reintroduction. Regarding the request that we describe the NCSO and SSN population sizes and isolation separately, we are unsure as to what further distinction the commenter is asking for, as we discuss the NCSO and SSN populations separately throughout the entirety of the draft Species Report. Similarly, we have appropriately and accurately represented the data provided in Šelf et al. (2008) for the general reader, and direct those wishing more detail on methods and results to the reference itself. Please also see our response to Comment (211) above.

(243) Comment: One commenter asserted that the draft Species Report fails to produce a reasonable estimate of the extant NCSO population, and further suggested that the Service’s estimate of “as few as 258 animals in NCSO population” defies any reasonable logical analysis. The commenter stated that the Service should provide a more precise population range for the fishers in the NCSO population in order to make a fair assessment of the risks to fishers in this population area. Another commenter requested the Service conduct a population viability analysis of the NCSO population, asserting that there is no other way to determine the effect of stressors or their trend on the NCSO population.

Similarly, another commenter asserted that the Service neglected to acknowledge what is known about fishers in the NCSO population/region, including overestimated impacts of stressors. This commenter also declared that the analysis of impacts to the NCSO population was arbitrary and capricious, citing numerous studies (i.e., Klug 1997, Farber and Franklin 2006 (although this appears to be incorrect and should be Farber and Franklin 2005), Aubrey and Raley 2006, Clayton 2013) that do not document any long-term decrease in this fisher population. Finally, this commenter also noted that reintroductions help demonstrate that both the NCSO and SSN populations are stable or expanding. 

Our Response: We appreciate the opinion of both commenters. However, the final Species Report presents the best available information regarding the status of the NCSO population, including the applicable references provided by the commenter (see the “Population Status” section of the Species Report (Service 2016, pp. 42–48) and Species Information, above. As noted above in our response to Comment (252), we reviewed a substantial amount of new information during the open comment periods. The new information, in addition to our analysis of the best scientific and commercial data available at the time of the proposed listing rule, was considered for this final decision. Please also see our response to Comment (81) above. With regard to the request for a population viability analysis, we consider those population viability analyses provided in peer reviewed literature and other reputable unpublished documents. 

(244) Comment: One commenter asserted that the overall fisher population is sufficiently robust to remain viable and thus does not warrant listing. Additionally, the commenter noted that the draft Species Report supports this conclusion through its discussions on recent detections of individuals that have been found where prior surveys did not detect them, all of which indicate the proposed DPS may actually be larger than estimated. The commenter said this is also supported by studies cited in the draft Species Report (e.g., Self et al. 2008) that have estimated the NCSO fisher population to be large, even though more information is needed to adequately determine the population size of fishers in southwest Oregon and northwest California. Another commenter similarly noted that the Service has underestimated the overall population size, as demonstrated, for example, by the recent discovery of fisher by ODFW in the Middle Fork Willamette watershed. As such, this second commenter asserted that a statistically valid population estimate should be conducted throughout the entire region, including wilderness areas and areas outside known inhabited areas, prior to any listing decision.

Our Response: As noted above, we reviewed a substantial amount of new information during peer review and public comment periods. All of this new information, in addition to our analysis of the best scientific and commercial data available at the time of the proposed listing rule, was considered for this final decision. Some of this information includes new estimates of population abundance, reproduction, and population growth for fisher populations within the proposed DPS; all of this information is incorporated into our final Species Report and is summarized in this document. We interpret the commenter to be recommending that additional information be collected to support a statistically valid population estimate. We agree that additional surveys would be beneficial in deriving a more robust population estimate, but we must make our listing determinations using the best scientific and commercial information available at the time of the listing determination (see our response to Comment (230). Thus, we cannot delay making a listing determination while additional survey data are collected. Please also see our response to Comment (81).

We also wish to correct the commenter’s apparent presumption that the recent detection of a single fisher in the Middle Fork Willamette watershed is indicative of a population increase. We have no population estimates for the SOC population, and even if we did, this single sighting would not affect any existing estimate. Second, even without a population estimate, this sighting, while encouraging, is not necessarily indicative of a population expansion of the SOC. There has been little monitoring of the northern portion of this population to assess distribution; furthermore, in the late 1990s a dispersing juvenile male from the SOC population was radio-tracked to the Deschutes National Forest, roughly due east of the recent Middle Fork sighting but across the Cascade crest (Aubry and
This alone is not sufficient information to suggest that the SOC population has expanded since the early 1990s.

(245) Comment: One commenter disagreed with the Service’s conclusion that “the greatest long-term risk to fishers [is] the isolation of small populations and the higher risk of extinction due to stochastic events” and that “small population size constitutes a threat to fisher, now and in the future.” The commenter noted that recent studies indicate that fisher in California and southern Oregon are stable and dispersing across the landscape, and that the fisher has endured all of the “stressors” identified in the draft Species Report for decades, or longer. Thus, the commenter stated that this information intuitively leads one to conclude that the fisher is not threatened or endangered.

Our Response: As noted above, we reviewed a substantial amount of new information that was made available during the comment period on our proposed rule. We have fully considered and evaluated all of the best scientific and commercial data available for this final decision. As a result of this assessment, we have reconsidered our evaluation of the level of threat posed by small population size and isolation of fisher populations, and we no longer conclude that this stressor rises to the level of a threat for fisher in the sense that it is either singly or in concert causing the proposed DPS to be in danger of extinction now or within the foreseeable future. Based on our evaluation of the persistence in the face of ongoing stressors, we conclude that the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act and are withdrawing our proposed rule (see Determination, above).

(246) Comment: One commenter stated that throughout the draft Species Report, population-level impacts from stressors are rarely assessed, and it is seldom acknowledged that the degree of impact is largely or entirely speculative. Thus, the commenter asserted that the Service should not conclude that the fisher is likely to become endangered in the future if there is uncertainty as to whether the taxon is declining. The commenter requested that the Service better explain why purported threats rise to the level of threatened status given that the population trend in the NCSO is unknown, that the best available scientific information indicates that rare population trend in the SSN is apparently increasing, and that actual effects of purported threats at the population level are unknown. Additionally, the commenter requested that the Service explicitly note that density estimates from various areas in the NCSO over the past 2 decades consistently fall within the range of 5 to 20 fishers per 100 km² (38.6 mi²), and that the best available scientific information does not indicate any widespread decline in density.

Our Response: In our draft Species Report, the scope of a potential stressor was used to describe the proportion of a subregion expected to be affected by the stressor. Only the percentage of the population or analysis area subregion that may potentially be impacted by the stressor was assessed (Service 2014, p. 50). Therefore, depending upon the scope of any one stressor, it may or may not have been assessed at the population level. When the information available regarding a stressor was contradictory or included a wide range of values, we provided that information in the draft Species Report to demonstrate the uncertainty or variability of the data we reviewed (e.g., Service 2014, pp. 38, 60, 65–66, 80–81). As suggested by the commenter, in this document we have clarified that although all species experience stressors, we consider a stressor to rise to the level of a threat to the species (or in this case the DPS) if the magnitude, intensity, or imminence of the stressor is such that it is resulting in significant impacts at either the population or rangewide scales. As described in our proposed rule (79 FR 60419, p. 60427), in considering what stressors might constitute threats, we must look beyond the mere exposure of the DPS to the stressor to determine whether the DPS responds to the stressor in a way that causes actual negative impacts to the DPS. In our draft Species Report, as described above, we attempted to evaluate the magnitude of the effects of identified stressors by quantifying the severity and scope of those stressors. However, that analysis required us to make assumptions or extrapolate impacts in an effort to quantify stressors in areas where stressor-specific information was not available. Our presentation of the scope and severity of stressors in quantitative terms may have created a false sense of the level of scientific accuracy underlying these estimates. To avoid this perception, in our final Species Report we use a qualitative approach to describe stressors (i.e., stressors are categorized as low, moderate, or high, as defined in that Report). We use quantitative data wherever possible, but if specific data are lacking, we rely on qualitative evidence to derive a qualitative descriptor of each stressor, based on the best scientific and commercial information available, rather than extrapolating.

In our final determination, we specifically evaluated whether there were any indications that the identified stressors acting on the proposed DPS were resulting in any significant impacts at either the population or rangewide scales to fishers or their habitat. The best available data for the NCSO population were included in that assessment. We did not find any indication that the stressors are manifesting themselves to a significant degree across the proposed DPS such that there are significant impacts (i.e., stressors functioning as operative threats) at either the population or rangewide scales. Thus, we conclude that the stressors acting on the proposed West Coast DPS are not so great that fishers in the DPS are currently in danger of extinction (endangered), or likely to become so within the foreseeable future (threatened). As a consequence, we are withdrawing our proposed rule to list the West Coast DPS of fisher (see Determination, above).

(247) Comment: One commenter stated that the Service’s analysis does not support the conclusion that “a significant amount of high quality habitat remains unoccupied within the current boundaries of the Northern California-Southern Oregon population.” Specifically, the commenter expressed concern that the Service’s discussion does not evaluate the validation of surveys with absence reported and the extent to which this lack impacts the analysis, and questions support for use of a 60 percent survey detection rate. Additionally, the commenter maintained that the Service’s analysis does not inform the public about the significance of the substantial amount of high quality habitat that remains unsurveyed.

Our Response: Figure 10 in the draft Species Report illustrates the surveyed and unsurveyed habitat within portions of California and Oregon (Service 2014, p. 41). Information in the “Distribution and Abundance” section of the draft Species Report discusses the various sources of information that we used to determine where fishers are found (Service 2014, pp. 23–41). The draft Species Report (Service 2014, p. 39) notes that “Fisher detection probabilities are affected by latitude, season, type of survey, and survey effort (Burnas 2014, pers. comm.; Slauson et al. 2009, entire), but given reported fisher detection probabilities are low (as reviewed by Slauson et al. 2009, pp. 15–19), we believe that 60 percent detection
probability is a conservative estimate that does not place undue confidence in the accuracy of negative results.” Finally, we assume the commenter is implying that the “substantial amount of unsurveyed high quality habitat” is significant because there may be more fisher present than current data indicate. However, the results of the Fisher Analysis Area Habitat Model (Service 2014, Figures 2 and 3) show that, in certain areas, connectivity within fisher population areas is disrupted as a result of habitat quality, possibly making it difficult for fishers to disperse into some habitat that may be suitable. Finally, it is possible that there are more fisher in areas of unsurveyed high-quality habitat, but at this time there are no data to support a conclusion that these areas are or are not occupied by fisher.

(248) Comment: One commenter asserted that there are fewer than 150 adult female fishers in the entire Sierra Nevada (although no citation was provided), indicating that Federal protections are warranted. Our Response: We agree with the commenter that the SSN population is comprised of low numbers of individuals, although the exact number is uncertain (see the “Population Status” section of the final Species Report (Service 2016, pp. 48–50) for additional discussion. Estimates for the SSN population range from a low of 100 to a high of 500 individuals (Lamberson et al. 2000, entire). A recent estimate of 256 female fishers was based on available data (Spencer et al. 2016, p. 44). Other population estimates are: (1) 125–250 adult fishers (Spencer et al. 2011, p. 788); (2) less than 300 adult fishers (Spencer et al. 2011, p. 801); and 276–359 fishers including juveniles and subadults (Spencer et al. 2011, p. 802).

Although we agree that this data does not indicate the SSN to constitute a large population of fishers, we additionally considered that all of the best scientific and commercial data indicate that this population has persisted at a relatively low population level for a very long time, in geographic isolation and in spite of the stressors acting on the population. We have no evidence to suggest that this population is in decline, or that its range is contracting. Finally, the SSN is only one of the fisher populations within the proposed West Coast DPS of fisher; as described above, our evaluation for the purposes of making a final listing determination was based on an assessment of the proposed DPS as a whole, as originally described in our proposed rule. When we considered all the potential impacts from the factors that may be affecting the proposed DPS, we determined there is no evidence to suggest significant impacts at either the population or rangewide levels, currently or in the foreseeable future (see the Determination and Significant Portion of the Range sections, above, for additional discussion). As our evaluation of all the best scientific and commercial data available did not allow us to conclude that the proposed DPS is in danger of extinction or likely to become so throughout all or a significant portion of its range within the foreseeable future, we are withdrawing our proposal to list the West Coast DPS of fisher.

Prey

(249) Comment: One Federal agency stated that abundant large prey (i.e., greater than 7 ounces (200 g)) is likely a limited food source in the SSN population (citing unpublished data from Slauson and Zielinski). Our Response: The main potential prey that is missing in the SSN population is the snowshoe hare (Lepus americanus). The best available data at this time does not indicate that the lack of this one species, which is also missing from much of northwestern California, is limiting the population of the fisher in this region.

(250) Comment: One commenter requested the Service acknowledge livestock grazing as a benefit to fisher. Specifically, the commenter asserted that vegetation management by livestock grazing allows easier access to prey for fishers, including fisher. Another commenter argued that positive changes to the fisher’s prey base as a result of vegetation management were overlooked in the Service’s analysis. Our Response: We are not aware of literature or reports specifically describing the benefits of livestock grazing on fisher prey, nor did the commenter provide any sources for our consideration. The second commenter is correct—our analysis of effects to fisher prey species was largely focused on negative impacts to prey habitat (e.g., Service 2014, pp. 43–46; Service 2016, pp. 50–53), although as discussed in the final species report and this document, initial indications are encouraging. The reintroductions in these areas are within the proposed West Coast DPS of fisher and, therefore, would not result in expansion of the current DPS. The draft Species Report also notes the detections in eastern Shasta County, California, and our uncertainty as to whether these detections represent a possible expansion or are a result of widespread or dispersing males (Service 2014, p. 34). Because data were not provided to support the claim that fisher now occupy areas that were occupying 10 to 30 years ago, we are not able to verify the locations and/or reliability of the claims made by the second commenter.

In sum, although we do not have sufficient information to substantiate the claim that the range of fisher is expanding, we do agree there is no evidence that suggests that the present range of fisher has diminished within the past few decades. This was one of the considerations we took into account as we conducted our final evaluation of all of the best scientific and commercial
data available regarding the status of the proposed West Coast DPS of fisher, including, as noted above, a substantial amount of new information obtained during peer review and public comment periods, recently published journal articles, and unpublished reports associated with management activities and research projects. All of this new information contributed to our conclusion that the proposed DPS does not meet the definition of an endangered or threatened species under the Act and, therefore, our final determination to withdraw the proposed listing of the West Coast DPS of fisher as threatened (see Determination, above).

(252) Comment: One Federal agency stated that the SSN fisher population is small (less than 500 individuals; Spencer et al. 2011), appears to be stable over the past decade (Zielinski et al. 2013), but apparently expanded in size and range from an even smaller population during the late 20th century (Tucker et al. 2014).

Our Response: Tucker et al.’s (2014, p. 131) statement of possible recent population expansion refers only to the northern portion of the SSN range, north of the Kings River. The small population size of fisher in the SSN population and the likely stability of the population are reflected in both the draft and final Species Reports. The long-term persistence of this small population, and lack of evidence for current or likely declines in the face of stressors, played a role in our final determination that the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act (see also our response to Comment (248)).

(253) Comment: One commenter stated that fishers have recolonized the central Sierra Nevada on the Stanislaus National Forest, per personal observations within areas where the taxon was thought to be extirpated.

Our Response: We use the best available scientific and commercial information to make determinations regarding species under the Act. Specifically regarding locations of fisher in the west coast States, as described in our draft and final Species Reports, we do not use anecdotal observations to support population distribution and extent, only verified location information based on track plate surveys, camera stations, scats, or other verifiable information. We appreciate the observation and comment.

Reintroductions

(254) Comment: Several commenters asserted that reintroduction efforts on managed timberlands in California (e.g., Stirling reintroduction area) and Washington have been successful. One of these commenters stated that the fisher has a history of successful reintroduction efforts and the draft Species Report provides evidence that reintroductions are more likely than not to be effective in the west (citing Lewis and Hayes 2004, p. 5). This commenter also stated that the fisher translocation effort in northern California shows the value of encouraging private partners to be involved with fisher conservation and reintroduction. Although not articulated clearly by another commenter, we assume this commenter’s statements are suggesting that reintroductions demonstrate the fisher’s adaptability to areas actively managed for forest products, and their ability to survive on managed timberlands, thus reinforcing the concept that timber management is not a threat to the proposed DPS.

In contrast, another commenter stressed that insufficient time has passed since the Stirling reintroduction (and other reintroductions) to assess whether fishers will continue to do well in managed forests given those forests are gradually converting to even-aged plantations.

Our Response: While we are encouraged by the status of the reintroduction efforts, we agree that it is too soon to determine if fisher reintroduced in California and Washington will persist (Service 2016, pp. 50–53). However, we also agree that early results demonstrating reproduction in these populations are encouraging, and indications are that fisher reintroductions have a good likelihood of success. In addition, we agree there is value in encouraging private landowners to be involved with fisher conservation and reintroductions and we will continue to look for opportunities to partner with landowners to promote fisher conservation. Please also see our response to Comment (85) above.

(255) Comment: One commenter insisted that reintroductions of fishers should be the Service’s primary goal as opposed to listing under the Act, especially given the extensive areas of unoccupied, suitable habitat and the likely unwillingness of private landowners to accept a listed species being present on their lands. Another commenter championed the Service’s tools of creating (or continuing to finalize) candidate conservation agreements with assurances specifically in Oregon and Washington to ensure private landowner cooperation (e.g., preventing a barrier to reintroduction activities on private timberlands) with the Service’s conservation objectives for this taxon.

Our Response: There are many tools that can be used to further species conservation. Listing under the Act is one of those tools, but it is not a discretionary tool. Section 4 of the Act lists the factors we use to determine whether or not a species is endangered or threatened, and requires that we make the determination based solely on the best scientific and commercial data available. In the case of the fisher, we have determined that the proposed West Coast DPS of fisher does not meet the definition of an endangered or a threatened species (see Determination, above). This means we are withdrawing our proposed rule and will not be enacting the protections of the Act at this time. However, this determination should not be taken to mean no further conservation measures to protect fishers in the west coast States are important or will occur. We encourage the continuation of other Federal, State, and private conservation efforts in the furtherance of fisher and habitat conservation, and are particularly supportive of efforts such as further reintroductions and the development of the mentioned CCAAs in Washington and Oregon, all of which we expect to contribute to maintaining and increasing fisher populations, and precluding the need to revisit the conservation status of fishers in the west coast States in the future.

Rodenticides

(256) Comment: Several commenters requested more information on how listing the fisher under the Act would ameliorate the threat from ARs associated with illegal marijuana growers, as the growers are already acting in violation of Federal regulations. Several other commenters felt that listing the fisher would not reduce illegal anticoagulant rodenticide use, that more law enforcement presence was needed rather than additional regulations, that regulations would only impact legal use of rodenticides, and that more information on the threat was needed before increased resources were dedicated to the problem.

In contrast, several other commenters believed that listing under the Act would increase funding for the Federal Government to combat illegal marijuana growers. Other commenters urged the Service to enact stronger penalties for illegal use of anticoagulant rodenticides and to provide more funding for eradication efforts. One commenter stated that the Service should encourage...
the EPA to ban rodenticides within and adjacent to occupied fisher habitat. Our Response: Section 4(a)(1) of the Act lists the factors we use to determine whether or not a species is endangered or threatened, as defined by the Act. Whether the Act can make a difference in ameliorating specific threats is not a consideration in our determination of whether the listing of a species is warranted; that determination rests solely upon our conclusion regarding the status of the species, as informed by the best scientific and commercial data available. See also our responses to Comments (122) and (241).

The Service does not have the authority to regulate the sale or use of toxicants, including ARs.

(257) Comment: Several commenters stated that illegal marijuana growers and ARs posed a significant threat to the fisher within the proposed West Coast DPS. One commenter stated that the loss of habitat was exacerbated by the threat from illegal marijuana growers. Two commenters urged the Service to list the fisher under the Act based on the impact of ARs given impacts from this stressor alone could drive the proposed DPS to extinction.

Our Response: We agree with the commenters that illegal marijuana cultivation and the use of ARs are a growing concern and a current stressor to fishers within the proposed DPS. Combined with habitat loss, among other factors, this threat may be acting synergistically and cumulatively to affect fishers in the proposed West Coast DPS. However, the best available information does not support concluding that these impacts rise to the level of a threat, based on the insufficient evidence that ARs are resulting in significant impacts at either the population or rangewide scales (see Exposure to Toxicants, above).

(258) Comment: Some commenters stated that the use of anticoagulant rodenticides poses no risk to fishers because it occurs in urban and suburban areas. The commenters also stated that there has already been recent regulatory activity aimed at preventing wildlife exposures to rodenticide. They believed that more regulation of this kind is unwarranted and would result in harm to human health by preventing necessary pesticide application in urban areas.

Our Response: The illegal use of ARs is a stressor to fisher in certain portions of its range, as discussed in our draft and final Species Reports. The claim that use of ARs is limited to urban and suburban areas is not supported by the evidence (Gabriel et al. 2012, pp. 11–13), which suggests that AR contamination of fishers is widespread and not clustered around urban or suburban areas. However, based on the best available scientific and commercial information, we have determined the level of this stressor alone and in combination with other stressors does not rise to the level of a threat such that the proposed DPS meets the definition of an endangered or threatened species (see Exposure to Toxicants and Determination, above). Thus, we are withdrawing the proposed rule to list the DPS. As noted above, the Service does not have the authority to regulate the sale or use of ARs or other pesticides or toxicants.

(259) Comment: One commenter provided data from a wildlife rehabilitation hospital in San Rafael, California, which indicated that among carnivores treated by that organization in 2013–2014, 86 percent tested positive for exposure to anticoagulant rodenticides (although we note that the commenter did not provide a ratio of mortality to non-mortality for the carnivores tested). In some cases this was sublethal exposure, and in other cases the animal died from toxicosis. The commenter stated that ARs are becoming more common, that the use of anticoagulant rodenticides poses a significant threat to predatory wildlife, and that in concert with small population size, the presence of anticoagulant rodenticides is making the fisher more vulnerable to extinction.

Our Response: We agree that 86 percent of carnivores testing positive for exposure to anticoagulant rodenticides is a high proportion, and reflects widespread exposure to anticoagulant rodenticides from a number of sources, not only illegal marijuana growers. However, this is only 1 year of data. We are not aware of any studies that have tracked the prevalence of ARs in wildlife over a number of years. Records on the sale and use of rodenticides do not exist, so it is not possible to determine whether ARs are becoming more common.

Insufficient information exists regarding what level of exposure creates sublethal effects that may compromise an individual animal’s persistence. We agree that ARs currently pose a significant concern to predatory wildlife, as documented by a number of studies cited in the final Species Report. We find that although individual fishers within three populations (i.e., NCSO, SSN, and ONP) have been exposed to toxicants at sublethal levels with an unknown degree of impact to those individuals, there is a lack of information rangewide regarding potential sublethal effects of toxicants to fishers within the proposed DPS. Only 15 mortalities directly caused by toxicant exposure have been documented within the native California populations Gabriel et al. 2015, p. 5; Wengert 2016, pers. comm.). Insufficient information exists regarding the extent of AR exposure in Washington and Oregon, and no rangewide studies have occurred to evaluate the population-level impacts across the fisher’s range in the west coast States. Therefore, the best available information does not indicate that these impacts rise to the level of a threat, based on the insufficient evidence that ARs are resulting in significant impacts at either the population or rangewide scales.

(260) Comment: One commenter stated that the Service neither overstated nor understated the threat of toxicants to fishers in Washington.

Our Response: New information about rodenticide exposure to the fisher population in Washington documents that these fishers forsy a threat posed by legal uses, such as on information from public lands, where illegal marijuana grow sites are more common than they are on private lands. The commenter further noted that even on public lands, multiple studies have not observed a negative demographic response from fishers due to ARs (Higley and Matthews 2009, Swiers 2013, Zieliinski et al. 2013), and that multiple California agencies are beginning to implement regulations that will help decrease the impact of anticoagulant rodenticides (such as forest practice rules and water quality laws). The commenter recommended that the Service review information on ARs on both public and private lands to better understand the impacts on fishers.

Our Response: We agree that more data are needed to assess the threat to fisher populations posed by the use of ARs on private lands, including the threat posed by illegal uses, such as around homes, golf courses, agricultural buildings, and on information available,
including new information received, which enabled us to provide clarity and corrections in the final Species Report (Service 2016, pp. 141–159) to some information that was presented in the draft Species Report (Service 2014, pp. 152–169). Two fisher carcasses from Oregon have been tested for rodenticides, of which both tested positive, and only three fishers can be confidently documented to have been exposed to, but not killed by, ARs in Washington. Insufficient information exists regarding the extent of AR exposure in Washington and Oregon, and no rangewide studies have occurred to evaluate the population-level impacts across the fisher’s range in the west coast States. We note the lack of information rangewide regarding potential sublethal effects of ARs to fishers within the proposed West Coast DPS. At this time, we have determined that the best available information do not indicate significant impacts at either the population or rangewide scales (see Exposure to Toxicants, above). See also our response to Comment (261).

(263) Comment: One commenter believed the severity of the threat from ARs was understated in the draft Species Report and proposed listing rule and should be increased because: (1) The analysis does not account for rodenticide used to decrease vole and mountain beaver damage to conifer seedlings on some private lands in Oregon and Washington; (2) the effects on fisher prey from such application of rodenticides is unknown; and (3) information on AR use by private industrial landowners is lacking. Based on these factors, the commenter stated that the Service should use a more conservative conservative quantification of the contaminant impact to fishers, especially in areas of high proportions of private land ownership.

Alternatively, another commenter believed the threat from ARs was overstated in the draft Species Report and proposed rule, and that it was unprecedented for the Service to take such a major threat and state that it was affecting the species on a population level. The commenter stated that only 58 fishers total have been impacted by ARs per the draft Species Report, and added that pesticides in general are so ubiquitous in our environment that they would even be found in human livers.

Our Response: We agree that more data are needed to assess the threat to fisher populations posed by the use of ARs on private lands, including the threat posed by legal uses, such as around homes, golf courses, agricultural buildings, and in forestry. We have reviewed the best scientific and commercial information available, including new information received, which enabled us to provide clarity and corrections in the final Species Report (Service 2016, pp. 141–159) to some information that was presented in the draft Species Report (Service 2014, pp. 152–169). Unfortunately, no records exist on the quantities, locations, and use patterns for ARs applied on private lands. The extent to which the legal use of ARs occurs at agricultural and commercial sites within the range of the fisher is unknown. Two fisher carcasses from Oregon have been tested for rodenticides, of which both tested positive, and only three fishers can be confidently documented to have been exposed to, but not killed by, ARs in Washington. Insufficient information exists regarding the extent of AR exposure in Washington and Oregon, and no rangewide studies have occurred to evaluate the population-level impacts across the fisher’s range in the west coast States. We note the lack of information rangewide regarding potential sublethal effects of ARs to fishers within the proposed West Coast DPS.

In reference to the potential effects of ARs on fisher prey, Wengert (2015, pers. comm.) reports that rodent diversity is reduced to only mice at marijuana cultivation sites that are treated with rodenticides, as compared to nearby untreated sites where large-bodied rodents (e.g., woodrats, squirrels, chipmunks), which are the prey species that the fisher prefers, are found. This provides support for the possibility that prey depletion may be associated with predator home range expansion and resultant increase in energetic demands, as well as other indirect effects such as predator breeding, impaired reproduction, and starvation.

With regard to the second commenter’s assertions, Gabriel et al. (2015, p. 7) found that, between 2012 and 2014, AR exposure to fishers in two California populations has increased from 79 percent (46 of 58 individual fishers) to 85 percent (86 of 101 fishers). In addition, the draft (Service 2014, pp. 152–169) and final Species Reports (Service 2016, pp. 120–121) discuss the fact that for any contaminant, collection of dead or moribund individuals is likely to represent only a subset of the actual exposure or mortality attributable to that contaminant.

Overall, the best available information at this time does not support concluding that the impacts described herein rise to the level of a threat, based on the insufficient evidence that ARs or other toxicants are resulting in significant impacts at either the population or rangewide scales (see Exposure to Toxicants, above).

(264) Comment: Several commenters stated that fishers in Washington were at low risk from ARs because: (1)
Marijuana was legalized in Washington in 2012; (2) new information shows that Washington fishers found to have been exposed to rodenticides were animals translocated from British Columbia; and (3) the most recent fisher necropsy that detected levels of AR was from an animal that lived in close proximity to commercial and residential areas.

Our Response: New information about rodenticide exposure to the fisher population in Washington documents that three fishers found dead from other apparent causes were exposed to ARs in Washington. Two of these were mortalities among the translocated individuals on the Olympic Peninsula that tested positive for bromadiolone too long after their relocation from British Columbia to have been exposed there. These individuals were found near rural areas where rodenticides could have been used legally. The most recent fisher mortality testing positive for an AR was born to a translocated female, and was found on the border of the Port Angeles City Limits, surrounded by a low-density housing area and commercial development. Thus, AR impacts for the reintroduced ONP population site could be from legally applied sources. None of these were in the vicinity of a known marijuana grow site, and they were found near rural or suburban areas where rodenticides could have been used legally on private land. However, insufficient information exists to draw any further conclusions regarding the impact that this exposure is having, either on individuals or the Washington population. There is not yet sufficient information to conclude what the effects of legalizing marijuana will have on fishers, if any.

(265) Comment: One commenter concurred with the Service that ARs are an emerging threat, with the magnitude greatest in California but less in southern Oregon. However, a second commenter asserted that the best available information demonstrates that ARs pose a significant threat to fishers and their habitat, specifically stating that AR contamination is widespread throughout California, with the greatest exposure on fishers in the vicinity of a known marijuana grow site. The commenter stated that though ARs were present, the physiological effects of this level of exposure on fishers were not clear. The commenter provided an example of the statement in the draft Species Report that “primary poisoning cannot be completely ruled out,” further stating that they disagreed with that wording and that few factors can be completely ruled out as a threat for any species.

Our Response: The full sentence in the draft Species Report reads: “Though no fisher necropsies in California have detected AR bait products in the stomach or gastrointestinal tract, primary poisoning cannot be completely ruled out” (Gabriel et al. 2012a, p. 8)” (Service 2014, p. 159). The statement was made in the context of describing the ways that fishers could be exposed to ARs, and explains that the baits themselves could be attractive to fishers. We have reviewed the best scientific and commercial information available, including new information received, which enabled us to provide clarity and corrections in the final Species Report (Service 2016, pp. 141–159) to some information that was presented in the draft Species Report (Service 2014, pp. 152–169). Two fisher carcasses from Oregon have been tested for rodenticides, of which both tested positive, and only three fishers can be confidently documented to have been exposed in Washington. Insufficient information exists regarding the extent of AR exposure in Washington and Oregon, and no rangewide studies have occurred to evaluate the population-level impacts across the fisher’s range in the west coast States. Finally, there is also a lack of information rangewide regarding potential sublethal effects of ARs to fishers within the proposed West Coast DPS. Therefore, based on our final evaluation of all of the best scientific and commercial data available, we conclude that the impacts do not rise to the level of a threat, based on the insufficient evidence that ARs are having significant impacts at either the population or rangewide scales. (see Exposure To Toxicants, above). We also note that we used the best available data available for mammals, which is consistent with the data used to support pesticide registrations.

(268) Comment: One commenter stated that the sampling of fishers for rodenticide poisoning was not representative, as the sampling primarily occurred in two areas in California. The commenter also questioned the sampling methodology of only testing dead animals or others discovered fortuitously, rather than a random sample. Therefore, the commenter stated that the results from California should not be extrapolated to the proposed DPS as a whole.

Our Response: Section 4(b)(1)(A) of the Act requires the Service to use the best available scientific and commercial information in determining a species’ status under the Act. Testing for ARs requires sampling the liver, which
cannot be done on a live animal. Consequently, a random sampling methodology would require removing live animals from the population and euthanizing them before testing, which raises ethical concerns, particularly as we are in the early stages of trying to understand the magnitude and extent of AR presence. Although the collection of fisher carcasses for testing may not be a random sample, it is the best available information upon which to base our conclusion.

We have reviewed the best scientific and commercial information available, including new information received, which enabled us to provide clarity and corrections in the final Species Report (Service 2016, pp. 141–159) to some information that was presented in the draft Species Report (Service 2014, pp. 152–169). Two fisher carcasses from Oregon have been tested for rodenticides, of which both tested positive, and only three fishers can be confidently documented to have been exposed in Washington. Insufficient information exists regarding the extent of AR exposure in Washington and Oregon, and no rangewide studies have occurred to evaluate the population-level impacts across the fisher’s range in the west coast States. We note the lack of information rangewide regarding potential sublethal effects of ARs to fishers within the proposed West Coast DPS. Therefore, the best available information does not support concluding that these impacts rise to the level of a threat, based on the insufficient evidence that ARs are having significant impacts at either the population or rangewide scales (see Exposure To Toxicants, above).

[270] Comment: One commenter suggested adding the following information to the analysis of ARs: (1) Legal marijuana cultivation on remote private lands, and associated AR use; (2) off-label use of rodenticides; (3) the current ease of use of large quantities of rodenticides and second generation ARs; and (4) population-level effects of AR use.

Our Response: We have reviewed the best scientific and commercial information available, including new information received, which enabled us to provide clarity and corrections in the final Species Report (Service 2016, pp. 141–159) to some information that was presented in the draft Species Report (Service 2014, pp. 152–169). Unfortunately, no records exist on the quantities, locations, and use patterns for ARs applied on private lands. There are no rodenticide labels that allow application to marijuana as a crop, so any current use of rodenticides within a marijuana grow site would be illegal under State and Federal laws, even in States where marijuana is legal.

The extent to which the legal use of ARs occurs at agricultural and commercial sites within the range of the fisher is unknown. Two fisher carcasses from Oregon have been tested for rodenticides, of which both tested positive, and only three fishers can be confidently documented to have been exposed in Washington. None of these were in the vicinity of a known marijuana grow site, and the Washington fishers were found near rural areas where rodenticides could have been used legally on private land. While the State of California in 2014 prohibited the sale of the second generation ARs (brodifacoum, bromadiolone, difethialone, and difenacoum) to the general public, they are still widely available in California and can be purchased by anyone with a State-issued pesticide applicator’s license. No records are kept on the sale and use of rodenticides that can be used to determine whether this new measure will reduce the illegal and legal uses of the second generation ARs within the range of the fisher.

[272] Comment: One commenter stated that illegal marijuana growth should not impact fishers in Washington, as marijuana is not grown outdoors there due to a short growing season.

Our Response: As we noted in the draft Species Report (Service 2014, p. 167), most marijuana is thought to be grown outdoors in western Washington, but in eastern Washington it is thought to be grown outdoors. However, the principal source of exposure for fishers in Washington is still unknown (i.e., legal uses or illegal marijuana grows), as is the extent of exposure. Based on the information in Figure 21 of the draft Species Report (Service 2014, p. 167), as well as information received during the open comment periods on the proposed rule, we agree that the use of rodenticides at illegal marijuana grows is likely considerably less of a stressor in Washington than in other portions of the range.
impact from illegal marijuana growers. One commenter believed that this information was not fully considered by the Service in the draft Species Report.

Our Response: Legalization of recreational marijuana in Oregon was the result of a ballot initiative that was passed by the Oregon voters in November 2014. Because the proposed rule was published prior to the passage of this initiative into law, we could not address this issue in the proposed rule. We have incorporated a discussion of the recent legalization of recreational marijuana in Oregon with regard to its potential impacts on fisher in the final Species Report.

(274) Comment: Two commenters noted that many of the rodenticides detected in fishers are not labeled for legal use in forestry operations. As an example, the commenters noted that Rozol, a rodenticide labeled for forestry use in Oregon, was only found in four of the fishers tested by Gabriel et al. (2012a). Based on that evidence, and on the stringently specific application requirements, the commenter found it highly unlikely that the legal use of Rozol to control mountain beavers could negatively impact fisher populations.

Our Response: There is not sufficient evidence to determine whether or not legal use of Rozol in forestry applications will affect fisher populations. The Rozol application described by the commenter (application of Rozol pellets to control mountain beavers in forest plantations) is limited to western Oregon and western Washington under a special local need label. We do not know to what degree the anticoagulant in the Rozol product (chlorophacinone) may affect fishers in Oregon because to date only two fishers from Oregon have been tested for the presence of anticoagulants, both of which tested positive for anticoagulant residue; both carcasses were tested for chlorophacinone, but it was not detected. In Washington, where Rozol application is also legal, 13 fishers have been tested for anticoagulant rodenticides, but none showed the presence of chlorophacinone. The sample sizes from Oregon and Washington are too small to satisfactorily conclude that Rozol application does not affect fishers.

The fishers tested by Gabriel et al. (2012a, p. 5), as referenced by the commenter, were fisher carcasses found in California, where the application of Rozol pellets to control mountain beavers is registered to control voles in forestry plantations, and the State also makes its own chlorophacinone baits that can be used to control a number of rodent species in forestry plantations. It is, therefore, possible that these legal uses of chlorophacinone could have been a source of the chlorophacinone detected in the four fishers that tested positive for chlorophacinone in California. Thus, we cannot use fisher toxicant results from California, where control of mountain beavers by Rozol is not legal, to conclude that Rozol application in Oregon or Washington specifically to control mountain beavers in forestry plantations is not likely to affect fishers.

We do note that the special local need label for Rozol pellets requires application designed to reduce the exposure of the product to nontarget species such as fisher (e.g., seasonal restrictions and placement of bait underground within beaver holes or burrows). However, fishers may still be exposed to the toxin because contaminated mountain beavers can still be active for several days after exposure. Mountain beavers are known prey for fishers in western Washington, and their range overlaps that of fishers in Oregon. As such, we cannot agree with the commenter’s conclusion that it is highly unlikely that use of Rozol for mountain beaver control will negatively impact fishers, as there is not yet enough information to support their claim.

(275) Comment: One commenter stated that over 35 percent of male fishers in the Hoopa Valley study area have died due to toxicosis. The commenter reasons that these deaths, in combination with habitat fragmentation, will make it difficult for fishers to find mates and reproduce.

Our Response: We have included new information in the “Synergistic Effects” section of the final Species Report (Service 2016, p. 161) that long-term studies on the Hoopa Valley Tribal Reservation report a toxicosis rate in male fishers of 35 percent from 2005–2012, which may be contributing to a decline in male fisher survival in that area over the same time period (Higley 2014, pers comm.). Although the biologist presenting the information mentioned the possibility that a reduction in the number of male fishers in combination with habitat fragmentation may result in fewer matings, he did not elaborate on the remark and did not provide evidence to support his assertion. The presenter in the video also did not posit a possible relationship between the male fisher toxicosis-related mortality rate and habitat fragmentation. We cannot explain how this combination of stressors would reduce fisher reproduction in an additive or synergistic manner. Based on the best available scientific information, we conclude that there is no direct evidence suggesting that a combination of a greater than 35 percent toxicosis-related mortality rate for male fishers and habitat fragmentation would make it difficult for fishers to find mates and reproduce within the Hoopa Valley Reservation.

(276) Comment: One commenter stated that fisher mortality due to AR use at illegal marijuana grow sites has occurred in close proximity to Redwood National and State Parks (RNSP), and that some fisher mortality in the RNSP may also have been due to the same factor. The commenter provided information on one case where a fisher was found dead at an illegal grow site within the boundaries of RNSP. In that case, the condition of the fisher prevented testing for AR exposure, although bite marks on the skull were suggestive of predation as the ultimate cause of death. The commenter suggested that predation may increase synergistically when fishers are exposed to ARs, and expressed the opinion that there is a high likelihood that additional fisher mortality will occur from rodenticide use adjacent to RNSP.

Our Response: We noted in the draft Species Report (citing Gabriel et al. 2012a, “Exposure to Toxicants” section)) that the relationship of AR concentration found in fishers and rate of fisher mortality is unknown. However, since then, Sweitzer et al. (2015b, p. 9) observed reduced fisher survival that may be a result of secondary exposure to toxicants used in marijuana grow sites, although they could not make a direct link. We agree that exposure to ARs may predispose fishers to predation due to the known physically debilitating effects of ARs on fishers and other mammals, and note that sublethal AR exposure may also combine with other stressors to have additive or synergistic adverse effects (citing Golden et al. 2012). We agree with the commenter that AR exposure may make fishers more vulnerable to predation, but currently lack adequate information to suggest whether exposure actually increases fisher predation rates. We also agree that fisher mortalities are likely to occur in the future as a result of ingesting lethal levels of ARs and possibly through accumulation of sublethal levels of ARs in combination with other stressors. However, information is currently lacking to estimate the probability of additional fisher mortalities in the future within or near RNSP.

(277) Comment: One commenter stated that rodenticides have not caused...
fisher declines on some private forestlands in Mendocino County, but that they could pose a threat to any fishers attempting to recolonize the areas. The commenter stated that in the past decade, employees of those forestlands have observed an increase in wildlife exposure to ARs used at illegal marijuana grow sites. The commenter also stated that the managers of these forestlands are concerned with the impacts of illegal AR use, and would like to work collaboratively with the Federal Government and other land managers to assess the problem and ameliorate the issue.

Our Response: We are not aware of any data regarding the populations of fishers on private forestlands in Mendocino County before and after the recent increasing trend in illegal marijuana grow sites. Based on information presented in the proposed rule (79 FR 60419) and the draft Species Report, we agree with the commenter that ARs are a management concern and look forward to working with the landowner and other land managers to assess the problem and ameliorate the issue.

(278) Comment: One commenter believed that the Service’s map showing illegal marijuana grow sites was misleading because it showed illegal marijuana grow sites to be widely dispersed across the landscape. The commenter stated that most illegal grow sites were found in close proximity to freeways, rather than deeper in forests where fishers live. The commenter also stated that only six illegal marijuana grow sites were found on public lands in Humboldt County.

Our Response: These comments were made during a November 17, 2014, public hearing in Redding, California, after we displayed a map of illegal marijuana grow sites prepared by the Service for the hearing. The commenter was providing his personal opinion and did not provide information to support his claim that illegal marijuana grow sites were mostly clustered along freeways and not within areas occupied by fishers. The commenter also did not provide information supporting his claim regarding the number of illegal grow sites found in Humboldt County in 2013. Information presented in the Exposure to Toxicants section of the draft Species Report (citing Thompson et al. 2014 and Gabriel et al. 2012a) shows that AR exposure in fishers in California is widespread, with residues found in 84 percent of fisher carcasses tested. Further, the commenter’s claim that fishers are clustered around freeways is contradicted by a spatial analysis of AR exposure of fishers in California conducted by Gabriel et al. (2012a, entire), which suggested that exposure of fishers to ARs was from a widespread use of ARs across the landscape. Figure 19 in the draft and final Species Reports (Service 2014, p. 156; Service 2016, p. 146; source information from Higley et al. 2013) shows dozens of known marijuana cultivation sites in Humboldt County in 2010 and 2011. Further, only a fraction of illegal grow sites are detected by law enforcement, suggesting many more exist than are displayed in Figure 19. We are unaware of any information that would lead us to conclude that the number of cultivation sites in Humboldt County was reduced from dozens in 2010 and 2011 to only six in 2013. Therefore, the best available information suggests that: (1) Marijuana cultivation sites are distributed across the landscape and occur within suitable fisher habitat, and are not clustered around freeways outside of suitable fisher habitat; and (2) the number of illegal marijuana cultivation sites in Humboldt County in 2013 is not substantially different from the years for which we had data (2010 and 2011).

(279) Comment: One commenter stated that Figure 19 in the draft Species Report was misleading, as the dots on the map are buffered by a 2.5-mi (4,000-m) radius to approximate the hypothetical home range of a male fisher. The commenter believed that this map leads to an overstatement of the threat of ARs from illegal marijuana grow sites, as it does not account for the fact that multiple female fishers will be found within an area of that size. The commenter stated that because female fishers are unlikely to cross another female’s territory, they might never encounter an illegal marijuana grow site.

Our Response: We agree with the commenter that the scope of toxicant exposure is too high. Our method for determining the scope of toxicant exposure to fishers may be decreasing, and moving instead to indoor operations. Based on Forest Service estimates of the size of illegal marijuana trespass sites and the number of sites eradicated, the commenter stated that it appears that only 2 percent of fisher habitat on Forest Service lands in California has been impacted by illegal marijuana cultivation, and although the effects of toxicants extend beyond these areas, the scope of 23 to 95 percent for California given in the draft Species Report is too high.

Our Response: We disagree with the commenter that the scope of toxicant exposure is too high. Our method for determining the scope of toxicant exposure to fishers may be decreasing, and moving instead to indoor operations. Based on Forest Service estimates of the size of illegal marijuana trespass sites and the number of sites eradicated, the commenter stated that it appears that only 2 percent of fisher habitat on Forest Service lands in California has been impacted by illegal marijuana cultivation, and although the effects of toxicants extend beyond these areas, the scope of 23 to 95 percent for California given in the draft Species Report is too high.

Our Response: We disagree with the commenter that the scope of toxicant exposure is too high. Our method for determining the scope of toxicant exposure to fishers may be decreasing, and moving instead to indoor operations. Based on Forest Service estimates of the size of illegal marijuana trespass sites and the number of sites eradicated, the commenter stated that it appears that only 2 percent of fisher habitat on Forest Service lands in California has been impacted by illegal marijuana cultivation, and although the effects of toxicants extend beyond these areas, the scope of 23 to 95 percent for California given in the draft Species Report is too high.
a greater degree because the total amount of habitat destroyed by illegal marijuana trespass sites is typically not reported. Further, we have not received any new information regarding annual trends in law enforcement effort to survey for illegal trespass cultivation sites, nor information on the total number of sites located each year. For the reasons we have discussed in the “Exposure to Toxictants” section of the final Species Report (Service 2016, pp. 141–159), we agree that the effects of toxictants extend beyond the actual area where they are found. In addition, we caution that many eradicated sites have not been remediated (toxictants have been removed from the environment). Therefore, we disagree with the commenter and conclude that in California, a broad range of scope (from low to high) is supported by the data that we have received to date. Although our overall conclusion about this stressor has changed (i.e., toxictants are not resulting in significant impacts at either the population or rangewide scales), we have not received any new information that would change our estimates of the scope of this stressor as that outlined in the draft Species Report.

(282) Comment: One commenter believed that the best available scientific data demonstrated that the scope and scale of the impacts of marijuana cultivation on the fisher are significant and shows no systematic decrease. The commenter provided a reference to Bauer (2015) to support this statement. We agree that Bauer (2015) supports the conclusion that the impacts of marijuana cultivation on northwestern California forested ecosystems are significant, especially with respect to the effects of water withdrawal on streamflow in creeks and rivers. However, we disagree that this article supports the conclusion that the impacts of marijuana cultivation on the fisher show no systematic decrease. Indeed, with regard to effects on wildlife, the article states: “Though these impacts have been documented by state and Federal agencies, the extent to which they affect sensitive fish and wildlife species and their habitat has not been quantified (Bauer 2015, p. 2).” On the other hand, Gabriel et al. (2015, p. 7) found that, between 2012 and 2014, exposure of fishers to toxictants in California has increased from 79 percent (46 of 58 individuals tested) to 85 percent (86 of 101 individuals tested), although the sample size is small. Thus, the data we have does not support a conclusion that there has been a systematic decrease in the scope and scale of the impacts of marijuana cultivation on fishers. However, we note the uncertainty as to the severity of impact that this stressor may have rangewide, given data are minimal across Oregon and Washington in particular, including the lack of information rangewide regarding potential sublethal effects of toxictants to fishers (i.e., we only have information on 15 mortalities rangewide). Therefore, the best available information does not indicate that these impacts rise to the level of a threat, based on the insufficient evidence that ARs are functioning as an operative threat on the fisher such that significant impacts are occurring at either the population or rangewide scales.

(283) Comment: One commenter stated that DDT and DDE had been previously found at illegal marijuana cultivation sites, but did not provide any further data about use of those pesticides.

Our Response: Table 10 in the final Species Report (Service 2016, pp. 153–155) lists the pesticides found on marijuana cultivation sites and specifies which are currently registered in the United States. Among those not registered for use in the United States are azinphos methyl, methamidophos, methyl parathion, and DDT. There are no rodenticide labels that allow application to marijuana as a crop; thus, any use of rodenticides within a marijuana grow would be illegal under State and Federal laws, regardless of whether marijuana is legal in that State.

(284) Comment: One commenter stated that the threat from illegal marijuana growers was overstated in the draft Species Report and proposed rule due to the increase in legal medical marijuana in California, Oregon, and Washington. Based on this legalization, the commenter believed that the drug cartels are less interested in growing marijuana on Federal lands, as legal growing of marijuana is now possible for some growers on private property. The commenter concluded that the impacts of ARs from illegal marijuana growers is short-term and on a rapid and measurable decline, as demonstrated in the draft Species Report and the decline in sites from the 2010 to 2011 maps. This commenter stated that they are working on a report related to the illegal growing of marijuana on Federal lands.

Our Response: Please see our response to Comment (281). We are not aware of any information documenting the decline of trespass marijuana sites as a result of the legalization of marijuana, including related to the U.S. Forest Service Law Enforcement Managing and Reporting System Database. The commenter stated that this information represented the best available scientific data on this matter, and that not using this data would make the analysis of scope and severity very speculative.

(285) Comment: Two commenters believed that the threat from illegal marijuana growers was overstated. One commenter pointed to publicly available information relating to the Forest Service (Region 5), which shows a 70 percent decline statewide in California of illegal marijuana grow sites from 2009 to 2013, and an estimate that successful Statewide raids of illegal grower sites is down 83 percent in 2014. Another commenter referred to a private communication with the Forest Service, which stated that the number of illegal marijuana plants seized on public lands in California declined by approximately 88 percent between 2009 and 2014.

Our Response: The commenters provide no information on the amount of survey effort for the years for which they are reporting declines in the number of plant seizures. Please see our response to Comment (281) regarding illegal marijuana grower information.

(286) Comment: One commenter believed that the Service’s analysis of ARs from illegal marijuana growers was incomplete, as it did not mention that the number of illegal marijuana grow sites is diminishing due to increased legalization of marijuana. The commenter suggested that the Service obtain information from the U.S. Forest Service Law Enforcement Managing and Reporting System Database. The commenter stated that this information represented the best available scientific data on this matter, and that not using this data would make the analysis of scope and severity very speculative.

Our Response: We are not aware of any information documenting the decline of trespass marijuana sites as a result of the legalization of marijuana, including related to the U.S. Forest Service Law Enforcement Managing and Reporting System Database. Please see our response to Comment (281).

Stressors

(287) Comment: The State of Washington proclaimed that the factors that affect the continued existence of fishers are not evenly distributed (noting that this is of greatest concern outside of Washington since the native population of the State was extirpated by the mid-1900s). With regards to the reintroduced population on the Olympic Peninsula, the commenter stated that it is exposed to numerous threats (e.g., illegal trapping, vehicle collisions, predation, disease, toxictants); however, this reintroduced population’s most significant threat may be its relatively small size. The commenter noted that historical and current information related to small population size impacts in Washington is not
known, yet the commenter also stated that ongoing monitoring indicates that the population is widely distributed and reproducing. The commenter expressed significant concern that a Federal listing may preclude the ability of the State to conduct further reintroductions, thus eliminating the most significant, beneficial action that can be taken to address threat of small population size.

Our Response: We agree with the State of Washington that stressors are not evenly distributed in the analysis area, as clearly stated in both our draft Species Report and our proposed rule. We disagree that a Federal listing of fishers in Washington would preclude the ability of the State to conduct further reintroductions; there are numerous examples of threatened and endangered species that have been reintroduced. We acknowledge there may be greater support for reintroductions if that effort is not accompanied by real or perceived regulatory burdens that may come with a Federal listing under the Act. However, such considerations cannot enter into our determination (see our response to Comment (122), above).

Regardless, based on our evaluation of the best scientific and commercial data available, we have concluded that the proposed West Coast DPS of fisher does not meet the Act’s definition of an endangered or threatened species throughout all or a significant portion of its range; therefore, we are withdrawing the proposed rule to list (see Determination, above). Conservation efforts by WDFW for fishers in Washington, including reintroductions, are, therefore, expected to continue unaffected by this rulemaking.

(288) Comment: The State of Oregon disagrees with the Service’s “overarching concern” to list the taxon based on a small and isolated nature of fisher populations, indicating that there is a lack of information on which to base this decision. The State also disagreed with the Service’s assumption that fisher are absent from the Oregon Cascades given they believe this determination without dedicated surveys following a peer-reviewed protocol is not reliable. The State asserted that it is possible that fisher occur at low population levels in portions of their range where they are presumed to be extirpated. Also, the State claimed that the Service may have overstated the uncertainty about the size of the NCSO population in the draft Species Report (i.e., range of 258–4,018 animals ([Service 2014, p. 39]) because the lower estimate comes from a study that examined genetic isolation in fisher using a technique that may be unreliable for estimating population size for management purposes, while the remaining references come from the “gray” literature and are either unpublished studies or personal communication. Overall, the State maintained that listing the fisher as a federally protected species/DPS is premature without additional research demonstrating the NCSO population is in decline and confirmation that fisher has been extirpated from the northern portion of the Oregon Cascades.

Our Response: The Act directs us to use the best scientific and commercial information available when determining whether a species is threatened or endangered. Regarding our “assumption” that fishers are absent from the Oregon Cascades, we do acknowledge their presence in the southern Cascades. We reference Aubry and Lewis (2003, p. 85), a peer-reviewed resource, who reviewed all known fisher occurrence records in Oregon. The authors also compiled information from standardized surveys, mostly based on sampling techniques recommended by Zielinski et al. (1995) and conducted in areas where fishers were historically reported. The authors concluded that, outside of the southern Cascades and southwest Oregon, fishers “appear to have been extirpated from all other portions of their presumed historical range in Oregon.” Although updated surveys in the central and northern Oregon Cascades would give us a more robust handle on fisher distributions, we described the known distribution of fishers based on the best available scientific and commercial data.

Regarding our description of the size of the NCSO population in the draft Species Report, we agree that the lower estimate of 258 is calculated from an effective population size based on genetic data. We include this information to represent the best scientific and commercial data available and to indicate the breadth of the range of values available to us on which to base our listing decision. We also have revised our final Species Report to include new population estimate values (Service 2016, pp. 42–48). We realize the remaining references do not come from peer-reviewed literature, but again, this is the best available information, which the Act requires us to use in making our listing decision.

We have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the proposed West Coast DPS of the fisher and are withdrawing our proposal to list this DPS (see Determination, above). We reached this conclusion in part because we have no evidence to suggest that any of the potential stressors are having significant impacts at either the population or rangewide scales (see Summary of Factors Affecting the Species, above).

(289) Comment: Many commenters agreed with the Service’s analysis regarding stressors affecting the threats that are impacting the fisher, including trapping, logging, wildfire, climate change, and rodenticides. The following are representative comments. One commenter proclaimed that logging of fisher habitat as well as road kill, disease, and other human-related impacts to fisher are what continues to contribute to decline of fishers across its range. A second commenter declared that fishers have declined dramatically in recent decades specifically due to trapping, logging, and wildfire (this commenter and another declared that the SSN population faces imminent extinction from threats). Two more commenters asserted that the species across its entire range necessitates listing as endangered primarily due to the small size and isolation of the remaining populations, as well as continued habitat loss from logging and development, and that the Service should ensure that the final listing rule limits mortality of fishers to the greatest extent possible. A fifth commenter stated that short-term impacts to fishers from logging and human-associated noise are likely causing behavior changes and negative impacts to fisher prey species. A sixth commenter asserted that small population size impacts are so significant that there is a low likelihood that the populations would expand other than through reintroduction efforts (as demonstrated by the SOC population that has been in place for 30 years with no apparent increase in size beyond the reintroduction area). A seventh commenter explicitly attributed past and present logging activities as the primary, significant threat to the fisher and its habitat, noting salvage logging on non-Federal lands in California as an impact that is poorly regulated and inadequately monitored.

In contrast, several commenters declare that the analysis of stressors in the proposed rule and draft Species Report overestimated actual impacts. One commenter asserted that the Service’s threats analysis overestimated the level of impact specifically in the southern Oregon and northern California region. Another commenter claimed that the three primary threats identified by the Service (habitat loss, toxicants, and cumulative and synergistic effects) are diminishing
impacts that are not resulting in population-level effects, thus demonstrating why the fisher is not in need of listing under the Act. A third commenter stated that there is no immediacy of the threats described in the proposed rule to necessitate listing the species as threatened or endangered, in part because there are no population-level effects, including within the NCSO and SSN populations.

Our Response: We appreciate the comments from those in support of and those with concerns regarding our analysis of stressors. The analysis of stressors is complex and takes into consideration such factors as timing, scope, and severity of stressors potentially acting on the proposed West Coast DPS of fisher using the best available scientific and commercial information. After review of new information and comments received during both the comment periods, as well as information used for the proposed rule, the best available information does not support concluding that the stressors individually or in combination, have a significant impact at the population or rangewide scales. Consequently, we have determined that the proposed West Coast DPS of fishers is neither threatened or endangered under the Act and are withdrawing our proposal to list this DPS (see Determination, above). We will continue to monitor the status of fishers and their habitat as we develop management strategies and work toward the conservation of fisher throughout its range.

(290) Comment: One commenter claimed that dichlorodiphenyltrichloroethane (DDT) and dichlorodiphenyldichloroethylene (DDE) are two chemicals/pesticides that are likely impacting fishers and other non-targeted species, and as such should be considered as part of the threats analysis.

Our Response: Evaluating the impacts of pesticide exposures on free-ranging wildlife can be difficult and is often limited to carcass counts in the field and detection of pesticides in postmortem samples, which primarily reflect acute intoxications. Unlike the information on ARs, such exposures of DDT are not documented in fishers, and their use in marijuana grow sites has been extremely limited (Service 2016, Table 10). Please see our response to Comment (283).

(291) Comment: One commenter declared that the Service implied (in the draft Species Report) that all stressors result in a negative effect on fishers or fisher habitat, and considered this viewpoint to be invalid because changes to natural or man-made habitat do not always result in negative effects to species. The commenter discussed wildfire and timber harvest as two examples to articulate their point, stating that wildfire and timber harvest can create habitat loss and concurrently create a heterogeneous landscape that benefits fisher prey species, and that can also (in the case of wildfire) create snags and down wood that facilitates prey, and provides denning and resting habitat.

Our Response: Please see our response to Comment (97).

Synergistic (Cumulative) Effects

(292) Comment: One commenter asserted that the synergistic impacts of climate change and fire behavior pose the most serious long-term threat specifically to the California populations, and, accordingly, listing is warranted. Another commenter highlighted synergistic habitat impacts across the entire range of the taxon (as proposed) as a significant concern due to multiple ongoing or future project impacts in conjunction with past habitat loss, noting that these impacts to already small and isolated fisher populations will likely further impair the survival and recovery of the proposed West Coast DPS of fisher.

Our Response: Please see our response to Comment (1).

(293) Comment: One commenter highlighted the information in the draft Species Report concerning studies that look at larger areas where wildfire and rodenticides are present. The commenter asserted that there was no decline in fisher populations despite surveys of a larger area. The commenter requested that we make this information more prominent by including it in the executive summary of the final Species Report.

Our Response: The draft and final Species Reports first review stressors individually, including wildfire and exposure to toxicants, and then consider whether these stressors act cumulatively or synergistically to determine if the proposed West Coast DPS of fisher meets the definition of an endangered or threatened species according to the Act. At this time, the best available information do not indicate that these stressors, by themselves or acting cumulatively or synergistically with other stressors on small populations, are resulting in significant impacts at either the population or rangewide scales. Therefore, based on our assessment of the best scientific and commercial data available, we have concluded that the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act, and we are withdrawing our proposed rule. While neither the draft nor final Species Report has an executive summary, this information is summarized in the Executive Summary, above.

Threatened Versus Endangered

(294) Comment: Many commenters urged the Service to list the proposed West Coast DPS of fisher as an endangered species because no reason was given, or based on a rationale such as limited distribution, isolated population, declining populations, questions about the success of a newly reintroduced population, rodenticides, or loss of historical habitat. Many other commenters urged the Service to list the taxon as a threatened species with no reason given, or based on a rationale such as significant threats to its survival (e.g., declining population numbers) and conservation, and ongoing threats (most commonly referencing degradation and loss of late-successional forests via logging activities, and to a lesser extent trapping, rodenticides, wildfire, road kill, or small/fragmented populations). In contrast, other commenters urged the Service not to list the taxon because they believed the populations to be stable or increasing, that there is significant suitable habitat available both currently and in the future, recovery efforts have occurred or are ongoing, robust State and Federal regulatory frameworks exist for the taxon’s long-term protection, or they claimed the proposed listing was based on uncertainty or was speculative.

Our Response: Sections 3(6) and 3(20) of the Act, respectively, define an endangered species as one that is in danger of extinction throughout all or a significant portion of its range, and a threatened species as one that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. Our task in evaluating a species for a potential listing under the Act is to determine whether that species meets the definition of either a threatened species or an endangered species, based solely on the best scientific and commercial data available. For this reason, comments merely expressing support for or opposition to a proposed listing, without supporting scientific rationale or data, do not meet the standard of information required by section 4(b)(1)(A) of the Act. At this time the best available information does not meet the criteria for a potential listing.
combination, based on the insufficient evidence that these stressors are having significant impacts at either the population or rangewide scales. We, therefore, have no scientific information to suggest that fishers in the proposed West Coast DPS are currently in danger of extinction, or likely to become so within the foreseeable future. For all of these reasons and as detailed in the Determination section of this document, we now conclude that the proposed West Coast DPS of fisher does not meet the definition of an endangered or threatened species under the Act, and we are withdrawing our proposed rule.

Trapping

(295) Comment: The State of Washington and several other commenters claimed that we underestimated the severity of trapping as a stressor in the draft Species Report and proposed rule, describing this impact as one that the Service previously recognized as a significant threat. The State claimed that there is a higher likelihood of incidental captures in Oregon given: (1) The legal use of leg-hold and body gripping traps, (2) the likely less than 100 percent reporting of incidental captures, (3) the potential for poaching of fishers with higher current pelt prices, and (4) probability of incidental captures of fishers in southwestern Oregon in the late 1980s and 1990s as reported from other unpublished observations (e.g., J. Lewis (WDFW) and K. Aubry (Forest Service)). Additionally, the State claimed that the severity of trapping as a stressor in coastal Washington and in California may be underestimated because of the potential for fishers to be injured when captured in a box/cage-type trap, the less than 100 percent reporting of incidental captures, and the possibility of poaching especially with the higher current pelt prices. Overall, the State asserted that a severity value of less than 1 percent is too low for the risks that exist in southwestern Oregon, and indicated that 5 to 10 percent may be more appropriate for Oregon and up to 5 percent for coastal Washington.

Alternatively, two other commenters stated that the severity of trapping is low and agreed with our assessment. One commenter asserted that trapping prohibitions have sufficiently reduced the effects of trapping as a stressor. The other commenter, a tribe in Washington, indicated that the threat of trapping is largely nonexistent in Washington (and specifically for the reintroduced population) because leg-hold and kill traps are not legal for use in Washington for general hunting/trapping. Although tribes can still authorize trapping for fur-bearers, they suggested that it is regulated appropriately and has low participation.

Our Response: See our response to Comment (161) for Washington. In addition, this response applies to Oregon [and California] as well. See our response to Comment (297).

(296) Comment: One commenter asserted that historical trapping activities for fur-bearing animals were the primary reason for fisher population declines, as opposed to old-growth forest loss, which the draft Species Report and proposed rule imply was a greater concern. The commenter believed that this piece of history (i.e., the idea that the British Crown directed trapping throughout Idaho, Oregon, and Washington to discourage American settlers from coming into this area) should not be overlooked when describing why fisher numbers are lower today compared to the past.

Our Response: We do not disagree that historical trapping likely played a key role in fisher population declines, as opposed to old-growth forest loss. We disagree with our conclusion that incidental trapping and poaching are not impacts to the taxon and requested that we reconsider our conclusion for the final rule.

Our Response: The draft Species Report determined the severity of trapping, including incidental trapping and poaching, to be very low in Washington and California and infrequent in Oregon (Service 2014, p. 112). Information received during public and peer review comment periods provided data on the incidental capture of two fishers reintroduced to the Olympic Peninsula in Washington. This information is consistent with our determination that incidental trapping is very low in Washington. We have updated the final Species Report with this new information; however, our conclusion regarding stressors associated with trapping has not changed. Based on our evaluation of the best scientific and commercial data available, we see no evidence that trapping is resulting in significant impacts to fishers at either the population or rangewide scales, such that we would consider trapping to pose a threat to the proposed West Coast DPS (see Trapping and Incidental Capture, above).

Wildfire

(298) Comment: One commenter cited Hanson (2013) as the best available science for potential impacts of fire on fisher and its habitat. Specifically, the commenter stated that fisher do not categorically avoid large, mixed-severity fire areas, particularly given these types of fires create "essential aspects of fisher habitat."

Our Response: Our draft and final Species Report includes a discussion of Hanson’s (2013, entire) observations of fisher use of burned areas in the southern Sierra Nevada. We agree that fishers likely use burned landscapes to varying degrees depending upon the presence of necessary habitat elements and structures for fisher foraging, denning, and resting. We received multiple comments on this subject, and have updated the final Species Report to include an expanded discussion of fisher use of burned landscapes, including any new information that has become available (Service 2016, pp. 62–77).

(299) Comment: One commenter stated that addressing the risk of catastrophic wildfire should be a higher priority than conservation of any particular species. We interpret the commenter’s various statements to imply that listing the fisher, particularly in the Sierra Nevada, should not occur, but that efforts should instead focus on wildfire prevention due to fire impacts that result in a landscape where “nothing survives.”

In contrast, multiple commenters stated that wildfire is not a significant issue or threat. One commenter stated that (in California) fewer acreage has burned in the past 5 years as compared to the previous 5 years, those fires that do occur are mostly a mosaic of high- and low-intensity burns, and the fires create more fisher habitat (e.g., prey habitat, denning or nesting structures) than what may be destroyed, thus setting the stage for better fisher habitat in the future. Five of the commenters articulated that the Species Report mischaracterizes, in general, the benefits of fire (or makes unsupported assumptions about fishers and fire). Several commenters asserted that fire plays a key role in creating prey foraging habitat (which can be enhanced by high-intensity fires (Hanson 2013) that can increase prey abundance) and denning/resting structures for fisher. One commenter also asserted that 20,000 acres of their lands experienced a 2008 catastrophic wildfire, which they subsequently salvage logged and later (in 2010) documented a fisher natal den inside the salvaged area (2 years after the fire and 1 year after salvage logging).

Our Response: While we understand that catastrophic, or stand-replacing, fire may impact more than one particular species and that the first commenter believes this issue should be addressed...
first, the purpose of this document is to assess the conservation status of fisher as required under the Act.

Fires over the last 5 years (2010 through 2014) in California did burn fewer acres than in the previous 5 years (2005 through 2009); however, extreme fire activity in 2008 was responsible for a large majority of acres burned. A more appropriate comparison would be to view a given year against a 5-year average to determine whether fire activity has increased or decreased. For example, California wildfires burned approximately 308,000 acres in 2015 (http://cdfdata.fire.ca.gov/incidents/incidents_stats?year=2015). When compared to the 5-year average of 110,000 acres burned (http://cdfdata.fire.ca.gov/incidents/incidents_stats?year=2015), 2015 was a year of increased fire activity in California.

Fire can have either a negative or positive effect on fisher habitat, depending on the specifics of the situation; many variables enter into the final outcome with respect to potential habitat suitability for fisher, and additionally the post-fire landscape may vary in suitability for fishers depending on the aspect of fisher life history under consideration (e.g., denning or resting versus foraging or movement). We understand that fire can create fisher habitat and that fishers have been documented in burned landscapes. We have incorporated all additional information submitted during the comment periods into our final Species Report, where we provide an expanded discussion on this topic (please also see our responses to Comments (87), (105), and (298).

(301) Comment: One local government expressed concern that species typically become listed under the Act after fire burns the landscape. We interpret the commenter’s remarks to imply that fisher may be listed under the Act specifically due to the recent impacts to fisher habitat following the recent 2007 Moonlight, 2012 Chips, 2013 Rim, and 2013 Aspen fires. The commenter stated that listing the fisher would preclude appropriate management for restoration, thus increasing the risk of, and noted that 90 percent of burned areas are not salvaged and reforested due to concerns about black-backed woodpecker habitat, thus converting the once suitable fisher forested habitat to brush ecotypes.

Our Response: The effect of fire on fishers and fisher habitat was one of the many potential stressors evaluated in our review of the status of the proposed West Coast DPS of fisher. At this time, the best available information does not support concluding that the stressors to fishers rise to the level of a threat, either singly or considered in combination, based on the insufficient evidence that these stressors are having significant impacts at either the population or range-wide scales currently or in the foreseeable future; this evaluation includes the consideration of fire as a stressor. Based on our review of the all of the best scientific and commercial information available, we have determined that the fisher does not meet the definition of an endangered or a threatened species and consequently have withdrawn the proposed rule to list the species (see Determination, above).

(302) Comment: One commenter disagreed with our assumption in the draft Species Report and proposed rule that high-intensity burns will increase, stating that calculations do not account for some other important potential sources of variation that would likely reduce the calculated values for scope and severity into the foreseeable future. For example, the commenter asserted that the increasing effect of continued forest management on Federal lands in both the NCFC and SSH population areas is designed to reduce the intensity of wildfire, including multiple fuels reduction projects at various stages of planning and implementation, thus helping prevent the taxon from potentially becoming an endangered species in the foreseeable future. The commenter stated that because the scope and severity estimates for wildfire are fairly small, balancing these values against the beneficial forest management activities would likely reduce the stressor of wildfire to a level of near insignificance. The commenter requested that the Service balance the projected effects of wildfire with a thorough analysis of the potential for ongoing and future vegetation management.

Our Response: The draft Species Report provided individual analyses of the potential effects of wildfire and vegetation management stressors on fisher and fisher habitat (Service 2014, pp. 58–72, 85–96). We recognize that vegetation management may result in...
reduced fire severity and appreciate the examples of planned or ongoing efforts by Federal agencies to accomplish fuels reduction projects. We have expanded our discussion of this topic in our final Species Report, including specific consideration of various fuels treatment projects that may ameliorate the effect of future wildfires throughout the analysis area (Service 2016, pp 62–77).

(304) Comment: One commenter urged the Service to consider the tradeoffs of mechanical treatments of fisher habitat to reduce fire severity given that fisher avoid areas of mechanical treatments. The commenter also stated that mechanical treatments may not be effective to retain fisher habitat because treated areas can still burn at high severity.

Our Response: We recognize that there are tradeoffs when otherwise suitable fisher habitat is treated to minimize the potential for fire risk. Depending upon the mechanical treatment, there may be short-term reductions in suitability (e.g., alterations to prey habitat); however, these treatments can also result in long-term benefits to fisher habitat (e.g., minimize risk of stand-replacing fire). We also understand that treated areas may still burn at low, moderate, and/or high severity levels, related to a variety of factors including the spatial arrangement and type of treatments, forest type, and weather. We received some new information during our open comment periods specific to fisher use of areas that have experienced mechanical treatments to reduce fire risk, and incorporated this new information into our final Species Report (Garner 2013, entire).

(305) Comment: Two commenters stated that catastrophic fires, which remove fisher habitat, are unlikely to occur on their lands on the California coast. One commenter stated this to be true due to the natural fire regime, their forest management practices, and effective fire suppression, and also provided examples of recent low-severity fires to demonstrate their opinion. The second commenter asserted this to be true because of their management practices, the strong coastal influence, road infrastructure and readily available heavy equipment, as well as employee training.

Our Response: We thank the commenters for suggesting that fisher habitat in certain areas of the California coast may not be subject to the catastrophic fires occurring elsewhere in the NCSO subregion. As described in our final Species Report, there is great variability in both observed and projected fire starts, severity, size, and effectiveness of suppression capabilities across the range of the proposed West Coast DPS of fisher (Service 2016, pp. 62, 67–76).

(306) Comment: One local government maintained that the Service contradicted itself by claiming that loss of habitat by both wildfire and vegetation management is a threat to fishers. The commenter believed that this type of argument illustrates how the Act (and other environmental laws) destroy what they intend to preserve. The commenter noted that the Siskiyou County Board of Supervisors has declared an ongoing state of emergency due to the potential for catastrophic wildfire, thus implying that vegetation management is needed to address the current situation.

Our Response: We acknowledge the frustration expressed by the commenter. The term “vegetation management,” as used and defined in our draft Species Report, applied not only to management actions intended to reduce the risk of catastrophic wildfire, but also to various forms of timber harvest and other activities. We understand and agree that strategic vegetation management aimed at fuels reduction can minimize the potential for catastrophic, or stand-replacing, fire. However, not all forms of vegetation management (e.g., clearcuts, even-aged management) are beneficial to fishers or necessarily reduce the risks of stand-replacing fire. In our final Species Report, we have attempted to make a more clear distinction between the various forms of vegetation management that we assessed across the fisher’s range in the west coast States, and have addressed management aimed toward fuels reduction separately (Service 2016, pp. 68–69, 98–110).

(307) Comment: Three commenters stated that the Service’s analysis of wildfire is incomplete and improperly biased toward negative impacts.

• One commenter asserted fire is not a significant threat overall, and stated there is no sound science for the assumption in Naney et al. 2012 (as discussed in the draft Species Report) that high-intensity fires lead to permanent loss of conifer forest. The commenter asserted (with multiple supporting citations) that existing data strongly indicate vigorous conifer regeneration occurs after high-intensity fire and is not precluded by native shrub cover after fire. They suggested there could be type conversion in some circumstances (without supporting evidence), but cautioned against this speculation noting that “lagged effects of fires, as suggested by studies which would prevent that from happening and maintain structural diversity on the landscape.” Additionally, the commenter stated that the draft Species Report does not present meaningful context about current rates and patterns of fire in forests occupied by fisher populations. Specifically, the commenter alleged that current fires are heavily dominated by low- and moderate-intensity fire effects; fire intensity is not increasing; high-intensity fire rotation intervals are currently 600 to 1,000 years or more in the Sierra Nevada, Klamath/Siskiyou, and southern Cascades due to fire suppression, which is far longer than natural; and that high-intensity fire occurred historically at long rotation intervals (providing multiple citations for each).

• A second commenter stated that the Service fails to attribute the benefits of fire absent fire suppression. Specifically, the commenter stated that, while firebreaks and back-burning may be necessary to stop wildfires, and undeniably inflict impacts that would not accrue absent fire, such practices are, in almost all circumstances, designed to prevent a fire from growing even larger. The commenter suggested that the Service calculate the difference between acres burned and acres projected to burn absent wildfire suppression, and derive a net anthropogenic conservation benefit. The commenter believed that this additional analysis should account for fire management regimes, and explicitly contrast the fire suppression strategies of the ODF against those of the Forest Service. Absent this calculation, the commenter declared the Service’s wildfire suppression discussion is meaningless.

• The third commenter questions our reference to Powell and Zielinski (1994, p. 64) for the hypothesis that fishers evolved in forests subject to fires, thus suggesting that management should mimic small, stand-replacing fires. The commenter noted that fishers also evolved in forests with large stand-replacing fires, so by this same logic, burned forests should not have a detrimental effect on fisher survival, even absent high quantities of late-successional conifer forest.

Our Response: In response to the first comment, the draft Species Report states: “Some fires may lead to vegetation type conversion from forest to shrublands, which may permanently change landscape permeability for fishers (Naney et al. 2012, p. 7).” The emphasis should be on “some”; we are not suggesting that all fires (or high-severity fires, as suggested by the commenter) lead to conversions from forest to shrubland, only that should
such a conversion occur, it would affect fishers. We reviewed the multiple references provided by the commenter and revised the final Species Report to refine our discussion of conifer regeneration after fire, in addition to discussions of fire intensity and rotation (Service 2016, pp. 63–64). We thank the commenter for the additional information.

The second commenter suggested that the final Species Report should account for the fact that fire suppression activities would not occur but for a wildfire event. Fire suppression activities are a part of normal firefighting activities and occur within fisher habitat. To the extent that fire suppression activities have the potential to impact fisher habitat, we have included a discussion of this stressor in the final Species Report. The additional calculation, and subsequent analysis, suggested by the commenter is outside the scope of this final rulemaking process.

While the logic posed by the third commenter is convincing, there is evidence suggesting that in some areas the frequency and size of wildfires appears to be increasing, which has the potential to alter fisher habitat at rates more rapidly than historically. We acknowledge that fishers utilize burned forest and are not obligate users of late-successional forests; we have also incorporated additional discussion of historical fire regimes in forests inhabited by fishers in the west coast States in our final Species Report. Please also see our responses to Comments (57), (87), and (105).

(308) Comment: With regard to the Service’s discussion (in the proposed rule and the draft Species Report) about the threat of wildfire to fisher, one commenter stated that management of Forest Service lands to reduce wildfire impacts is important to long-term fisher viability, and if the Service lists the fisher, increased regulatory burden may reduce the Forest Service’s ability to prevent catastrophic wildfire and its effects to fishers and their habitat. The commenter also articulated that based on their experience, it is difficult to conduct vegetation management activities on lands that harbor federally listed species. The commenter expressed concern related to how advocacy groups routinely challenge these projects, slowing the Forest Service’s ability to accomplish project goals, such that listing the proposed West Coast DPS of fisher could potentially increase the risk of catastrophic wildfires. Finally, the commenter asserted that even in areas where Forest Service projects are not challenged, the threat of ESA litigation slows Federal agencies’ ability to accomplish treatments that would reduce the threat of fire.

Our Response: The commenter’s concerns appear to be focused on the impacts our proposal to list fisher could have on the ability of Federal agencies to complete or initiate vegetation management projects, some of which may reduce fuels. As noted above, we have determined that the proposed West Coast DPS of fisher does not warrant listing at this time (see Determination, above), and are withdrawing our proposal to list the West Coast DPS of fisher as a threatened species. Accordingly, the protections afforded by the ESA will not apply to the proposed West Coast DPS of Fisher. In addition, responding to the commenter’s concerns regarding litigation on other species and a general perceived threat of litigation over fuel reduction treatments is beyond the scope of this document.

References Cited

A complete list of all references cited in this document is available on the Internet at http://www.regulations.gov at Docket No. FWS–R8–ES–2014–0041 or upon request from the Field Supervisor, Yreka Fish and Wildlife Office (see ADDRESSES).

Authors

The primary authors of this document are the staff members of the Pacific Southwest Regional Office, Pacific Regional Office, and Yreka Fish and Wildlife Office (see ADDRESSES).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).


Noah Matson,
Acting Director, U.S. Fish and Wildlife Service
Part III

Environmental Protection Agency

40 CFR Part 82
Protection of Stratospheric Ozone: Proposed New Listings of Substitutes; Changes of Listing Status; and Reinterpretation of Unacceptability for Closed Cell Foam Products Under the Significant New Alternatives Policy Program; and Revision of Clean Air Act Section 608 Venting Prohibition for Propane; Proposed Rule
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82


RIN 2060–AS80

Protection of Stratospheric Ozone: Proposed New Listings of Substitutes; Changes of Listing Status; and Reinterpretation of Unacceptability for Closed Cell Foam Products Under the Significant New Alternatives Policy Program; and Revision of Clean Air Act Section 608 Venting Prohibition for Propane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: Pursuant to the U.S. Environmental Protection Agency’s (EPA) Significant New Alternatives Policy program, this action proposes to list a number of substances as acceptable, subject to use conditions; to list several substances as unacceptable; and to modify the listing status for certain substances from acceptable to unacceptable; and to modify the listing status for certain high-global warming potential alternatives for certain end-uses in the refrigeration and air conditioning sector; and to modify the listing status for certain substances from acceptable to acceptable, subject to narrowed use limits, or to unacceptable. Specifically, this action proposes to list as acceptable, subject to use restrictions, propane and HFO-1234yf in the refrigeration and air conditioning, and 2-bromo-3,3,3-trifluoroprop-1-ene in the fire suppression and explosion protection sectors; to list as unacceptable certain hydrocarbons and hydrocarbon blends in specific end-uses in the refrigeration and air conditioning sector; and to modify the listing status for certain high-global warming potential alternatives for certain end-uses in the refrigeration and air conditioning, foam blowing, and fire suppression and explosion protection sectors. This action also proposes to exempt propane in certain refrigeration end-uses from the Clean Air Act section 608 prohibition on venting, release, or disposal on the basis of current evidence that its venting, release, or disposal does not pose a threat to the environment. In addition, this action proposes to apply unacceptability determinations for foam-blowing agents to closed cell foam products and products containing closed cell foam that are manufactured or imported using these foam-blowing agents. This action also proposes to clarify the listing for Powdered Aerosol D (Stat-X®), which is currently listed as both acceptable and acceptable subject to use conditions, by removing the listing as acceptable subject to use conditions.

DATES: Comments must be received on or before June 2, 2016. Any party requesting a public hearing must notify the contact listed below under FOR FURTHER INFORMATION CONTACT by 5 p.m. Eastern Daylight Time on May 3, 2016. If a hearing is held, it will take place on or about May 18, 2016 in Washington, DC and further information will be provided on EPA’s Stratospheric Ozone Web site at www.epa.gov/ozone/snap.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0663, to the Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. 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, 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-epadockets.

FOR FURTHER INFORMATION CONTACT: Chenise Farquharson, Stratospheric Protection Division, Office of Atmospheric Programs (Mail Code 6205 T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–564–7768; email address: Farquharson.chenise@epa.gov. Notices and rulemakings under EPA’s Significant New Alternatives Policy program are available on EPA’s Stratospheric Ozone Web site at www.epa.gov/ozone/snap/snap-regulations.

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V. How does EPA regulate substitute refrigerants under CAA section 608?

A. What are the statutory requirements concerning venting, release, or disposal of refrigerants and refrigerant substitutes under CAA section 608?

B. What are EPA’s regulations concerning venting, release, or disposal of refrigerant substitutes?

C. What did EPA recently propose regarding management of refrigerant substitutes under CAA section 608?

VI. What is EPA proposing in this action?

A. Retail Food Refrigeration and Stationary AC

1. Proposed Listing of Propane as Acceptable, Subject to Use Conditions, for Commercial Ice Machines, Water Coolers, and Very Low Temperature Refrigeration Equipment

a. What are the affected end-uses?

b. How does propane compare to other refrigerants for these end-uses with respect to SNAP criteria?

c. What are the proposed use conditions?

d. What recommendations does EPA have for the safe use of propane?

e. When would the listing apply?

f. What is the relationship between this proposed SNAP rule and other federal rules?

g. On which topics is EPA specifically requesting comment?

2. Proposed Exemption for Propane From the Venting Prohibition Under CAA Section 608 for the End-Uses in the Proposed New SNAP Listing

a. What is EPA’s proposal regarding whether venting of propane in the end-uses in this action would pose a threat to the environment?

b. What is EPA’s proposal regarding whether venting of propane in the end-uses in this action should be exempted from the venting prohibition under CAA section 608?

c. When would the exemption from the venting prohibition apply?

3. Proposed Listing of New Refrigerants as Unacceptable

b. How does propane compare to other refrigerants for these end-uses with respect to SNAP criteria?

c. When would the exemption from the venting prohibition apply?

d. What is the relationship between this proposed exemption under CAA section 608 and other EPA rules?

e. On which topics is EPA specifically requesting comment?
a. Proposed Listing of Certain Flammable Refrigerants as Unacceptable for Retrofits in Unitary Split AC Systems and Heat Pumps
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?
   iv. When would the listings apply?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

   i. What are the affected end-uses?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?
   iv. When would the listings apply?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

4. Proposed Changes in Listing Status

   a. Proposed Change of Status for Certain HFC Refrigerants for New Positive Displacement Chillers
      i. What is the affected end-use?
      ii. Which refrigerants is EPA proposing to list as unacceptable?
      iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?
      iv. When would the status change?
      v. What is the relationship between this proposed SNAP rule and other federal rules?
      vi. On which topics is EPA specifically requesting comment?

b. Proposed Change of Status for Certain HFC Refrigerants for New Cold Storage Warehouses
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

c. Proposed Change of Status for Certain HFC Refrigerants for New Household Refrigerators and Freezers
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

d. Proposed Change of Status for Certain HFC Refrigerants for Positive Displacement Chillers
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

e. Proposed Change of Status for Certain HFC Refrigerants for New Household Refrigerators and Freezers
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

2. Proposed Listing of 2-Bromo-3,3,3-Trifluoropropene (2-BTP) as Acceptable, Subject to Use Conditions, for Newly Manufactured MVAC Systems
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?
   iv. When would the listing apply?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

B. Motor Vehicle Air Conditioning

   1. Proposed Listing of HFO-1234yf as Acceptable, Subject to Use Conditions, for Newly Manufactured MVAC Systems
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

   2. What is the affected end-use?

   d. Proposed Listing of HFO-1234yf as Acceptable, Subject to Use Conditions, for Newly Manufactured MVAC Systems
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

C. Foam Blowing Agents

   1. Proposed Listing of HFO-1234yf as Acceptable, Subject to Use Conditions, for Newly Manufactured MVAC Systems
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

   2. Proposed Change of Status for Certain HFC Refrigerants for New Household Refrigerators and Freezers
   i. What is the affected end-use?
   ii. Which refrigerants is EPA proposing to list as unacceptable?
   iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

D. Fire Suppression and Explosion Protection

   1. Proposed Listing of 2-Bromo-3,3,3-Trifluoropropene (2-BTP) as Acceptable, Subject to Use Conditions, for Total Flooding and Streaming
   i. What is the affected end-use?
   ii. Which fire suppressants is EPA proposing to list as unacceptable?
   iii. How does 2-BTP compare to other fire suppressants for these end-uses with respect to SNAP criteria?
   iv. When would the listing apply?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?

   2. Proposed Change of Status for Certain Perfluorocarbons
   i. What is the affected end-use?
   ii. Which fire suppressants is EPA proposing to list as unacceptable?
   iii. How do the proposed unacceptable fire suppressants compare to other fire suppressants for this end-use with respect to SNAP criteria?
   iv. When would the status change?
   v. What is the relationship between this proposed SNAP rule and other federal rules?
   vi. On which topics is EPA specifically requesting comment?
about whether suitable alternatives could be found in all cases, and in the larger sense, about how to limit negative societal impacts from use of alternatives.

Over the past twenty years, the SNAP program has played an important role in assisting with a continuous smooth transition to safer alternatives, by addressing in concrete and highly technical terms, end-use by end-use, these myriad issues. From the first SNAP framework rule published in 1994, which provided confidence and certainty by identifying safer alternatives in key consumer and industrial uses, the SNAP program has continued to ensure that businesses and consumers have access to information about suitable alternatives. The SNAP program works with many stakeholders, domestically and abroad, to continuously evaluate and provide updates on safer alternatives and new technologies. Thanks to these efforts and the work of individuals, businesses, and organizations, the transitions generally have been successful. Perhaps the best evidence of the program's success has been the lack of fanfare with which so many important consumer and industrial uses have moved to adopt safer SNAP-listed alternatives. When reviewing a substitute, EPA compares the risk posed by that substitute to the risks posed by other alternatives and determines whether that specific substitute under review poses significantly more risk than other alternatives for the same use. EPA recently has begun to review the lists in a broader manner to determine whether substitutes added to the lists early in the program pose significantly more risk than substitutes that have more recently been added. As with initial listing decisions, decisions to change the status of an already listed alternative are based on applying our comparative risk framework.

Global warming potential (GWP) is one of several criteria EPA considers in the overall evaluation of the alternatives under the SNAP program. The President's June 2013 Climate Action Plan (CAP) states that, "to reduce emissions of HFCs, the United States can and will lead both through international diplomacy as well as domestic actions." Furthermore, the CAP states that "we will use our authority through the Significant New Alternatives Policy Program to encourage private sector investment in low-emissions technology by identifying and approving climate-friendly chemicals while prohibiting certain uses of the most harmful chemical alternatives." On July 20, 2015 (80 FR 42870), EPA issued a final regulation that was our first effort to take a broader look at the SNAP lists, where we focused on those listed substitutes that have a high GWP relative to other alternatives in specific end-uses, while otherwise posing comparable levels of risk.

In this action, EPA is proposing to list a number of substances as acceptable, subject to use restrictions; to list several substances as unacceptable; and to modify the listing status for certain substances from acceptable to unacceptable. We performed a comparative risk analysis, based on our criteria for review, with other alternatives for the relevant end-uses. For particular substances, EPA found significant potential differences in risk with respect to one or more specific criteria, such as flammability, toxicity, or local air quality concerns, while otherwise posing comparable levels of risk to those of other alternatives in specific end-uses. EPA is also proposing that the existing listing decisions for foam blowing agents apply to closed cell foam products and products containing closed cell foam. See section VI.C.4 for the details of this proposal.

Additionally, EPA is proposing to list propane (R-290) as acceptable, subject to use conditions, as a refrigerant in new self-contained commercial ice machines, in new water coolers, and in new very low temperature refrigeration equipment. EPA is proposing to exempt propane in these end-uses from the venting prohibition under CAA section 608(c)(2). See section VI.A.2.a. “What is EPA’s proposal regarding whether venting of propane in the end-uses in this action would pose a threat to the environment?” for the details of this proposal.

For the guiding principles of the SNAP program, this action does not specify that any alternative is acceptable or unacceptable across all sectors and end-uses. Instead, in all cases, EPA considered the intersection between the specific alternative and the particular end-use and the availability of substitutes for those particular end-uses. In the case of refrigeration and air conditioning (AC), we consider new equipment to be a separate end-use from retrofitting existing equipment with a different refrigerant from that for which the equipment was originally designed. EPA is not setting a “risk threshold” for any specific SNAP criterion, such that the only acceptable substitutes pose risk
below a specified level of risk. Because the substitutes available and the types of risk they may pose vary by sector and end-use and under the SNAP comparative risk framework, our review focuses on the specific end-use and the alternatives for that end-use, including the other risks alternatives might pose. Thus, there is no bright line that can be established. Also, EPA recognizes that there are a range of substitutes with various uses that include both fluorinated (e.g., hydrofluorocarbons (HFCs), hydrofluoroolefins (HFOs)) and non-fluorinated (e.g., hydrocarbons (HCs), carbon dioxide (CO2)) substitutes that may pose lower overall risk to human health and the environment. Consistent with CAA section 612 as we have historically interpreted it under the SNAP program, EPA is proposing both initial listings and certain modifications to the current lists based on our evaluation of the substitutes addressed in this action using the SNAP criteria for evaluation and considering the current suite of other alternatives for the specific end-use at issue.

1. Proposed Acceptable Alternatives, With Use Conditions, by End-Use (Initial Listings)

(1) For refrigeration, we are proposing to list as acceptable, subject to use conditions, as of 30 days after publication of a final rule

- Propane in new commercial ice machines, new water coolers, and new very low temperature refrigeration equipment.

(2) For motor vehicle air conditioning (MVAC) systems, we are proposing to list, as acceptable, subject to use conditions, as of 30 days after publication of a final rule

- HFC-1234yf in newly manufactured medium-duty passenger vehicles (MDPVs), heavy-duty (HD) pickup trucks, and complete HD vans.

(3) For fire suppression and explosion protection end-uses, we are proposing to list as acceptable, subject to use conditions, as of 30 days after publication of a final rule

- 2-BTP as a total flooding agent for use in engine nacelles and auxiliary power units (APUs) on aircraft; and
- 2-BTP as a streaming agent for use in handheld extinguishers in aircraft.

2. Proposed Unacceptable Alternatives by End-Use (Initial Listings)

(1) For retrofit residential and light commercial AC and heat pumps—unitary split AC systems and heat pumps, we are proposing to list as unacceptable, as of 30 days after publication of a final rule

- All refrigerants identified as flammability Class 3 in American National Standards Institute (ANSI)/American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 34–2013; and
- All refrigerants meeting the criteria for flammability Class 3 in ANSI/ASHRAE Standard 34–2013—

(2) For new residential and light commercial AC and heat pumps, cold storage warehouses, centrifugal chillers, and positive displacement chillers, we are proposing to list as unacceptable, as of 30 days after publication of a final rule

- Propylene and R-443A.

3. Proposed Change of Listing Status by End-Use:

(1) For new centrifugal chillers, we are proposing to list as unacceptable, except as otherwise allowed under a narrowed use limit, as of January 1, 2024


(2) For new positive displacement chillers, we are proposing to list as unacceptable, except as otherwise allowed under a narrowed use limit, as of January 1, 2024

- FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/290/134a/600a (28/1.70/1.9), R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-423A, R-424A, R-434A, R-438A, R-507A, RS-44 (2003 composition), and THR-03.

(3) For new centrifugal chillers, we are proposing to list as acceptable, subject to narrowed use limits, as of January 1, 2024

- HFC-134a for military marine vessels and HFC-134a and R-404A for human-rated spacecraft and related support equipment

(4) For new positive displacement chillers, we are proposing to list as acceptable, subject to narrowed use limits, as of January 1, 2024

- HFC-134a for military marine vessels and HFC-134a and R-404A for human-rated spacecraft and related support equipment

(5) For new cold storage warehouses, we are proposing to list as unacceptable, as of January 1, 2023


(6) For new retail food refrigeration (refrigerated food processing and dispensing equipment), we are proposing to list as unacceptable, as of January 1, 2021


(7) For new household refrigerators and freezers, we are proposing to list as unacceptable, as of January 1, 2021


(8) For rigid polyurethane (PU) high-pressure two-component spray foam, we are proposing to list as unacceptable for all uses, except military or space- and aeronautics-related applications, as of January 1, 2020; as acceptable, subject to narrowed use limits, for military or space- and aeronautics-related applications, as of January 1, 2020; and as unacceptable for military or space- and aeronautics-related applications as of January 1, 2025

- HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel T1.

(9) For rigid PU low-pressure two-component spray foam, we are proposing to list as unacceptable for all uses, except military or space- and aeronautics-related applications, as of January 1, 2021; as acceptable, subject to narrowed use limits, for military or space- and aeronautics-related applications,
as of January 1, 2021; and as unacceptable for military or space-aeronautics-related applications as of January 1, 2025.
• HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TL.

(10) For rigid PU one-component foam sealants, we are proposing to list as unacceptable, as of January 1, 2020
• HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TL.

(11) For all foam blowing end-uses except for rigid PU spray foam, we are proposing for all HFCs and HFC blends previously listed as unacceptable for space-aeronautics-related applications as of January 1, 2022 that
• These HFCs and HFC blends would be unacceptable for space-aeronautics-related applications as of January 1, 2025.
(12) For flexible PU foam applications, we are proposing to list as unacceptable, as of 30 days after publication of a final rule
• Methylene chloride.
(13) For integral skin PU foam applications, we are proposing to list as unacceptable, as of January 1, 2017
• Methylene chloride.
(14) For polyolefin foam applications, we are proposing to list as unacceptable, as of January 1, 2020
• Methylene chloride.
(15) For fire suppression total flooding uses, we are proposing to list as unacceptable, as of one year after publication of a final rule
• Perfluorocarbons (PFCs) (CF$_3$F and CaF$_2$).

4. Other Changes
(1) For all foam blowing end-uses, we are proposing to prohibit
• Use of closed cell foam products and products that contain closed cell foam manufactured with an unacceptable foam blowing agent on or after the later of (1) one year after publication of a final rule or (2) the date of the unacceptability listing.
(2) For fire suppression and explosion protection total flooding end-use, we are proposing to clarify the listing for Powdered Aerosol D (Stat-X®), which is currently listed as both “acceptable” and “acceptable subject to use conditions,” by removing the listing as “acceptable subject to use conditions,” as of 30 days after publication of a final rule.

B. Does this action apply to me?
Potential entities that may be affected by this proposed rule include:

TABLE 1—POTENTIALLY REGULATED ENTITIES BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE

<table>
<thead>
<tr>
<th>Category</th>
<th>NAICS Code</th>
<th>Description of regulated entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>238220</td>
<td>Plumbing, Heating, And Air Conditioning Contractors.</td>
</tr>
<tr>
<td>Industry</td>
<td>325199</td>
<td>All Other Basic Organic Chemical Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>325412</td>
<td>Pharmaceutical Preparation Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>325520</td>
<td>Adhesive Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>325998</td>
<td>All Other Miscellaneous Chemical Product and Preparation Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>326150</td>
<td>Urethane and Other Foam Product (Except Polystyrene) Manufacturing.</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>332919</td>
<td>Nozzles, Firefighting, Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>333415</td>
<td>Manufacturers of Refrigerating Freezers, and Other Refrigerating or Freezing Equipment, Electric or Other (NESO); Heat Pumps Not Elsewhere Specified or Included; and Parts Thereof.</td>
</tr>
<tr>
<td>Industry</td>
<td>334345</td>
<td>Air Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>334390</td>
<td>Fire Detection and Alarm Systems Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>335222</td>
<td>Household Refrigerator and Home Freezer Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>336120</td>
<td>Heavy Duty Truck Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>33636</td>
<td>Motor Vehicle Parts Manufacturing.</td>
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<tr>
<td>Manufacturing</td>
<td>336410</td>
<td>Aerospace Product and Parts Manufacturing.</td>
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<tr>
<td>Manufacturing</td>
<td>336411</td>
<td>Aircraft Manufacturing.</td>
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<tr>
<td>Manufacturing</td>
<td>336413</td>
<td>Other Aircraft Parts and Auxiliary Equipment Manufacturing.</td>
</tr>
<tr>
<td>Industry</td>
<td>339113</td>
<td>Surgical Appliance and Supplies Manufacturing.</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>339999</td>
<td>Fire Extinguishers, Portable, Manufacturing.</td>
</tr>
<tr>
<td>Retail</td>
<td>423620</td>
<td>Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers.</td>
</tr>
<tr>
<td>Retail</td>
<td>423740</td>
<td>Refrigeration Equipment and Supplies Merchant Wholesalers.</td>
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<td>Retail</td>
<td>423930</td>
<td>Recyclable Material Merchant Wholesalers.</td>
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<tr>
<td>Retail</td>
<td>443111</td>
<td>Appliance Stores: Household-Type.</td>
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<tr>
<td>Retail</td>
<td>445110</td>
<td>Supermarkets and Other Grocery (Except Convenience) Stores.</td>
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<tr>
<td>Retail</td>
<td>445120</td>
<td>Convenience Stores.</td>
</tr>
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<td>Retail</td>
<td>445220</td>
<td>Meat Markets.</td>
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<td>Retail</td>
<td>44522</td>
<td>Fish and Seafood Markets.</td>
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<td>Retail</td>
<td>44523</td>
<td>Fruit and Vegetable Markets.</td>
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<td>Retail</td>
<td>445291</td>
<td>Baked Goods Stores.</td>
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<td>Retail</td>
<td>445292</td>
<td>Confectionery and Nut Stores.</td>
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<td>Retail</td>
<td>445299</td>
<td>All Other Specialty Food Stores.</td>
</tr>
<tr>
<td>Retail</td>
<td>445300</td>
<td>Beer, Wine, and Liquor Stores.</td>
</tr>
</tbody>
</table>

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4 Closed cell foam products and products containing closed cell foams manufactured on or before January 1, 2021, may be used after that date.
5 Closed cell foam products and products containing closed cell foams manufactured on or before January 1, 2020, may be used after that date.
6 Closed cell foam products and products containing closed cell foams manufactured on or before January 1, 2017, may be used after that date.
7 Closed cell foam products and products containing closed cell foams manufactured on or before January 1, 2020, may be used after that date.
TABLE 1—POTENTIALLY REGULATED ENTITIES BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE—Continued

<table>
<thead>
<tr>
<th>Category</th>
<th>NAICS Code</th>
<th>Description of regulated entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retail ..........</td>
<td>446110</td>
<td>Pharmacies and Drug Stores.</td>
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<tr>
<td>Retail ..........</td>
<td>44711</td>
<td>Gasoline Stations With Convenience Stores.</td>
</tr>
<tr>
<td>Retail ..........</td>
<td>452910</td>
<td>Warehouse Clubs and Supercenters.</td>
</tr>
<tr>
<td>Retail ..........</td>
<td>452990</td>
<td>All Other General Merchandise Stores.</td>
</tr>
<tr>
<td>Services .......</td>
<td>72111</td>
<td>Hotels (Except Casino Hotels) and Motels.</td>
</tr>
<tr>
<td>Services .......</td>
<td>72112</td>
<td>Casino Hotels.</td>
</tr>
<tr>
<td>Retail ..........</td>
<td>72241</td>
<td>Drinking Places (Alcoholic Beverages).</td>
</tr>
<tr>
<td>Retail ..........</td>
<td>722513</td>
<td>Limited-Service Restaurants.</td>
</tr>
<tr>
<td>Retail ..........</td>
<td>722514</td>
<td>Cafeterias, Grill Buffets, and Buffets.</td>
</tr>
<tr>
<td>Retail ..........</td>
<td>722515</td>
<td>Snack and Nonacoholic Beverage Bars.</td>
</tr>
<tr>
<td>Services .......</td>
<td>81119</td>
<td>Other Automotive Repair and Maintenance.</td>
</tr>
<tr>
<td>Services .......</td>
<td>811142</td>
<td>Appliance Repair and Maintenance.</td>
</tr>
<tr>
<td>Services .......</td>
<td>922160</td>
<td>Fire Protection.</td>
</tr>
</tbody>
</table>

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR part 82. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the FOR FURTHER INFORMATION CONTACT section.

C. What acronyms and abbreviations are used in the preamble?

Below is a list of acronyms and abbreviations used in the preamble of this document:

- AIHA—American Industrial Hygiene Association
- AC—Air Conditioning
- ACGIH—American Conference of Governmental Industrial Hygienists
- ACH—Changes Per Hour
- ASRAC—Application Standards and Rulemaking Federal Advisory Committee
- AEGL—Acute Emergency Guideline Limits
- AHR—Air Conditioning, Heating and Refrigeration Institute
- AIAH—Australian Institute of Refrigeration, Air conditioning and Heating
- ANSI—American National Standards Institute
- API—Auxiliary Power Unit
- ASHRAE—American Society of Heating, Refrigerating and Air-Conditioning Engineers
- BTU—British Thermal Units
- CAA—Clean Air Act
- CAP—Climate Action Plan
- CAS Reg. No.—Chemical Abstracts Service Registry Identification Number
- CBI—Confidential Business Information
- CFC—Chlorofluorocarbon
- CFR—Code of Federal Regulations
- CH₄—Methane
- CMAQ—Community Multiscale Air Quality
- CO₂—Carbon Dioxide
- CO₂eq—Carbon Dioxide Equivalent
- CUAAC—Commercial Unitary Air Conditioner
- CUAHP—Commercial Unitary Heat Pump
- DOD—United States Department of Energy
- DIX—Direct Expansion
- EAP—Environmental Effects Assessment Panel
- EIA—Environmental Investigation Agency
- EO—Executive Order
- EPA—United States Environmental Protection Agency
- EU—European Union
- FCA—Fiat Chrysler Automobiles
- FMEA—Failure Mode and Effects Analysis
- FAA—Federal Aviation Administration
- FR—Federal Register
- FTA—Fault Tree Analysis
- GHG—Greenhouse Gas
- GtCO₂eq—Gigatones of Carbon Dioxide Equivalent
- GWP—Global Warming Potential
- GVWR—Gross Vehicle Weight Rating
- HBFC—Hydrobromofluorocarbon
- HC—Hydrocarbon
- HFO—Hydrofluoroolefin
- HFO—Hydrofluorocarbon
- HFC—Hydrofluorocarbon
- HFL—Lower Flammability Limit
- LOAEL—Lowest Observed Adverse Effect Level
- LPG—Liquefied Petroleum Gas
- MDPV—Medium-Duty Passenger Vehicle
- MIR—Maximum Incremental Reactivity
- MMTCO₂eq—Million Metric Tons of Carbon Dioxide Equivalent
- MS—Material Safety Data Sheet
- NADA—North American Industrial Classification System
- NAAQS—National Ambient Air Quality Standards
- NADA—National Automobile Dealers Association
- NAICS—North American Industrial Classification System
- NESHAP—National Emission Standards for Hazardous Air Pollutants
- NNPA—National Fire Protection Association
- NHTSA—National Highway Traffic Safety Administration
- NIK—Not In Kind
- NIOSH—United States National Institute for Occupational Safety and Health
- NPRM—Notice of Proposed Rulemaking
- NRDC—Natural Resources Defense Council
- ODP—Ozone Depletion Potential
- ODS—Ozone-depleting Substance
- OMB—United States Office of Management and Budget
- OSHA—United States Occupational Safety and Health Administration
- PEL—Permissible Exposure Limit
- PFC—Perfluorocarbons
- PBS—Pantone Matching System
- ppb—Parts Per Billion
- PPE—Personal Protective Equipment
- ppm—Parts Per Million
- PSM—Process Safety Management
- PTAC—Packaged Terminal Air Conditioners
- PTHP—Packaged Terminal Heat Pumps
- PU—Polyurethane
- RCHA—Resource Conservation and Recovery Act
- REL—Recommended Exposure Limit
- RJC—Reference Concentration
- RMP—Risk Management Plan
- RSES—Refrigeration Service Engineers Society
- RTAC—Refrigeration, Air Conditioning and Heat Pumps Technical Options Committee
- SARPS—Standards and Recommended Practices
- SIP—State Implementation Plan
- SAE ICC—SAE International’s Interior Climate—SAE International’s Interior Climate Control Committee
- SAP—Scientific Assessment Panel
II. How does the SNAP program work?

A. What are the statutory requirements and authority for the SNAP program?

CAA section 612 requires EPA to develop a program for evaluating alternatives to ODS. This program is known as the SNAP program. The major provisions of section 612 are:

1. Rulemaking

Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon (CFC), halon, carbon tetrachloride, methyl chloroform, methyl bromide, hydrobromofluorocarbon (HBFC), and chlorobromomethane) or class II hydrobromofluorocarbon (HBFC) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment and (2) is currently or potentially available.

2. Listing of Unacceptable/Acceptable Substitutes

Section 612(c) requires EPA to publish a list of the substitutes that it finds to be unacceptable for specific uses and to publish a corresponding list of acceptable substitutes for specific uses. The list of “acceptable” substitutes is found at www.epa.gov/ozone/snap/substitutes-sector and the lists of “unacceptable,” “acceptable subject to use conditions,” and “acceptable subject to narrowed use limits” substitutes are found in the appendices to 40 CFR part 82 subpart G.

3. Petition Process

Section 612(d) grants the right to any person to petition EPA to add a substance to, or delete a substance from, the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, EPA must publish the revised lists within an additional six months.

4. 90-Day Notification

Section 612(e) directs EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer’s unpublished health and safety studies on such substitutes.

5. Outreach

Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

B. What are EPA’s regulations implementing CAA section 612?

On March 18, 1994, EPA published the initial SNAP rule (59 FR 13044) which established the process for administering the SNAP program and issued EPA’s first lists identifying acceptable and unacceptable substitutes in major industrial use sectors (40 CFR part 82 subpart G). These sectors include the following: Refrigeration and AC; Foam blowing; solvents cleaning; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors comprise the principal industrial sectors that historically consumed the largest volumes of ODS.

C. How do the regulations for the SNAP program work?

Under the SNAP regulations, anyone who produces a substitute to replace a class I or II ODS in one of the eight major industrial use sectors listed above must provide the Agency with notice and the required health and safety information on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative. 40 CFR 82.176(a). While this requirement typically applies to chemical manufacturers as the person likely to be planning to introduce the substitute into interstate commerce, it may also apply to importers, formulators, equipment manufacturers, and end users when they are responsible for introducing a substitute into interstate commerce. The 90-day SNAP review process begins once EPA receives the submission and determines that the submission includes complete and adequate data. 40 CFR 82.180(a). The CAA and the SNAP regulations, 40 CFR 82.174(a), prohibit use of a substitute earlier than 90 days after a complete submission has been provided to the Agency.

The Agency has identified four possible decision categories for substitute submissions: Acceptable; acceptable, subject to use conditions; acceptable, subject to narrowed use limits; and unacceptable. 40 CFR 82.180(b). Use conditions and narrowed use limits are both considered “use restrictions” and are explained below. Substitutes that are deemed acceptable without use conditions can be used for all applications within the relevant sector end-uses and without limits under SNAP on how they may be used. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. Substitutes that are found to be unacceptable may not be used after the date specified in the rulemaking adding them to the list of unacceptable substitutes.

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9 As defined at 40 CFR 82.104, “interstate commerce” means the distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or District of Columbia. The entry points for which a product is introduced into interstate commerce are the release of a product from the facility in which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance.

10 As defined at 40 CFR 82.172, “end-use” means processes or classes of specific applications within major industrial sectors where a substitute is used to replace an ozone-depleting substance.

11 The SNAP regulations also include “pending,” referring to submissions for which EPA has not reached a determination, under this provision.

12 As defined at 40 CFR 82.172, “use” means any use of a substitute for a class I or class II ozone-depleting compound, including but not limited to use in a manufacturing process or product, in consumption by the end-user, or in intermediate uses, such as formulation or packaging for other subsequent uses.
After reviewing a substitute, the Agency may determine that a substitute is acceptable only if certain conditions in the way that the substitute is used are met to ensure risks to human health and the environment are not significantly greater than other substitutes. EPA describes such substitutes as “acceptable subject to use conditions.” Entities that use these substitutes without meeting the associated use conditions are in violation of CAA section 612 and EPA’s SNAP regulations. 40 CFR 82.174(c).

For some substitutes, the Agency may permit a narrow range of use within an end-use or sector. For example, the Agency may limit the use of a substitute to certain end-uses or specific applications within an industry sector. The Agency generally requires a user of a substitute subject to narrowed use limits to demonstrate that no other acceptable substitutes are available for their specific application.\(^{12}\) EPA describes these substitutes as “acceptable subject to narrowed use limits.” A person using a substitute that is acceptable subject to narrowed use limits in applications and end-uses that are not consistent with the narrowed use limit is using these substitutes in violation of CAA section 612 and EPA’s SNAP regulations. 40 CFR 82.174(c).

The section 612 mandate for EPA to prohibit the use of a substitute that may present risk to human health or the environment where a lower risk alternative is available or potentially available \(^{13}\) provides EPA with the alternative is available or potentially present risk to human health or the environment are not significantly greater than other substitutes. EPA prohibits substitutes, to list a substitute as acceptable only subject to use conditions or narrowed use limits, or to remove a substitute from either the list of prohibited or acceptable substitutes.

In contrast, EPA publishes “notices of acceptability” to notify the public of substitutes that are deemed acceptable with no restrictions. As described in the preamble to the rule initially implementing the SNAP program (59 FR 13044; March 18, 1994), EPA does not believe that rulemaking procedures are necessary to list substitutes that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

Many SNAP listings include “comments” or “further information” to provide additional information on substitutes. Since this additional information is not part of the regulatory decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements so listed are binding under other regulatory programs (e.g., worker protection regulations promulgated by the U.S. Occupational Safety and Health Administration (OSHA)). The “further information” classification does not necessarily include all other legal obligations pertaining to the use of the substitute. While the items listed are not legally binding under the SNAP program, EPA encourages users of substitutes to apply all statements in the “further information” column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building codes or standards. Thus, many of the statements, if adopted, would not require the affected user to make significant changes in existing operating practices.

D. What are the guiding principles of the SNAP program?

The seven guiding principles of the SNAP program, elaborated in the preamble to the initial SNAP rule and consistent with section 612, are discussed below.

- **Evaluate substitutes within a comparative risk framework**
  The SNAP program evaluates the risk of alternative compounds compared to available or potentially available substitutes to the ozone depleting compounds which they are intended to replace. The risk factors that are considered include ozone depletion potential (ODP) as well as flammability, toxicity, occupational health and safety, and contributions to climate change and other environmental factors.
  - Do not require that substitutes be risk free to be found acceptable
    Substitutes found to be acceptable must not pose significantly greater risk than other substitutes, but they do not have to be risk free. A key goal of the SNAP program is to promote the use of substitutes that minimize risks to human health and the environment relative to other alternatives. In some cases, this approach may involve designating a substitute acceptable even though the compound may pose a risk of some type, provided its use does not pose significantly greater risk than other alternatives.
  - Restrict those substitutes that are significantly worse
    EPA does not intend to restrict a substitute if it has only marginally greater risk. Drawing fine distinctions would be extremely difficult. The Agency also does not want to intercede in the market’s choice of substitutes by designating one substitute acceptable and one substitute unacceptable for each end-use, and does not intend to restrict substitutes on the market unless a substitute has been proposed or is being used that is clearly more harmful to human health or the environment than other alternatives.
  - Evaluate risks by use
    Central to SNAP’s evaluations is the intersection between the characteristics of the substitute itself and its specific end-use application. Section 612 requires that substitutes be evaluated by use. Environmental and human health exposures can vary significantly depending on the particular application of a substitute. Thus, the risk characterizations must be designed to represent differences in the environmental and human health effects associated with diverse uses. This approach cannot, however, imply fundamental tradeoffs with respect to different types of risk to either the environment or to human health.
  - Provide the regulated community with information as soon as possible
    The Agency recognizes the need to provide the regulated community with information on the acceptability of various substitutes as soon as possible. To do so, EPA issues notices or determinations of acceptability and rules identifying substitutes as unacceptable; acceptable, subject to use conditions; or acceptable, subject to narrowed use limits, in the Federal Register. In addition, we maintain lists of acceptable and unacceptable alternatives on our Web site, [www.epa.gov/ozone/snap](http://www.epa.gov/ozone/snap).
  - Do not endorse products manufactured by specific companies

\(^{12}\) In the case of the July 20, 2015, final rule, EPA established narrowed use limits for certain substitutes over a limited period of time for specific MVAC and foam applications, on the basis that other acceptable alternatives would not be available for those specific applications within broader end-uses, but acceptable alternatives were expected to become available over time, e.g., after military qualification testing for foam blowing agents in military applications or after development of improved servicing infrastructure in a destination country for MVAC in vehicles destined for export.

\(^{13}\) In addition to acceptable commercially available alternatives, the SNAP program may consider potentially available alternatives. The SNAP program’s definition of “potentially available” is “any alternative for which adequate health, safety, and environmental data, as required for the SNAP notification process, exist to make a determination of acceptability, and which the Agency reasonably believes to be technically feasible, even if not all testing has yet been completed and the alternative is not yet produced or sold.” (40 CFR 82.172)
The Agency does not issue company-specific product endorsements. In many cases, the Agency may base its analysis on data received on individual products, but the addition of a substitute to the acceptable list based on that analysis does not represent an endorsement of that company’s products.

- **Defer to other environmental regulations when warranted**

  In some cases, EPA and other federal agencies have developed extensive regulations under other sections of the CAA or other statutes that address potential environmental or human health effects that may result from the use of alternatives to class I and class II substances. For example, use of some substitutes may in some cases entail increased use of chemicals that contribute to tropospheric air pollution. The SNAP program takes existing regulations under other programs into account when reviewing substitutes.

**E. What are EPA’s criteria for evaluating substitutes under the SNAP program?**

EPA applies the same criteria for determining whether a substitute is acceptable or unacceptable. These criteria, which can be found at § 82.180(a)(7), include atmospheric effects and related health and environmental effects, ecosystem risks, consumer risks, flammability, and cost and availability of the substitute. To enable EPA to assess these criteria, we require submitters to include various information including ODP, GWP, toxicity, flammability, and the potential for human exposure.

When evaluating potential substitutes, EPA evaluates these criteria in the following groupings:

- **Atmospheric effects**—The SNAP program evaluates the potential contributions to both ozone depletion and climate change. The SNAP program considers the ODP and the 100-year integrated GWP of compounds to assess atmospheric effects.
- **Exposure assessments**—The SNAP program uses exposure assessments to estimate concentration levels of substitutes to which workers, consumers, the general population, and the environment may be exposed over a determined period of time. These assessments are based on personal monitoring data or area sampling data if available. Exposure assessments may be conducted for many types of releases including:
  1. Releases to the workplace and in home settings, include toxicological data and exposure assessments conducted for many types of releases.
  2. Releases to ambient air and surface water;
  3. Releases from the management of solid wastes.

- **Toxicity data**—The SNAP program uses toxicity data to assess the possible health and environmental effects of exposure to substitutes. We use broad health-based criteria such as:
  1. Permissible Exposure Limits (PELs) for occupational exposure;
  2. Inhalation reference concentrations (RfCs) for non-carcinogenic effects on the general population;
  3. Cancer slope factors for carcinogenic risk to members of the general population.

  When considering risks in the workplace, if OSHA has not issued a PEL for a compound, EPA then considers Recommended Exposure Limits from the National Institute for Occupational Safety and Health (NIOSH), Workplace Environmental Exposure Limits (WEELs) set by the American Industrial Hygiene Association, or threshold limit values (TLVs) set by the American Conference of Governmental Industrial Hygienists (ACGIH).

- **EPA’s consideration of cost in listing substitutes**

  EPA’s consideration of cost in listing decisions is limited to evaluating the cost of the substitute under review pursuant to section 82.180(a)(7)(vii). This is distinct from consideration of costs associated with the use of other alternatives to which the substitute is being compared. See Honeywell v. EPA, 374 F.3d 1363 (D.C. Cir. 2004) at 1,378 (J. Rogers, concurring in part and dissenting in part) (“While the SNAP regulations make the ‘cost and availability of the substitute’ an element of acceptability . . . that concern is limited to whether EPA ‘has . . . reason to prohibit its use,’ not to whether cleaner alternatives for the substance are already ‘currently or potentially available’. . . . Consideration of transition costs is thus precluded by the SNAP regulations as currently written, irrespective of whether it might be permitted under CAA § 612(c) . . . ’).

  Over the past twenty years, the menu of substitutes has become much broader and a great deal of new information has been developed on many substitutes. Because the overall goal of the SNAP program is to ensure that substitutes listed as acceptable do not pose significantly greater risk to human health and the environment than other substitutes, the SNAP criteria continue to be informed by our current overall understanding of environmental and human health impacts and our experience with and current knowledge about alternatives. Over time, the range of substitutes reviewed by SNAP has changed, and, at the same time, scientific approaches have evolved to more accurately assess the potential environmental and human health impacts of these chemicals and alternative technologies.

**F. How are SNAP determinations updated?**

Three mechanisms exist for modifying the list of SNAP determinations. First, under section 612(d), the Agency must review and either grant or deny petitions to add or delete substances from the SNAP list of acceptable or unacceptable substitutes. That provision allows any person to petition the Administrator to add a substance to the list of acceptable or unacceptable substitutes or to remove a substance from either list. The second means is through the notifications which must be submitted to EPA 90 days before introduction of a substitute into interstate commerce for significant new uses as an alternative to a class I or class II substance. These 90-day notifications are required by CAA section 612(e) for
producers of substitutes to class I substances for new uses and, in all other cases, by EPA regulations issued under sections 114 and 301 of the Act to implement section 612(c).

Finally, since the inception of the SNAP program, we have interpreted the section 612 mandate to find substitutes acceptable or unacceptable to include the authority to act on our own to add or remove a substance from the SNAP lists (59 FR 13044, 13047; March 18, 1994). In determining whether to add or remove a substance from the SNAP lists, we consider whether there are other alternatives that pose lower overall risk to human health and the environment.

In determining whether to modify a listing of a substitute we undertake the same consideration, but do so in the light of new data that may not have been available at the time of our original listing decision, including information on substitutes that were not included in our comparative review at the time of our initial listing decision and new information on substitutes previously reviewed.

G. What does EPA consider in deciding whether to modify the listing status of an alternative?

As described in this document and elsewhere, including in the initial SNAP rule published in the Federal Register on March 18, 1994 (59 FR 13044), CAA section 612 requires EPA to list as unacceptable any substitute substance where it finds that there are other alternatives that reduce overall risk to human health and the environment.

The initial SNAP rule included submission requirements and presented the environmental and health risk factors that the SNAP program considers in the comparative risk framework it uses to determine whether there are other alternatives that pose significantly lower risk than the substitute under review. EPA makes decisions based on the particular end-use where a substitute is to be used. EPA has, in many cases, found certain substitutes acceptable only for limited end-uses or subject to use restrictions.

It has now been over twenty years since the initial SNAP rule was promulgated. When the SNAP program began, the number of substitutes available for consideration was, for many end-uses, somewhat limited. Thus, while the SNAP program’s initial comparative assessments of overall risk to human health and the environment were rigorous, often there were few substitutes upon which to apply the comparative assessments. The immediacy of the class I phaseout often meant that EPA listed class II ODS (i.e., HCFCs) as acceptable, recognizing that they too would be phased out and, at best, could offer an interim solution. Other Title VI provisions such as the section 610 Nonessential Products Ban and the section 605 Use Restriction made clear that a listing under the SNAP program could not convey permanence.

Since EPA issued the initial SNAP rule in 1994, the Agency has issued 20 rules and 30 notices that generally expanded the menu of options for the various SNAP sectors and end-uses. Thus, comparisons today apply to a broader range of alternatives—both chemical and non-chemical—than at the inception of the SNAP program.

Industry experience with substitutes has also grown during the history of the program.

In addition to an expanding menu of substitutes, developments over the past 20 years have improved our understanding of global environmental issues. With regard to that information, our review of alternatives in this proposed rule includes comparative assessments that consider our evolving understanding of a variety of factors. For example, GWPs and climate effects are not new elements in our evaluation framework, but as is the case with all of our review criteria, the amount of information has expanded and the quality has improved.

To the extent possible, EPA’s ongoing management of the SNAP program considers new information, including new substitutes, and improved understanding of the risk to the environment and human health. EPA previously has taken several actions revising listing determinations from acceptable or acceptable with use conditions to unacceptable. On January 26, 1999, EPA listed the refrigerant blend known by the trade name MT-31 as unacceptable for all refrigeration and AC end-uses for which EPA had previously listed this blend as an acceptable substitute (62 FR 30275; June 3, 1997). EPA based this decision on new information about the toxicity of one of the chemicals in the blend.

Another example of EPA revising a listing determination occurred in 2007, when EPA listed HCFC-22 and HCFC-142b as unacceptable for use in the foam sector (72 FR 14432; March 28, 2007). These HCFCs, which are ozone depleting and subject to a global production phaseout, were initially listed as acceptable substitutes since they had a lower ODP than the substances they were replacing and there were no other alternatives that posed lower overall risk at the time of EPA’s listing decision. HCFCs offered a path forward for some sectors and end-uses at a time when the number of substitutes was far more limited. In light of the expanded availability of other alternatives with lower overall risk to human health and the environment in specific foam end-uses, and taking into account the 2010 class II ODS phase-down step, EPA changed the listing for these HCFCs in relevant end-uses from acceptable to unacceptable. In that rule, EPA noted that continued use of these HCFCs would contribute to unnecessary depletion of the ozone layer and delay the transition to substitutes that pose lower overall risk to human health and the environment. EPA established a change of status date that recognized that existing users needed time to adjust their manufacturing processes to safely accommodate the use of other substitutes.

In a final rule published on July 20, 2015 (80 FR 42870), various HFCs and HFC-containing blends that were previously listed as acceptable under the SNAP program were listed as unacceptable in various end-uses in the aerosols, foam blowing, and refrigeration and AC sectors where there are other alternatives that pose lower overall risk to human health and the environment for specific uses. The July 2015 rule also changed the status from acceptable to unacceptable for certain HCFCs being phased out of production under the Montreal Protocol and CAA section 605(a). Per the guiding principles of the SNAP program, the July 2015 rule did not specify that any HFCs or HCFCs are unacceptable across all sectors and end-uses. Instead, in all cases, EPA considered the intersection between the specific substitute and the particular end-use and the availability of substitutes for those particular end-uses when making its determinations.

H. Where can I get additional information about the SNAP program?

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, refer to EPA’s Web site at www.epa.gov/ozone/snap. For more information on the Agency’s process for administering the SNAP program or criteria for evaluation of substitutes, refer to the initial SNAP rule published March 18, 1994 (59 FR 13044), codified at 40 CFR part 82 subpart G. A complete chronology of SNAP decisions and the appropriate citations are found at www.epa.gov/ozone/snap/chron.html.
III. What actions and information related to greenhouse gases have bearing on this proposed action?

GHGs is one of several criteria EPA considers in the overall evaluation of alternatives under the SNAP program. During the past two decades, the general science on climate change and the potential contributions of greenhouse gases (GHGs) such as HFCs to climate change have become better understood. On December 7, 2009, at 74 FR 66496, the Administrator issued an endangerment finding determining that, for purposes of CAA section 202(a), the current and projected concentrations of the six key well-mixed greenhouse gases in the atmosphere—CO2, methane (CH4), nitrous oxide (N2O), HFCs, PFCs, and sulfur hexafluoride (SF6)—threaten the public health and welfare of current and future generations.

Like the ODS they replace, HFCs are potent GHGs. Although they represent a small fraction of the current total volume of GHG emissions, their warming impact is very strong. While GHGs such as CO2 and CH4 are unintentional byproducts from industrial activities and mobile source emissions, HFCs are intentionally produced chemicals. The most commonly used HFC is HFC-134a. HFC-134a is 1,430 times more damaging to the climate system than CO2. Because of their role in replacing ODS, both in the United States and globally, and because of the increasing use of refrigeration and AC, HFC emissions are projected to increase substantially and at an increasing rate over the next several decades if left unregulated. In the United States, emissions of HFCs are increasing more quickly than those of any other GHGs, and globally they are increasing 10–15 percent annually. At that rate, emissions are projected to double by 2020 and triple by 2030.

HFCs are rapidly accumulating in the atmosphere. The atmospheric concentration of HFC-134a, the most abundant HFC, has increased by about 10 percent per year from 2006 to 2012, and the concentrations of HFC-143a and HFC-125 have risen over 13 percent and 16 percent per year from 2007–2011, respectively.

Annual global emissions of HFCs are projected to rise to about 6.4 to 9.9 gigatons of CO2 equivalent (GtCO2-eq) in 2050, which is comparable to the drop in annual GHG emissions from ODS of 8.0 GtCO2-eq between 1988 and 2010. By 2050, the buildup of HFCs in the atmosphere is projected to increase radiative forcing by up to 0.4 W m–2. This increase may be as much as one-fifth to one-quarter of the expected increase in radiative forcing due to the buildup of CO2 since 2000, according to the Intergovernmental Panel on Climate Change’s (IPCC’s) Special Report on Emissions Scenarios (SRES). To appreciate the significance of the effect of projected HFC emissions within the context of all GHGs, HFCs would be equivalent to five to 12 percent of the CO2 emissions in 2050 based on the IPCC’s highest CO2 emissions scenario and equivalent to 27 to 69 percent of CO2 emissions based on the IPCC’s lowest CO2 emissions pathway.

Additional information concerning the peer-reviewed scientific literature and emission scenarios is available in the socket for this rulemaking (EPA–HQ–OAR–2015–0663). Today’s notice of proposed rulemaking (NPRM) includes status change proposals for certain HFCs or HFC blends in specific refrigeration and AC end-uses and in rigid polyurethane spray foam.

IV. What petitions has EPA received requesting a change in listing status for HFCs?

A. Summary of Petitions

EPA recently received two petitions requesting EPA to modify certain acceptability listings of high-GWP substances in various end-uses. The petitions were both submitted on October 6, 2015. The first was submitted by the Natural Resource Defense Council (NRDC) and the Institute for Governance and Sustainable Development (IGSD) and the second by the Environmental Investigation Agency (EIA). Today’s proposal is relevant to certain aspects of these petitions.

The NRDC and IGSD petition requests that EPA change the listing status of certain high-GWP chemicals they believe are used most frequently in the United States in various end-uses in the refrigeration and AC, foam blowing, and fire suppression and explosion protection sectors. The EIA petition requests that EPA list additional high-GWP HFCs as unacceptable or nonacceptable, subject to certain restrictions, in a number of end-uses in the refrigeration and AC, and fire suppression and explosion protection sectors. EPA requests that the schedule for changing the status of the substances listed in their petition be based on a three-tiered approach: (1) January 1, 2017, or one year following the passage of a final rule for SF6, HFC-23, and HFC-23 blends R-506A and R-508B; (2) January 1, 2019, for all chemicals with a GWP greater than 3,000 (e.g., includes HFC-236fa, HFC-227ea, R-507A, and R-404A) in all remaining stationary refrigeration end-uses; and (3) January 1, 2022, for all remaining substitutes with
consumption of HFCs. Global benefits of the amendment proposal are estimated to yield significant reductions in emissions of over 90 GtCO₂ through 2050.

This action also addresses certain aspects of the various petitions referred to above in section IV.A. While the two recent petitions have not been found complete and earlier petitions have been found incomplete, EPA possesses sufficient information to propose action on some of the end-uses covered by the petitions. EPA’s action is responsive to certain aspects of the petitions that relate to the refrigeration and AC, foam blowing, SA fire suppression and explosion protection sectors. EPA is proposing to change the listing from acceptable to unacceptable for:

- HFC-134a in new centrifugal chillers, new positive displacement chillers, new household refrigerators and freezers, and rigid PU spray foam;
- R-404A, R-410A, R-410B, and R-507A in new centrifugal chillers, new positive displacement chillers, new household refrigerators and freezers, and new cold storage warehouses;
- R-407A in new cold storage warehouses;
- R-421A, R-422B, R-422C, R-422D, R-424A, and R-434A in new centrifugal chillers and new positive displacement chillers;
- HFC-227ea in new cold storage warehouses, new centrifugal chillers, and new positive displacement chillers;
- HFC-245fa, HFC-365mfc, and HFC-227ea in rigid PU spray foam;
- HFC-245fa and HFC-227ea in new centrifugal chillers and new positive displacement chillers;
- PFCs (i.e., C₂F₆ and C₃F₁₀) for total flooding applications; and
- a number of refrigerant blends with higher GWP in certain new refrigeration and AC equipment.

EPA is also requesting comment and updated information on total refrigeration chillers, HFC-23, and HFC-125, and on both total refrigeration and streamlining uses of HFC-227ea. Throughout the process of our discussions with the regulated community, we have sought to convey our continued understanding of the role that certainty plays in enabling the robust development and uptake of alternatives. As noted above, some of the key strengths of the SNAP program, such as its substance and end-use specific consideration, its multi-criteria basis for action, and its petition process, tend to mitigate against measures some have advocated could provide more certainty, such as setting specific numerical criteria for environmental evaluations (e.g., all compounds with GWP greater than 150). That said, we believe that the action we are taking today does provide additional certainty in the specific cases addressed. In addition, we remain committed to continuing to actively seek stakeholder views and to share our thinking at the earliest moment practicable on any future actions, as part of our commitment to provide greater certainty to producers and consumers in SNAP-regulated industrial sectors.

V. How does EPA regulate substitute refrigerants under CAA section 608?

A. What are the statutory requirements concerning venting, release, or disposal of refrigerants and refrigerant substitutes under CAA section 608?

The statutory requirements concerning venting, release, or disposal of refrigerants and refrigerant substitutes are under CAA section 608, and EPA’s authority to promulgate the regulatory revisions in this action is based in part on CAA section 608. Section 608 of the Act as amended, titled National Recycling and Emission Reduction Program, requires, among other things, that EPA establish regulations governing the use and disposal of ODS used as refrigerants, such as certain CFCs and HCFCs, during the service, repair, or disposal of appliances and industrial process refrigeration (IPR). Section 608(c)(1) provides that it is unlawful for any person, in the course of maintaining, servicing, repairing, or disposing of an appliance (or IPR), to knowingly vent, or otherwise knowingly release or dispose of, any class I or class II substance used as a refrigerant in that appliance (or IPR) in a manner which permits the ODS to enter the environment.

Section 608(c)(1) further exempts from this self-effectuating prohibition de minimis releases associated with good faith attempts to recapture and recycle or safely dispose of such a substance. EPA, as set forth in its regulations, interprets releases to meet the criteria for exempted de minimis releases if they occur when the recycling and recovery requirements of specified regulations promulgated under sections 608 and 609 are followed. 40 CFR 82.154(a)(2).

Section 608(c)(2) extends the prohibition in section 608(c)(1) to knowingly venting or otherwise knowingly releasing or disposing of any refrigerant substitute for class I or class II substances by any person maintaining, servicing, repairing, or disposing of appliances or IPR. This prohibition applies to any substitute unless the Administrator determines that such venting, releasing, or disposing does not pose a threat to the
environment. Thus, section 608(c) provides EPA authority to promulgate regulations to interpret, implement, and enforce this prohibition on venting, releasing, or disposing of class I or class II substances and their refrigerant substitutes, which we refer to as the “venting prohibition” in this action. EPA’s authority under section 608(c) includes authority to implement section 608(c)(2) by exempting certain substitutes for class I or class II substances from the venting prohibition when the Administrator determines that such venting, release, or disposal does not pose a threat to the environment.

B. What are EPA’s regulations concerning venting, releasing, or disposal of refrigerant substitutes?

Regulations promulgated under CAA section 608, published on May 14, 1993 (58 FR 28660), established a recycling program for ozone-depleting refrigerants recovered during the servicing and maintenance of refrigeration and AC appliances. In the same 1993 rule, EPA also promulgated regulations implementing the section 608(c) prohibition on knowingly venting, releasing, or disposing of class I or class II controlled substances. These regulations were designed to substantially reduce the use and emissions of ozone-depleting refrigerants.

EPA issued a final rule on March 12, 2004 (69 FR 11946) and a second rule on April 13, 2005 (70 FR 19273) clarifying how the venting prohibition in section 608(c) applies to substitutes for CFC and HCFC refrigerants (e.g., HFCs and PFCs) during the maintenance, service, repair, or disposal of appliances. These regulations are codified at 40 CFR part 82, subpart F. In relevant part, they provide that no person maintaining, servicing, repairing, or disposing of appliances may knowingly vent or otherwise release into the environment any refrigerant or substitute from such appliances, with the exception of the certain specified substitutes in the specified end-uses, as provided in 40 CFR 82.154(a).

As explained in an earlier EPA rulemaking concerning refrigerant substitutes, EPA has not promulgated regulations requiring certification of refrigerant recycling/recovery equipment intended for use with substitutes to date (70 FR 19275; April 13, 2005). The Agency has recently proposed, but not yet finalized, regulations to address certification of such equipment used to recover and/or recycle substances that are not exempt from the venting prohibition (80 FR 69458; November 9, 2015). However, as EPA has noted, the lack of a current regulatory provision should not be considered as an exemption from the venting prohibition for substitutes that are not expressly exempted in § 82.154(a) (80 FR 69466, 69478). EPA has also noted that, in accordance with section 608(c) of the Act, the regulatory prohibition at § 82.154(a) reflects the statutory references to de minimis releases of substitutes as they pertain to good faith attempts to recover and recycle or safely dispose of non-exempted substitutes but does not provide clear guidance about what constitutes such a “good faith attempt” for substitutes. (80 FR 69470).

On May 23, 2014 (79 FR 29682), EPA exempted from the venting prohibition three HC refrigerant substitutes listed as acceptable, subject to use conditions, in the specified end-uses: Isobutane and R-441A, as refrigerant substitutes in household refrigerators, freezers, and combination refrigerators and freezers; and propane as a refrigerant substitute in retail food refrigerators and freezers (stand-alone units only). Similarly, on April 10, 2015 (80 FR 19453), EPA exempted from the venting prohibition four HC refrigerant substitutes listed as acceptable, subject to use conditions, in the specified end-uses: Isobutane and R-441A, in retail food refrigerators and freezers (stand-alone units only); propane in household refrigerators, freezers, and combination refrigerators and freezers; ethane in very low temperature refrigeration equipment and equipment for non-mechanical heat transfer; R-441A, propane, and isobutane in vending machines; and propane and R-441A in self-contained room air conditioners for residential and light commercial AC and heat pumps. Those regulatory exemptions do not apply to blends of HCs with other refrigerants or containing any amount of any CFC, HCFC, HFC, or PFC.

In those actions, EPA determined that for the purposes of CAA section 608(c)(2), the venting, release, or disposal of such HC refrigerant substitutes in the specified end-uses does not pose a threat to the environment, considering both the inherent characteristics of the substances and the limited quantities used in the relevant applications. EPA further concluded that other authorities, controls, or practices that apply to such refrigerant substitutes help to mitigate environmental risk from the release of those HC refrigerant substitutes.

C. What did EPA recently propose regarding management of refrigerant substitutes under CAA section 608?

In addition to the prohibition on knowingly releasing ozone-depleting and substitute refrigerants during the maintenance, service, repair, and disposal of appliances, the existing regulations established under CAA section 608 require that persons servicing or disposing of air-conditioning and refrigeration equipment observe certain service practices that reduce emissions of ozone-depleting refrigerant. The current regulatory provisions only apply to ozone-depleting refrigerants and appliances containing ozone-depleting refrigerants. The current requirements include: Requiring that technicians be certified to work on appliances; restricting the sale of refrigerant to certified technicians; specifying the proper evacuation levels before opening up an appliance; requiring the use of certified refrigerant recovery and/or recycling equipment; requiring the maintenance and repair of appliances that meet certain size and leak rate thresholds; requiring that refrigerants be removed from appliances prior to disposal; requiring that air-conditioning and refrigeration equipment be provided with a servicing aperture or process stub to facilitate refrigerant recovery; requiring that refrigerant reclaimers be certified in order to reclaim and sell used refrigerant; and establishing standards for technician certification programs, recovery equipment, and quality of reclaimed refrigerant.

On November 9, 2015 (80 FR 69457), EPA proposed to update these existing requirements found in 40 CFR part 82, subpart F that currently apply to ozone-depleting refrigerants and then to generally extend those requirements, as appropriate, to non-ozone-depleting substitute refrigerants, including but not limited to HFCs and PFCs. However, as proposed, the rule requirements would not extend to substitute refrigerants that are exempt from the venting prohibition. This proposed rule would also streamline the regulations at 40 CFR part 82, subpart F to improve clarity. For more information on this proposed rule, see docket EPA–HQ–OAR–2015–0453.

VI. What is EPA proposing in this action?

EPA is proposing to list certain newly submitted alternatives as acceptable, subject to use conditions, and other newly submitted alternatives as unacceptable. EPA is also proposing to modify the listings from acceptable to
acceptable, subject to narrowed use limits, or to unacceptable for certain alternatives in various end-uses in the refrigeration and AC, foam blowing, and fire suppression and explosion protection sectors. In each instance where EPA is proposing to list a newly submitted substitute as unacceptable or is changing the status of a substitute from acceptable to unacceptable, EPA has determined that there are other alternatives that pose lower overall risk to human health and the environment. EPA is also proposing that the existing listing decisions for foam blowing agents apply to closed cell foam products and products containing closed cell foam. See section VLC.3 for the details of this proposal. The emissions that would be avoided from the proposed changes of status in this action are estimated to be approximately 5.5 to 6.6 MMTCO₂eq in 2025 and approximately 9.8 to 11.3 MMTCO₂eq in 2030.27

In each listing decision, EPA is considering the intersection between the specific alternative and the particular end-use, per the guiding principles stated above. This action does not propose that any specific alternative is acceptable or unacceptable across all sectors and end-uses. EPA is also not proposing that, for any specific sector, the only acceptable substitutes are non-fluorinated. EPA recognizes that both fluorinated (e.g., HFCs, HFOs) and non-fluorinated (e.g., HCs, CO₂) substitutes may pose lower overall risk to human health and the environment, depending on the particular use.

Change of Listing Status

In determining whether to modify the previous listing decisions for substitutes based on whether other alternatives are available that pose lower risk to human health and the environment, we considered, among other things: Scientific findings, information provided by the Technology and Economic Assessment Panel (TEAP) that supports the Montreal Protocol, journal articles, submissions to the SNAP program, the regulations and supporting dockets for other EPA rulemakings, presentations and reports presented at domestic and international conferences, and materials from trade associations and professional organizations. The materials on which we have relied may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663). Key references are highlighted in section VIII of today’s notice.

Change of Status Dates

Here, as in the July 20, 2015, final rule, the proposed change of status dates are based upon EPA’s understanding of the availability of alternatives, considering factors such as commercial availability and supply of alternatives, time required to work through technical challenges with using alternatives, and time required to meet other federal regulatory requirements with redesigned equipment or formulations.

Consideration of Costs and Benefits

Under the SNAP criteria for review in 40 CFR 82.180(a)(7), consideration of cost is limited to cost of the substitute under review, and that consideration does not include the cost of transition when a substitute is found unacceptable. EPA requires information on cost and availability of substitutes as part of SNAP submissions in order to judge how widely a substitute might be used, and therefore, what its potential environmental and health effects might be. The SNAP criteria do not identify other cost considerations and thus we have not historically used cost information independent of environmental and health effects to determine the acceptability of substitutes under review—that is, we have never determined a substitute under review to be unacceptable or acceptable on the basis of its cost. When considering a change of status for substitutes already listed as acceptable, the SNAP program has not considered the costs of transition away from HFCs, HFC blends, PFCs, and other alternatives affected by the changes of status as part of determining the status of the substitute or the availability of other alternatives for the same uses. We are not revising this rulemaking whether to revise the regulatory criteria to include an expanded role for the consideration of costs in SNAP listing decisions. We have simply applied the existing regulatory criteria in determining whether to change the listing status of the substitutes addressed in this action.

Nevertheless, EPA has estimated the costs of the proposed changes of status in this action in order to provide information to the public and to meet various statutory and executive order requirements. We have estimated costs28 for applicable NAICS codes in a


28 Using a 7% discount rate, total annualized compliance costs across the roughly 100 affected businesses are estimated to range from $59.2 million–$71.3 million. Using a 3% discount rate, total annualized compliance costs are estimated to range from $58.8 million–$70.6 million. In terms of the percentage of the estimated total annualized costs by sectors: Refrigeration and air conditioning is about 97–98%, foams is about 2–3% and fire suppression is about 0%.


30 ICF, 2016b. Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives used in Refrigeration and Air Conditioning, Foams, and Fire Suppression.

31 ICF, 2016b. Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives used in Refrigeration and Air Conditioning, Foams, and Fire Suppression. Based upon these analyses, EPA does not expect this proposed rule to have major economic impacts (greater than $100 million per year) or to have a significant impact on a substantial number of small entities, if it is finalized as proposed. In addition, we have analyzed costs and impacts on small businesses in a document titled, “Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives used in Refrigeration and Air Conditioning, Foams, and Fire Suppression.” These analyses are available in the docket for this rulemaking (EPA–HQ–OAR–2015–0663). Based upon these analyses, EPA does not expect this proposed rule to have major economic impacts (greater than $100 million per year) or to have a significant impact on a substantial number of small entities, if it is finalized as proposed. In addition, we have analyzed costs and impacts on small businesses in a document titled, “Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives used in Refrigeration and Air Conditioning, Foams, and Fire Suppression.”
expect this proposed rule to have major economic impacts (greater than $100 million per year) or to have a significant impact on a substantial number of small entities, if it is finalized as proposed. As noted, EPA’s consideration of cost in listing decisions is limited to evaluating the cost of the substitute under review pursuant to § 82.180(a)(7)(vii). However, for purposes of ensuring that the cost analysis EPA prepared for purposes of providing information to the public and complying with statutory and executive order requirements is as accurate as possible, EPA requests comment on the preliminary cost analysis and the economic impact screening analysis for purposes of updating the analysis. These analyses are available in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

The refrigeration and air conditioning and fire suppression end-uses that would be affected by this proposed rule were not affected by the changes of status promulgated in the July 20, 2015, final rule. For the foams sector, the rigid PU spray foam end-use was not affected by the changes of status in the July 20, 2015, final rule. For some other foam end uses, we changed the status in the July 20, 2015, final rule with respect to use of the blowing agent and are now proposing to change the status with respect to use of closed cell foam products and products containing closed cell foam that are manufactured or imported using these foam-blowing agents.

Narrowed Use Limits

EPA notes that it may be reasonable for several of the end-uses to be broken down further. Consistent with previous practice and as EPA is proposing in certain instances in this proposal, EPA could consider adopting narrowed use limits. We could also consider adopting temporary narrowed use limits for a specific application within an end-use if the Agency determined that substitutes would be available for all but that specific application as of a particular date. In that case, for applications in that end-use not covered by the narrowed use limit, the proposed rule would list the substitute as unacceptable as of that date. For the specific application at issue, the proposed rule could contain both a temporary narrowed use limit with an expiration date and a listing as unacceptable upon the expiration of the narrowed use limit. Any end user within the covered application would need to comply with the requirement to analyze and document that there are no other alternatives that are technically feasible for their specific end-use in order to use the substitute identified in the narrowed use limit.

Requests for Comment

EPA requests comment on all aspects of this proposal, including proposed decisions to list additional substitutes as acceptable in certain end uses, to list new substitutes as unacceptable in certain end uses and to change the listing status of certain substitutes from acceptable to unacceptable, subject to narrowed use limits or unacceptable, and the dates when the change of status would apply to users of these substitutes. EPA is particularly interested in information concerning whether the supply of substitutes is sufficient to meet the dates proposed in this action or whether there are technical challenges in meeting a proposed change of status date. EPA is also interested in whether EPA should adopt a temporary narrowed use limit for a specific application of an end-use in the final rule. In such a case, the commenter should explain why other alternatives would not be available for the specific application of that end-use and for what period of time. EPA is also requesting comments on the determination that the SNAP listing decisions for foam blowing agents would apply to closed cell foam products and products containing closed cell foam that are manufactured or imported after one year after publication of a final rule. In addition, EPA is requesting comments on its proposed decision regarding the venting prohibition under section 608. More specific requests for comment are included with the discussion of each of the proposed decisions.

A. Retail Food Refrigeration and Stationary AC

1. Proposed Listing of Propane as Acceptable, Subject to Use Conditions, for Commercial Ice Machines, Water Coolers, and Very Low Temperature Refrigeration Equipment

EPA is proposing to list propane (R-290) as acceptable, subject to use conditions, as a refrigerant in new self-contained commercial ice machines, in new water coolers, and in new very low temperature refrigeration equipment. The proposed use conditions include conditions requiring conformity with industry standards, limits on charge size, and requirements for warnings and markings on equipment. The use conditions are detailed below in section VI.A.1.c., “What are the proposed use conditions?”

a. What are the affected end-uses?

Commercial ice machines are used in commercial establishments to produce ice for consumer use, such as in hotels, restaurants, and convenience stores. Many commercial ice machines are self-contained units, while some have the condenser separated from the portion of the machine making the ice and have refrigerant lines running between the two. The proposed listing applies only to self-contained commercial ice machines.

Water coolers are self-contained units providing chilled water for drinking. They may or may not feature detachable containers of water.

Very low temperature refrigeration equipment is intended to maintain temperatures considerably lower than for refrigeration of food—generally, –80 °C (–170 °F) or lower. In some cases, very low temperature refrigeration equipment may use a refrigeration system with two refrigerant loops containing different refrigerants or with a direct expansion (DX) refrigeration loop coupled with an alternative refrigeration technology (e.g., Stirling cycle).

b. How does propane compare to other refrigerants for these end-uses with respect to SNAP criteria?

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks (e.g., flammability, exposure, and toxicity) are discussed below. In addition, a technical support document 32 that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives in the relevant end-uses may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

i. Environmental Impacts

The ODP is the ratio of the impact on stratospheric ozone of a substance compared to the impact of an identical mass of CFC-11. Thus, the ODP of CFC-11 is defined to be one. Other ODS have ODPs that range from 0.01 to 10.0.

Propane has an ODP of zero.\(^{33}\) The most commonly used substitutes in the commercial ice machine, water cooler, and very low temperature refrigeration end-uses also have an ODP of zero (e.g., R-404A and R-134a). Some less common alternatives for these end-uses, such as R-401A, R-403B, R-414A and other blends containing HCFC-22 or HCFC-142b,\(^{34}\) have ODPs ranging from 0.01 to 0.047. Thus, propane has an ODP lower than or identical to the ODPs of other alternatives in these end-uses.\(^{35}\)

The GWP is a means of quantifying the potential integrated climate forcing of various greenhouse gases relative to a value of one for CO\(_2\). Propane has a relatively low integrated GWP of three.\(^{36}\) For comparison, some other commonly used acceptable refrigerants in these end-uses are R-134a and R-404A, with GWPs of about 1,430 and 3,920, respectively. As shown in Table 2, the GWPs for acceptable refrigerants in commercial ice machines ranges from zero for ammonia vapor compression, ammonia absorption, and the not-in-kind Stirling cycle technology to approximately 3,990 for R-507A, while for water coolers, acceptable substitutes have GWPs ranging from 31 for THR-02 to approximately 3,990 for R-507A.\(^{37}\) In very low temperature refrigeration, a common refrigerant is R-508B, with a GWP of 13,400, while the recently listed refrigerant ethane has a GWP of approximately six and CO\(_2\) has a GWP of one; the GWPs for substitutes in this end-use range from one for CO\(_2\) to 14,800 for HFC-23. Propane’s GWP is comparable to or significantly lower than those of other alternatives in these end-uses.

### TABLE 2—GWP, ODP, AND VOC STATUS OF PROPANE COMPARED TO OTHER REFRIGERANTS IN NEW COMMERCIAL ICE MACHINES, WATER COOLERS, AND VERY LOW TEMPERATURE REFRIGERATION EQUIPMENT \(^{1,2,3}\)

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane</td>
<td>3</td>
<td>0</td>
<td>Yes</td>
<td>Acceptable, subject to use conditions.</td>
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</table>

#### Commercial Ice Machines

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<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOR12A, FOR12B, FRIGC FR-12 (HCFC Blend Beta)</td>
<td>30–3,610</td>
<td>0–0.009</td>
<td>Yes</td>
<td>No change.</td>
</tr>
</tbody>
</table>

#### Water Coolers

<table>
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<th>Refrigerants</th>
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<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
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</thead>
<tbody>
<tr>
<td>FOR12A, FOR12B, FRIGC FR-12 (HCFC Blend Beta)</td>
<td>30–3,090</td>
<td>0–0.009</td>
<td>Yes</td>
<td>No change.</td>
</tr>
</tbody>
</table>

#### Very Low Temperature Refrigeration Equipment

<table>
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<th>Refrigerants</th>
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<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISCEON 89</td>
<td>2,530–8,500</td>
<td>0</td>
<td>Yes</td>
<td>No change.</td>
</tr>
</tbody>
</table>

\(^{1}\) The table does not include not-in-kind technologies listed as acceptable for the stated end-use.\(^{2}\) HCFC-22 and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production and consumption.\(^{3}\) One or more constituents of the blend are VOC.

The overall GHG effects of these refrigerants in various end-uses depend upon the design of the appliances, since the “indirect” GHG emissions associated with electricity consumption typically exceed the GHG emissions from the refrigerants over the full lifecycle of the appliance products.\(^{38}\) These indirect emissions values taken from IPCC, 2007. Climate Change 2007: The Physical Science Basis.\(^{37}\) The GWPs of the ozone-depleting substances historically used in these end-uses are: CFC-12 (GWP = 10,900); HCFC-22 (GWP = 1,810); R-13B1/halon 1301 (GWP = 7,140) and R-502 (GWP = 4,660).\(^{38}\) RTOC, 2015. 2014 Report of the Refrigeration, Air-Conditioning and Heat Pumps Technical...
occur from combustion of fossil fuel at power plants in order to supply electric power for operation of the refrigeration equipment. We do not have a practice in the SNAP program of including energy efficiency in the overall risk analysis. We do, however, consider issues such as technical needs for energy efficiency (e.g., to meet Department of Energy (DOE) conservation standards) in determining whether alternatives are “available.” We recognize that the energy efficiency of any given piece of equipment is in part affected by the choice of refrigerant and the particular thermodynamic and thermophysical properties that refrigerant possesses, as well as other factors. For example, appliances that are optimized for a specific refrigerant will operate more efficiently. While theoretical efficiency of any given Rankine cycle is not dependent on the refrigerant used, the refrigerant, the design of the equipment, and other factors will affect the actual energy efficiency achieved in operation. Although we cannot know what energy efficiency will be achieved in future products using propane, or any other specific acceptable refrigerant, we can point to both actual equipment and testing results that suggest that equipment optimized for propane may improve energy efficiency, and is unlikely to negatively impact it. Further, testing data, peer-reviewed journal articles and other information provided by the submitters for propane in the proposed end-uses indicate that equipment using propane is likely to require a smaller refrigerant charge, to have a higher coefficient of performance, and to use less energy than equipment currently being manufactured that uses other refrigerants that currently are listed as acceptable under SNAP in these end-uses. Also see section VI.A.3.f below concerning the role of the DOE energy conservation standards in ensuring that overall energy efficiency of equipment will be maintained or improved over time.

In addition to global impacts on the atmosphere, EPA evaluated potential impacts of propane and other HC refrigerants on local air quality. Propane is a VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of State Implementation Plans (SIPs) to attain and maintain the National Ambient Air Quality Standards (NAAQS). Potential emissions of VOC from all substitutes for all end-uses in the refrigeration and AC sector are addressed by the venting prohibition under CAA section 608. Under that prohibition, refrigerant substitutes (and thus the VOC they contain) may only be emitted where EPA issues a final determination exempting a refrigerant substitute from the venting prohibition on the basis that venting, releasing or disposing of such substance does not pose a threat to the environment, as proposed elsewhere in this action (see section VI.A.2.a, “What is EPA’s proposal regarding whether venting of propane in the end-uses in this action would pose a threat to the environment?” below). EPA estimates that potential emissions of HCs, including propane, when used as refrigerant substitutes in all end-uses in the refrigeration and AC sector, have little impact on local air quality, with the exception of unsaturated HCs such as propylene.42

EPA analyzed a number of scenarios to consider the potential impacts on local air quality if HC refrigerants were used widely.43 The analysis considered both worst-case and more realistic scenarios. The worst-case scenario assumed that the most reactive HC listed as acceptable (isobutane) was used in all refrigeration and AC uses even though isobutane has not been listed acceptable for use in all refrigeration and AC uses, and that all refrigerant used was emitted to the atmosphere. In that extreme scenario, the model predicted that the maximum increase in any single 8-hour average ground-level ozone concentration would be 0.72 ppb in Los Angeles, which is the area with the highest level of ozone pollution in the United States. Given the potential sources of uncertainty in the modeling, the conservativeness of the assumptions, and the finding that the incremental emissions from refrigerant emissions would not cause any area that would otherwise meet the 2008 ozone NAAQS to exceed it,44 we believe that the use of isobutane consistent with the use conditions required in EPA’s regulations will not result in significantly greater risk to the environment than other alternatives. Further, propane is less reactive than isobutane and thus we reach a similar conclusion for propane.

In a less conservative analysis potential impacts on ambient ozone levels, EPA looked at a set of end-uses that would be more likely to use HC refrigerants between now and 2030, including end-uses where they previously have been listed as acceptable and where they are proposed to be acceptable under this rule. For example, we assumed use of propane in water coolers and commercial ice machines and in end-uses where it is listed as acceptable, including room air conditioners and household and retail food refrigeration equipment and we assumed the use of other HCs such as isobutane in household and retail food refrigeration equipment and R-441A in room air conditioners and household and retail food refrigeration equipment. For further information on the specific assumptions, see the docket for this rulemaking.45 Based on this less conservative but more probable assessment of refrigerant use, we found that even if all the refrigerant in appliances in end-uses addressed in this proposed rule and in appliances in end-uses for which HCs are listed as acceptable were to be emitted, there would be a worst-case impact of a 0.15 ppb increase in ozone for a single 8-hour average concentration in the Los Angeles area, which is the area with the highest level of ozone pollution in the United States. 46 In the other cities examined in the analysis, Houston and Atlanta, impacts were smaller (no more than 0.03 and 0.01 ppb for a single 8-hour average concentration, respectively).47 For areas in the analysis that were not violating the 2008 ozone NAAQS, the impacts did not cause an exceedance of the 2008 ozone NAAQS.

Because of the relatively low air quality impacts of propane if it is acceptable under SNAP in these end-uses for which HCs are listed as acceptable, including room air conditioners and household and retail food refrigeration equipment and we assumed the use of other HCs such as isobutane in household and retail food refrigeration equipment and R-441A in room air conditioners and household and retail food refrigeration equipment. For further information on the specific assumptions, see the docket for this rulemaking. Based on this less conservative but more probable assessment of refrigerant use, we found that even if all the refrigerant in appliances in end-uses addressed in this proposed rule and in appliances in end-uses for which HCs are listed as acceptable were to be emitted, there would be a worst-case impact of a 0.15 ppb increase in ozone for a single 8-hour average concentration in the Los Angeles area, which is the area with the highest level of ozone pollution in the United States. In the other cities examined in the analysis, Houston and Atlanta, impacts were smaller (no more than 0.03 and 0.01 ppb for a single 8-hour average concentration, respectively). For areas in the analysis that were not violating the 2008 ozone NAAQS, the impacts did not cause an exceedance of the 2008 ozone NAAQS.

Because of the relatively low air quality impacts of propane if it is acceptable under SNAP in these end-uses for which HCs are listed as acceptable, including room air conditioners and household and retail food refrigeration equipment and we assumed the use of other HCs such as isobutane in household and retail food refrigeration equipment and R-441A in room air conditioners and household and retail food refrigeration equipment. For further information on the specific assumptions, see the docket for this rulemaking. Based on this less conservative but more probable assessment of refrigerant use, we found that even if all the refrigerant in appliances in end-uses addressed in this proposed rule and in appliances in end-uses for which HCs are listed as acceptable were to be emitted, there would be a worst-case impact of a 0.15 ppb increase in ozone for a single 8-hour average concentration in the Los Angeles area, which is the area with the highest level of ozone pollution in the United States. In the other cities examined in the analysis, Houston and Atlanta, impacts were smaller (no more than 0.03 and 0.01 ppb for a single 8-hour average concentration, respectively). For areas in the analysis that were not violating the 2008 ozone NAAQS, the impacts did not cause an exceedance of the 2008 ozone NAAQS.

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43 This less conservative analysis included some use of R-443A in room AC units because the substitute was under evaluation for that end-use. Elsewhere in this proposal, we propose to find R-443A and propylene unacceptable in residential and light-commercial AC and heat pumps, including room AC units. The propylene in R-443A, representing 12 percent of refrigerant emitted, was responsible for about 75 percent of the 0.15 ppb increase in ozone in this scenario. Thus, only 0.03 ppb of the 0.15 ppb observed in Los Angeles would be due to propane and other acceptable HCs.


44 The analysis described here was conducted prior to finalization of the 2015 ozone NAAQS. EPA has not yet made ozone attainment area designations for the 2015 ozone NAAQS.
released to the atmosphere from the proposed end-uses even in a worst-case scenario, we propose that propane does not have a significantly greater overall impact on human health and the environment based on its effects on local air quality than other refrigerants listed as acceptable in commercial ice machines, water coolers, and very low temperature refrigeration equipment.

Propane is highly volatile and typically evaporates or partitions to air, rather than contaminating surface waters. Propane’s effects on aquatic life are expected to be small and pose no greater risk of aquatic or ecosystem effects than those of other alternatives for these uses.

ii. Flammability

Propane’s flammability risks are of potential concern because commercial ice machines, water coolers, and very low temperature refrigeration equipment have traditionally used refrigerants that are not flammable. Without appropriate use conditions, the flammability risk posed by propane would be higher than non-flammable refrigerants because individuals may not be aware that their actions could potentially cause a fire. In this section, we discuss the flammability risks posed by propane and identify proposed use conditions that would mitigate those risks such that propane would not pose significantly greater risk due to flammability than other substitutes in these end-uses.

Because of its flammability, propane could pose a significant safety concern for workers and consumers in the end-uses addressed in this proposal if it is not handled correctly. In the presence of an ignition source (e.g., static electricity spark resulting from closing a door, use of a torch during service, or a short circuit in wiring that controls the motor of a compressor), an explosion or a fire could occur when the concentration of refrigerant exceeds its lower flammability limit (LFL). Propane’s LFL is 21,000 ppm (2.1%). Therefore, to use propane safely, it is important to minimize the presence of potential ignition sources and to reduce the likelihood that the concentration of propane will exceed the LFL. Under the proposed listing decision, propane would be acceptable for use only in new equipment (self-contained commercial ice machines, water coolers, and very low temperature refrigeration equipment) specifically designed for this refrigerant. OSHA and building code requirements generally address flammability risks in the workplace and we presume that the original equipment manufacturers (OEMs), who would be storing large quantities of the refrigerant, are familiar with and use proper safety precautions to minimize the risk of explosion, consistent with those requirements. Therefore, we are not proposing use conditions to address workplace risk, which would be redundant of already existing requirements. We are proposing, however, to include recommendations in the “Further Information” section of the SNAP listings that these facilities be equipped with proper ventilation systems and be properly designed to reduce possible ignition sources.

To determine whether flammability would be a concern for service personnel or for consumers, EPA analyzed a plausible worst-case scenario to model a catastrophic release of propane. The worst-case scenario analysis for water coolers and for very low temperature refrigeration equipment revealed that even if the unit’s full charge is emitted within one minute, the leaked refrigerant concentration did not reach propane’s LFL of 2.1%, provided that the charge sizes were no greater than those specified in the relevant standard from UL. The maximum charge size specified in the standard as a use condition; thus, there would not be an unacceptable risk of fire or explosion, even under those worst-case assumptions, so long as the charge does not exceed the use conditions in this proposed rule. In the case of commercial ice machines, the worst-case scenario with use of a charge size of 150 g and assuming stratification of refrigerant into the bottom 0.4 m of the room resulted in attaining 102 percent of the LFL; less conservative, but reasonable, assumptions (e.g., larger room size, greater mixing of the refrigerant in the entire room, same charge size of 150 g) resulted in concentrations at 18 percent or less of the LFL. Thus, we expect there would not be an unacceptable risk of fire or explosion provided that the charge size is limited to 150 g. EPA also reviewed the submitters’ detailed assessments of the probability of events that might create conditions and approaches to avoid sparking from the refrigeration equipment. Further information on these analyses and EPA’s risk assessments are available in the docket for this rulemaking (EPA–HQ–OAR–2015–0663). Further, service personnel or consumers may not be familiar with refrigeration or AC equipment containing a flammable refrigerant. Therefore, use conditions are necessary to ensure people handling such equipment are aware that equipment contains a flammable refrigerant and to ensure safe handling.

iii. Toxicity

In evaluating potential toxicity impacts of propane on human health in these end-uses, EPA considered both occupational and consumer risks. In general when evaluating non-cancer toxicity risks of a substitute, we use measured exposure concentrations if available, or modeled exposure concentrations using conservative assumptions appropriate to an end-use, and compare these exposure levels to recommended or required exposure limits for a compound or class intended to protect against adverse health effects. Where measured or modeled exposure levels are below relevant exposure limits for a chemical, we consider toxicity risks to be acceptable. Other acceptable substitutes listed for these end-uses have been evaluated for toxicity in this manner, including ethane for very low temperature refrigeration, ammonia for commercial ice machines, and a number of HFC blends for all three end-uses. EPA investigated the risk of asphyxiation and of exposure to toxic levels of refrigerant for a worst-case scenario and a typical use. In the worst-case scenario of a catastrophic leak, we modeled release of the unit’s full charge within one minute into a confined space to estimate concentrations that might result. We considered a conservatively small space appropriate to each end-use, such as a small galley kitchen of 18 m³ for a water cooler, a kitchen of a fast food restaurant of 22 m³ for a commercial ice machine or in a laboratory module of 28 m³ for very low temperature refrigeration equipment.

To evaluate the toxicity of propane, EPA estimated the maximum time weighted average (TWA) exposure both for a short-term exposure scenario, with a 30-minute TWA exposure, and for an 8-hour TWA that would be more typical of occupational exposure for a technician servicing the equipment or a worker disposing of appliances. We compared these short-term and long-term exposure values to relevant industry and government workplace exposure limits for propane. The modeling results indicate that both the

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short-term (30-minute) and long-term (8-hour) worker exposure concentrations would be below the relevant workplace exposure limits, such as the OSHA PEL of 1000 ppm (8-hr TWA), and the National Research Council’s Acute Emergency Guideline Limit Level 1 (AEGL–1) of 6,900 ppm over 30 minutes.

A similar analysis of asphyxiation risks considered whether a worst-case release of refrigerant in the same room sizes would result in oxygen concentrations of 12 percent or less. This analysis found that impacts on oxygen concentrations were minimal, with oxygen concentrations remaining at approximately 21 percent.

For equipment with which consumers might come into contact, such as water coolers and commercial ice machines, EPA performed a consumer exposure analysis. In this analysis, we examined potential catastrophic release of the entire charge of the substitute in one minute under a worst-case scenario. We did not examine exposure to consumers in very low temperature refrigeration, as equipment for this end-use would typically be used in the workplace, such as in laboratories, and not in a home or public space. The analysis was undertaken to determine the 30-minute TWA exposure levels for the substitute, which were then compared to the toxicity limit to assess the risk to consumers.

EPA considered toxicity limits for consumer exposure that reflect a short-term exposure such as might occur at home or in a store or other public setting where a member of the general public could be exposed and could then escape. The toxicity limit that we used in our analysis of consumer exposure was an AEGL–1 of 6,900 ppm over 30 minutes. The analysis of consumer exposure assumed that 100 percent of the unit’s charge would be released over one minute, at which time the concentration of refrigerant would peak in an enclosed space, and then steadily decline. Refrigerant concentrations were modeled under two air change scenarios, believed to represent the baseline of potential flow rates for a home or public space, assuming flow rates of 2.3 air changes per hour (ACH) in a household kitchen and 20 ACH in a restaurant kitchen. The highest concentrations of the refrigerant occur in the lower stratum of the room when assuming the lower ventilation level of 2.3 ACH. Calculating the TWA exposure using 2.3 ACH results in a higher concentration than calculating the TWA exposure using 20 ACH. Even under the very conservative assumptions used in the consumer exposure modeling, the estimated 30-minute consumer exposures to propane are lower than the relevant toxicity limits.

Based upon our analysis, workplace and consumer exposure to propane when used in these end-uses according to the proposed use conditions is not expected to exceed relevant exposure limits. Thus, propane does not pose significantly greater toxicity risks to other acceptable refrigerants in these end-uses. For further information, including EPA’s risk screens and risk assessments as well as information from the submitters of propane as a substitute refrigerant, see docket EPA–HQ–OAR–2015–0663.

c. What are the proposed use conditions?

In order to ensure that use of propane in these three end-uses would not cause greater risk to human health or the environment than use of other alternatives, we have identified and are proposing use conditions to address flammability and toxicity concerns. The proposed use conditions include conditions consistent with industry standards, limits on charge size, and requirements for warnings and markings on equipment.

i. New Equipment Only; Not Intended for Use as a Retrofit Alternative

EPA is proposing that, in the specified end-uses, propane be limited to use only in new equipment that has been designed and manufactured specifically for use with propane. Propane was not submitted under the SNAP program to be used in retrofit equipment, and no information was provided on how to mitigate hazards of flammable refrigerants when used in equipment that was not designed for flammable refrigerants. If this use condition is finalized as proposed, use of propane in equipment not designed for its use, including existing equipment designed for another refrigerant, would be in violation of CAA section 612(c) and the corresponding SNAP regulations at 40 CFR part 82, subpart G.

ii. Standards

EPA is proposing that propane be used only in equipment that meets all requirements in the relevant supplements for flammable refrigerants in certain applicable UL standards for refrigeration and AC equipment. Specifically, Supplement SA to the 8th edition of UL 563 standard, dated July 31, 2009, applies to self-contained commercial ice machines using flammable refrigerants; the UL standard for water coolers using flammable refrigerants is Supplement SB to the 7th edition of UL 399, dated August 22, 2008; and very low temperature refrigeration equipment is sufficiently similar to stand-alone commercial refrigerators that an appropriate standard is Supplement SB to the 10th edition of UL 471, dated November 24, 2010. UL has tested equipment for flammability risk in household and retail food refrigeration and for commercial freezers for very low temperature refrigeration. Further, UL has developed acceptable safety standards including requirements for construction, for markings, and for performance tests concerning refrigerant leakage, ignition of switching components, surface temperature of parts, and component strength after being scratched. These standards were developed in an open and consensus-based approach, with the assistance of experts in the AC and refrigeration industry as well as experts involved in assessing the safety of products. While similar standards exist from other bodies such as the International Electrotechnical Commission (IEC), we...
are proposing to rely on UL standards as those that are most applicable to and recognized by the U.S. market. This proposed approach is the same as that adopted in our previous rules on flammable refrigerants (76 FR 78832, December 20, 2011; 80 FR 19453, April 10, 2015).

iii. Charge Size
EPA is proposing use conditions that limit the amount of propane allowed in each refrigerant circuit to 150 g. It is necessary to set limits on charge size in order for propane not to pose a risk to human health or the environment that is greater than the risk posed by other substitutes. These limits will reduce the risk to workers and consumers since under scenarios we analyzed, a leak of the proposed charge sizes did not result in concentrations of the refrigerant that met or exceeded the LFL.

EPA is proposing limitations on refrigerant charge size for self-contained commercial ice machines, water coolers, and very low temperature refrigeration equipment that reflect the UL 563, UL 399, and UL 471 standards. As discussed above in paragraph ii of this section, we believe UL standards are appropriate because they are the most applicable to and recognized by the U.S. market and offer requirements developed by a consensus of experts.

UL Standards 563 (ice machines), 399 (water coolers), and 471 (commercial stand-alone refrigeration equipment) limit the amount of refrigerant leaked to 150 grams (5.29 ounces). We note that the charge size limit for propane in the UL standards is in line with the IEC 60335–2–89 standard addressing these end-uses, which also has a charge size limit of 150 grams.

iv. Color-Coded Hoses and Piping
EPA proposes that equipment designed for use with propane must have distinguishing color-coded hoses and piping to indicate use of a flammable refrigerant. This will help technicians immediately identify the use of a flammable refrigerant, thereby reducing the risk of using sparking equipment or otherwise having an ignition source nearby. The AC and refrigeration industry currently uses distinguishing colors as means to identify different refrigerants. Likewise, distinguishing coloring has been used elsewhere to indicate an unusual and potentially dangerous situation, for example in the use of orange-insulated wires in hybrid electric vehicles. Currently, no industry standard exists

contain letters at least ¼ inch high and that they be permanently affixed to the equipment. Warning label language requirements are as follows:

- **DANGER**—Risk of Fire or Explosion. Flammable Refrigerant Used. Do Not Use Mechanical Devices To Defrost Refrigerator. Do Not Puncture Refrigerant Tubing. This marking must be provided on or near any evaporators that can be contacted by the consumer.
- **DANGER**—Risk of Fire or Explosion. Flammable Refrigerant Used. To Be Repaired Only By Trained Service Personnel. Do Not Puncture Refrigerant Tubing. This marking must be located near the machine compartment.
- **CAUTION**—Risk of Fire or Explosion. Flammable Refrigerant Used. Consult Repair Manual/Owner’s Guide Before Attempting To Service This Product. All Safety Precautions Must be Followed. This marking must be located near the machine compartment.
- **CAUTION**—Risk of Fire or Explosion. Dispose of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used. This marking must be provided on the exterior of the refrigeration equipment.
- **CAUTION**—Risk of Fire or Explosion Due To Puncture Of Refrigerant Tubing: Follow Handling Instructions Carefully. Flammable Refrigerant Used. This marking must be provided near all exposed refrigerant tubing.

The warning label language is similar to or exactly the same as that required in UL standards: For commercial ice machines in UL 563 in section SB6.1, for water coolers in UL 399 in section SA6.1, and for commercial refrigerators and freezers, including very low temperature freezers, in UL 471 in section SB6.1.

It would be difficult to see warning labels with the minimum lettering height requirement of ½ inch in these UL standards. Therefore, as in the requirements in our previous HC refrigerants rules for residential and commercial refrigerator-freezers, vending machines, very low temperature refrigeration equipment, non-mechanical heat transfer equipment, and room air conditioners (76 FR 78832, December 20, 2011; 80 FR 19453, April 10, 2015), EPA is proposing the minimum height for lettering must be ¼ inch as opposed to ½ inch, which will make it easier for technicians, consumers, retail storeowners, and first responders to view the warning labels.

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59 To place this in context, a 150 g charge is about five times the charge in a disposable lighter (30 g).
d. What recommendations does EPA have for the safe use of propane?

In addition to establishing regulatory use conditions, which are binding on end users, EPA may also make recommendations for use of a substitute. EPA is proposing to recommend that only technicians specifically trained in handling flammable refrigerant substitutes dispose of or service refrigeration and AC equipment containing these substances. Trained technicians should know how to minimize the risk of fire and the procedures for using flammable refrigerant substitutes safely. Releases of large quantities of flammable refrigerants during servicing and manufacturing, especially in enclosed, poorly ventilated spaces or in areas where large amounts of refrigerant are stored, could cause an explosion if an ignition source exists nearby. For these reasons, technicians should be properly trained to handle flammable refrigerant substitutes when maintaining, servicing, repairing, or disposing of water coolers, commercial ice machines, and very low temperature freezers. In addition, EPA recommends that if propane would be vented, released, or disposed of (rather than recovered), as is proposed for the specified end-uses in this rule, the release should be in a well-ventilated area, such as outside of a building. Ensuring proper ventilation and avoiding ignition sources are recommended practices, whether venting or recovering a flammable refrigerant.

The Australian Institute of Refrigeration, Air Conditioning and Heating (AIRAH) provides useful guidance on safety precautions technicians can follow when servicing equipment containing flammable refrigerants or when venting refrigerant. One of those practices is to connect a hose to the appliance to allow for venting the refrigerant outside. EPA has reviewed several training programs provided as part of SNAP submissions from persons interested in flammable refrigerant substitutes. The agency intends to update the test bank for technician certification under CAA section 608 as we have done previously, and will consider including additional questions on flammable refrigerants. By adding such questions to the test bank, EPA would supplement but would not replace technician training programs currently provided by non-government entities. EPA will seek additional information and guidance on how best to incorporate this content through a separate process outside the scope of this final rule.

e. When would the listing apply?

EPA proposes that this listing would apply 30 days after the date of publication of a final rule. This date, the same as the proposed effective date of this regulation, allows for the safe use of this substitute at the earliest opportunity.

f. What is the relationship between this proposed SNAP rule and other federal rules?

i. How would this proposed listing relate to federal energy conservation standards?

For some of the types of equipment covered in this proposal, DOE has established energy conservation standards. For example, DOE energy conservation standards apply to automatic commercial ice machines. Thus, total energy use with propane can be expected to be no higher than that required by the standards for those classes of equipment. DOE does not have an energy conservation standard that would apply to water coolers or to very low temperature refrigeration equipment. EPA considers technical needs for energy efficiency (e.g., to meet DOE energy conservation standards) in determining whether alternatives are available. Based on available information, we found no evidence that propane would reduce energy efficiency or that equipment using propane would be unable to meet DOE energy efficiency standards in the end-uses proposed in this rule, and we found some evidence that propane may improve energy efficiency.

ii. How would this proposed listing relate to regulations implementing the venting prohibition under CAA section 608?

Below in section VI.A.2 of this document, EPA is proposing to exempt propane from the venting prohibition under CAA section 608 when propane is used as a refrigerant in self-contained commercial ice machines, water coolers, or very low temperature refrigeration equipment.

g. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of the proposed listing of propane as an acceptable refrigerant in self-contained commercial ice machines, water coolers, and very low temperature refrigeration equipment, including the proposed use conditions discussed in section VI.A.1.c. We request comment on our risk screens and the assumptions and exposure and flammability levels EPA used to evaluate risk. We are particularly interested in comment of two of the proposed use conditions: (1) The use of red marking for pipes, hoses and other devices including direct color application on the applicable parts of the system, such as a red plastic sleeve (see section VI.A.1.c.iv, “Color-coded hoses and piping”); and (2) the UL standards that EPA proposes to incorporate by reference (i.e., Supplement SA to the 8th edition of UL 563, dated July 31, 2009, for self-contained commercial ice machines, Supplement SB to the 7th edition of UL 399, dated August 22, 2008, for water coolers; and Supplement SB to the 10th edition of UL 471, dated November 24, 2010, for very low temperature refrigeration equipment.

62 Refrigeration or AC equipment in the applicable covered equipment class would still be subject to DOE’s standards, regardless of the refrigerant that the equipment uses. If a manufacturer believes that its design is subjected to undue hardship by DOE’s regulations, the manufacturer may petition DOE’s Office of Hearing and Appeals (OHA) for exception relief or exemption from the standard pursuant to OHA’s authority under section 504 of the DOE Organization Act (42 U.S.C. 7194), as implemented at subpart B of 10 CFR part 1003. OHA has the authority to grant such relief on a case-by-case basis if it determines that a manufacturer has demonstrated that meeting the standard would cause hardship, inequity, or unfair distribution of burdens.

2. Proposed Exemption for Propane From the Venting Prohibition Under CAA Section 608 for the End-uses in the Proposed New SNAP Listing

a. What is EPA’s proposal regarding whether venting of propane in the end-uses in this action would pose a threat to the environment?

EPA is proposing to list the refrigerant substitute propane under the SNAP program as acceptable, subject to use conditions, in newly manufactured water coolers, self-contained commercial ice machines, and very low temperature refrigeration equipment. EPA is also proposing to exempt propane in these end-uses from the venting prohibition under CAA section 608(c)(2). For purposes of CAA section 608(c)(2), EPA considers two factors in determining whether or not venting, release, or disposal of a refrigerant substitute during the maintenance, servicing, repairing, or disposing of appliances or equipment is a threat to the environment. See 69 FR 11948, March 12, 2004; 79 FR 29682, May 23, 2014; and 80 FR 19453, April 10, 2015. First, EPA analyzes the threat to the environment due to inherent characteristics of the refrigerant substitute, such as GWP. Second, EPA determines whether and to what extent venting, release, or disposal actually takes place during the maintenance, servicing, repairing, or disposing of appliances, and to what extent such actions are controlled by other authorities, regulations, or practices. To the extent releases are adequately controlled by other authorities, EPA defers to those authorities.

i. Potential Environmental Impacts

EPA has evaluated the potential environmental impacts of releasing into the environment propane, the substitute that we are proposing to list under the SNAP program as acceptable, subject to use conditions, in water coolers, self-contained commercial ice machines, and very low temperature refrigeration equipment. In particular, we assessed the potential impact of the release of propane on local air quality and its ability to decompose in the atmosphere, its ODP, its GWP, and its potential impacts on ecosystems.

As explained above in section VI.A.1.b.i, “Environmental impacts,” propane’s ODP is zero, its GWP is approximately three, and its effects on aquatic life are expected to be small. As to potential effects on local air quality, based on analysis and modeling results described in section VI.A.1.b.i of this preamble, EPA proposes to conclude that release of propane from the end-uses proposed in this action, in addition to the HCs previously listed as acceptable, subject to use conditions, for their specific end-uses, is expected to have little impact on local air quality. In this regard, EPA finds particularly noteworthy that even assuming 100 percent market penetration of propane and the other acceptable HCs in the proposed and acceptable end-uses, which is a conservative assumption, the highest impact for a single 8-hour average concentration based on this analysis would be 0.03 ppb in Los Angeles.

b. What is EPA’s proposal regarding whether propane in the end-uses specified in this action would pose a threat to the environment?

EPA is proposing to list the refrigerant substitute propane under the SNAP program as acceptable, subject to use conditions, in newly manufactured water coolers, self-contained commercial ice machines, and very low temperature refrigeration equipment. EPA is also proposing to exempt propane in these end-uses from the venting prohibition under CAA section 608(c)(2). For purposes of CAA section 608(c)(2), EPA considers two factors in determining whether or not venting, release, or disposal of a refrigerant substitute during the maintenance, servicing, repairing, or disposing of appliances or equipment is a threat to the environment. See 69 FR 11948, March 12, 2004; 79 FR 29682, May 23, 2014; and 80 FR 19453, April 10, 2015. First, EPA analyzes the threat to the environment due to inherent characteristics of the refrigerant substitute, such as GWP. Second, EPA determines whether and to what extent venting, release, or disposal actually takes place during the maintenance, servicing, repairing, or disposing of appliances, and to what extent such actions are controlled by other authorities, regulations, or practices. To the extent releases are adequately controlled by other authorities, EPA defers to those authorities.

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ii. Flammability and Toxicity

As discussed above in sections VI.A.1.b.ii, “Flammability” and VI.A.1.b.iii, “Toxicity,” EPA’s SNAP program evaluated the flammability and toxicity risks from propane in the proposed end-uses in this rule. EPA is providing some of that information in this section as well.

Propane is classified as an A3 refrigerant by ASHRAE Standard 34–2010 and subsequent addenda, indicating that it has low toxicity and high flammability. Propane has an LFL of 2.1%. To address flammability risks, this proposal provides recommendations for its safe use (see section VI.A.1.d, “What recommendations does EPA have for the safe use of propane?” above). The SNAP program’s analysis suggests that the proposed use conditions in this proposed rule will mitigate flammability risks.

Like most refrigerants, at high concentrations HCs can displace oxygen and cause asphyxiation. Various industry and regulatory standards exist to address asphyxiation and toxicity risks. The SNAP program’s analysis of asphyxiation and toxicity risks suggests that the proposed use conditions in this proposed rule will mitigate asphyxiation and toxicity risks. Furthermore, it is the Agency’s understanding that flammability risks associated with occupational exposures to HCs are adequately regulated by OSHA and building and fire codes at a local and national level.

iii. Authorities, Controls, or Practices

EPA expects that existing authorities, controls, and/or practices will mitigate environmental risk from the release of propane. Analyses performed for both this proposed rule and the SNAP rules issued in 1994, 2011, and 2015 (59 FR 13044, March 17, 1994; 76 FR 38832, December 20, 2011; and 80 FR 19453, April 10, 2015, respectively) indicate that existing regulatory requirements and industry practices limit and control the emission of propane. As explained below, EPA proposes that the limits and controls under other authorities, regulations, or practices adequately control the release of and exposure to propane and mitigate risks from any possible release.

As mentioned above, the determination of whether venting, release, or disposal of a substitute refrigerant poses a threat to the environment includes considering
whether such venting, release, or disposal is adequately controlled by other authorities, regulations, or practices. This information is another part of EPA’s proposal that the venting, release, or disposal of propane, in the specified end-uses and subject to the use conditions in this proposed action, does not pose a threat to the environment.

Industry service practices and OSHA standards and guidelines that address HC refrigeration equipment include monitoring efforts, engineering controls, and operating procedures. OSHA requirements that apply during servicing include continuous monitoring of explosive gas concentrations and oxygen levels. In general, HC emissions from refrigeration systems are likely to be significantly smaller than those emanating from the industrial process and storage systems, which are controlled for safety reasons. In the SNAP listings in section VI.A.1.c, “What are the proposed use conditions?” we note that the amount of refrigerant substitute from a refrigerant loop is limited to 150 g in the end-uses proposed in this rule. This indicates that HC emissions from such uses are likely to be relatively small.

The release and/or disposal of many refrigerant substitutes, including propane, are controlled by other authorities including various standards, and state and local building codes. To the extent that release during maintaining, repairing, servicing, or disposing of appliances is controlled by regulations and standards of other authorities, these practices and controls for the use of propane are sufficiently protective. These practices and controls mitigate the risk to the environment that may be posed by the venting, release, or disposal of propane during the maintaining, servicing, repairing, or disposing of appliances.

EPA is aware of equipment that can be used to recover HC refrigerants. While there are no relevant U.S. standards for such recovery equipment currently, to the extent that propane is recovered rather than vented in specific end-uses and equipment, EPA recommends the use of recovery equipment designed specifically for flammable refrigerants in accordance with applicable safe handling practices. See section VI.A.1.d above, “What recommendations does EPA have for the safe use of propane?”

b. What is EPA’s proposal regarding whether venting of propane in the end-uses in this action should be exempted from the venting prohibition under CAA section 608?

Consistent with the proposed listing under SNAP in this action, EPA proposes that venting, releasing or disposing of propane in water coolers, self-contained commercial ice machines, and very low temperature refrigeration equipment is not expected to pose a threat to the environment. As discussed more fully above, we propose this on the basis of the inherent characteristics of this substance, the limited quantities used in the relevant end-uses, and the limits and controls under other authorities, regulations, or practices that adequately control the release of and exposure to propane and mitigate risks from any possible release. Accordingly, EPA is proposing to revise the regulations at § 82.154(a)(1) to add propane in these end-uses to the list of substitute refrigerants that are exempt from the venting prohibition. We also note that EPA has recently proposed to revise the format of the text of this section to include separate paragraphs for each substitute refrigerant, rather than grouping refrigerants in an end-use (80 FR 69457; November 9, 2015). Thus, the final text of § 82.154(a)(1) may reflect revised language related to both the November 2015 proposal and to this proposal.

c. When would the exemption from the venting prohibition apply?

We are proposing that propane would be exempt from the venting prohibition as of 30 days after the publication of a final rule in the Federal Register. This would be the same as the date of the SNAP listing of propane in commercial ice machines, water coolers, and very low temperature refrigeration equipment.

d. What is the relationship between this proposed exemption under CAA section 608 and other EPA rules?

If this proposed exemption were to become final as proposed, it would not mean that propane could be vented in all situations. Propane and other HCs being recovered, vented, released, or otherwise disposed of from commercial and industrial appliances are likely to be hazardous waste under RCRA (see 40 CFR parts 261 through 270). As discussed in the final rules addressing the venting of ethane, isobutane, propane, and R-441A as refrigerant substitutes in certain end-uses, incidental releases may occur during the maintenance, service, and repair of appliances subject to CAA section 608 (79 FR 29682, May 23, 2014; 80 FR 19454, April 10, 2015). Such incidental releases would not be subject to RCRA requirements for the disposal of hazardous waste, as such releases would not constitute disposal of the refrigerant charge as a solid waste, per se. Disposal or venting of propane from household appliances used in the home, such as a water cooler, is also generally not considered disposal of a hazardous waste under the existing RCRA regulations and could be vented under the household hazardous waste exemption, assuming other state or local requirements do not prohibit venting. See 40 CFR 261.4(b)(1). However, for commercial and industrial appliances such as self-contained commercial ice machines, very low temperature refrigeration equipment, or water coolers used in an industrial or office setting, it is likely that propane and other flammable HC refrigerant substitutes would be classified as hazardous waste and disposal of propane from such appliances would need to be managed as hazardous waste under the RCRA regulations (40 CFR parts 261 through 270), unless it is subject to a limited exception in those regulations if the ignitable refrigerant is to be recycled.

e. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of our proposal to exempt from CAA section 608’s venting prohibition the venting or release of propane used as a refrigerant substitute in water coolers, self-contained commercial ice machines, and very low temperature refrigeration equipment, as well as seeking comment on the proposed exemption language at 40 CFR 82.154(a)(1).

3. Proposed Listing of New Refrigerants as Unacceptable

a. Proposed Listing of Certain Flammable Refrigerants as Unacceptable for Retrofits in Unitary Split AC Systems and Heat Pumps

EPA is proposing to list the following flammable refrigerants as unacceptable for use in existing unitary split AC and heat pumps for residential and light commercial AC and heat pumps because they pose significantly more risk to human health or the environment than other available alternatives:

- All refrigerants identified as flammability Class 3 in ANSI/ASHRAE Standard 34–2013.
- All refrigerants meeting the criteria for flammability Class 3 in ANSI/
ASHRAE Standard 34–2013. These include, but are not limited to, refrigerant products sold under the names R-22a, 22a, Blue Sky 22a refrigerant, Coolant Express 22a, DURACOOL-22a, EC-22, Ecofreeze 22a, EF-22a, EnviroSafe 22a, ES-22a, Frost 22a, HC-22a, Maxi-Fridge, MX-22a, Oz-Chill 22a, Priority Cool, and RED TEK 22a.

Existing unitary split AC systems and heat pumps were not designed to use a flammable refrigerant. We are aware of instances in which people or property have been harmed by retrofit or so-called ‘drop-in’ use of certain of the specified flammable refrigerants in equipment designed to use HCFC-22. For new equipment, we have listed certain flammable refrigerants as acceptable on the basis that flammability risks can be addressed in designing the equipment and mitigated through use conditions. In contrast, existing equipment has not been designed for flammable refrigerants and we have not identified appropriate use conditions that can manage the flammability risk for retrofits such that these flammable refrigerants would pose similar or lower risk than other available refrigerants in this end-use.

i. What is the affected end-use?

The residential and light commercial AC and heat pumps end-use includes equipment for cooling air in individual rooms, in single-family homes, and sometimes in small commercial buildings. This end-use differs from commercial comfort AC, which uses chillers that cool water that is then used to cool air throughout a large commercial building, such as an office building or hotel. This proposal specifically concerns unitary split systems and heat pumps, commonly called central AC. These systems include an outdoor unit with a condenser and a compressor, refrigerant lines, an indoor unit with an evaporator, and ducts to carry cooled air throughout a building. Central heat pumps are similar but offer the choice to either heat or cool the indoor space. We are proposing that certain flammable refrigerants would be listed as unacceptable for retrofit use in this type of equipment.

We are not currently proposing that the unacceptability determination for certain flammable refrigerants applies to other types of residential AC and heat pump equipment, but we may do so in the future. The presence of a proposal for a single type of equipment within this end-use could find certain substitutes acceptable, subject to use conditions, in a specific type of equipment does not imply that other uses are acceptable (e.g., listing as acceptable, subject to use conditions in new equipment does not mean retrofit use is acceptable). Other types of residential AC and heat pump equipment not included in this proposed unacceptability determination include:

- Multi-split air conditioners and heat pumps. These systems include one or more outdoor unit(s) with a condenser and a compressor and multiple indoor units, each of which is connected to the outdoor unit by refrigerant lines. For ductless multi-split systems, the cooled air exits directly from the indoor unit rather than being carried through ducts.
- Mini-split air conditioners and heat pumps. These systems include an outdoor unit with a condenser and a compressor and a single indoor unit that is connected to the outdoor unit by refrigerant lines. Cooled air exits directly from the indoor unit rather than being carried through ducts.
- Packaged outdoor air conditioners and heat pumps. These systems include an outdoor unit with a condenser and a compressor and a heating assembly, often used on top of the roof of a building such as a commercial office building or apartment building. These units carry cool air to the inside of the building through ducts, so they are not completely self-contained units; however, the refrigerant remains within the packaged unit, thus reducing the chance of leaks from refrigerant lines.
- Window air conditioners and heat pumps. These are self-contained units that fit in a window with the condenser extending outside the window.
- Packaged terminal air conditioners (PTACs) and packaged terminal heat pumps (PTHP). These are self-contained units that consist of a separate, unencased combination of heating and cooling assemblies mounted through a wall.
- Portable room air conditioners and heat pumps. These are self-contained, factory-sealed, single package units that are designed to be moved easily from room to room and are intended to provide supplemental cooling within a room. These units typically have wheels or casters for portability and have a fan which operates continuously when the unit is on. Portable room air conditioners and heat pumps may contain an exhaust hose that can be placed through a window or door to eject heat to the outside.

Compared to self-contained AC equipment such as window air conditioners, PTAC, PTHP, and portable room air conditioners, unitary split AC systems and heat pumps are much more likely to have a refrigerant release due to having larger charge sizes, more locations that are prone to leak, and because they are more likely to require servicing by a technician. A higher risk of refrigerant releases and a potential for larger releases and higher concentration releases results in higher risk that flammable refrigerant could be ignited from unitary split AC systems and heat pumps compared to self-contained equipment.

EPA is aware of a number of situations where companies have sold highly flammable refrigerants for use in residential AC that have not been submitted to SNAP for review. EPA has conducted enforcement actions against companies that have sold such substitutes in violation of EPA’s regulations.66 EPA is aware of multiple cases, where people and property using the “22a” refrigerant in a residential AC system were harmed in explosions and fires, in part because the person servicing the AC system was not aware that the system contained a highly flammable refrigerant. Considering this demonstration of the flammability risks of retrofitting residential AC systems as well as the lack of risk mitigation available for existing equipment (e.g., charge limits, design for reduced leakage), EPA is proposing to list R-22a, 22a, and other similar liquefied petroleum gases as unacceptable, as well as refrigerants with a flammability classification of 3 in ASHRAE 34–2013.

ii. Which refrigerants is EPA proposing to list as unacceptable?

EPA is proposing that the following flammable refrigerants be listed as unacceptable for retrofits in unitary split AC systems and heat pumps:

- All refrigerants identified as flammability Class 3 in ANSI/ASHRAE Standard 34–2013.
- All refrigerants meeting the criteria for flammability Class 3 in ANSI/ASHRAE Standard 34–2013. These include, but are not limited to, refrigerant products sold under the names R-22a, 22a, Blue Sky 22a refrigerant, Coolant Express 22a, DURACOOL-22a, EC-22, Ecofreeze 22a, EF-22a, EnviroSafe 22a, ES-22a, Frost 22a, HC-22a, Maxi-Fridge, MX-22a, Oz-Chill 22a, Priority Cool, and RED TEK 22a.

Refrigerants with a flammability classification of 3 identified by ASHRAE in ASHRAE 34–2013 include the HCs R-1150 (ethylene), R-170 (ethane), R-1270 (propylene), R-290 (propane), R-50 (CH₄), R-600 (n-butane), R-600a (isobutane), R-601 (n-pentane), and R-601a (isopentane); the HC blends R-433A, R-433B, R-433C, R-436A, R-436B, R-441A, and R-443A; and the refrigerant blends R-429A, R-430A, R-431A, R-432A, R-435A, and R-511A. All but one of these refrigerants contain HCs, with some also containing the flammable compounds dimethyl ether and HFC-152a.

In addition to refrigerants specifically identified in the ASHRAE 34–2013 standard as having a flammability classification of 3, EPA is proposing that refrigerants meeting the criteria of that standard are unacceptable. In other words, refrigerants are unacceptable if they exhibit flame propagation and either have a heat of combustion of 19,000 kJ/kg (8,174 BTU/lb) or greater or an LFL of 0.10 kg/m³ or lower. Refrigerants with flammability classification 2 may optionally be designated in the LFL subclass “2L” if they have a maximum burning velocity of 10 cm/s or lower when tested at 23.0 °C and 101.3 kPa. The flammability classification “3” is given to refrigerants that, when tested, exhibit flame propagation and that either have a heat of combustion of 19,000 kJ/kg (8,174 BTU/lb) or greater or an LFL of 0.10 kg/m³ or lower. Thus, refrigerants with flammability classification “3” are highly flammable while those with flammability classification “2” are less flammable and those with flammability classification “2L” are mildly flammable. For both toxicity and flammability classifications, refrigerant blends are designated based on the worst-case of fractionation determined for the blend (which may be different when evaluating toxicity than when evaluating flammability).

![Figure 1. Refrigerant Safety Group Classification](image-url)
classification of 3 and those refrigerants currently identified in the ASHRAE standard with a flammability classification of 3. We also request comment on whether the listing decision should specifically describe the criteria, i.e., “Any refrigerant that (1) exhibits flame propagation when tested by ASTM E681 at standard temperature and pressure and at 60 °C and (2) that either has a heat of combustion of 19,000 kJ/kg (8,174 BTU/lb) or greater or has an LFL of 0.10 kg/m³ or lower.”

ii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks (e.g., flammability, exposure, and toxicity) are discussed below. In addition, a technical support document 71 that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives in the relevant end-uses may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

(a) Environmental Impacts

EPA has listed a number of alternatives as acceptable for retrofit usage in unitary split AC systems and heat pumps. All of the listed alternatives are HFC blends, with some containing small percentages of HCs. Specific blends include: R-125/134a/600a (28.1/70.0/1.9), R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-407F, R-417A, R-417C, R-421A, R-422B, R-422C, R-422D, R-424A, R-427A, R-434A, R-438A, R-507A, and RS-44 (2003 composition). These blends are all non-ozone-depleting. As shown in Table 3, they have GWPs ranging from approximately 1,770 for R-407C to 3,990 for R-507A. Knowingly venting or releasing these refrigerants is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1). The HFC components of these refrigerant blends are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS, while the HC components are VOC.

### Table 3—GWP, ODP, and VOC Status of Flammable Refrigerants Compared to Other Refrigerants for Retrofit in Existing Equipment for Residential and Light Commercial AC (Unitary Split AC Systems and Heat Pumps) 1 2 3 4

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>All refrigerants identified as flammability Class 3 in ANSI/ASHRAE Standard 34–2013. All refrigerants meeting the criteria for flammability Class 3 in ANSI/ASHRAE Standard 34–2013, including, but not limited 1, to the products named R-22a, 22a, Blue Sky22a refrigerant, Coolant Express 22a, DURACOOL-22a, EC-22, Ecocfreeze EF-22a, EF-22a, Envirosafe 22a, ES-22, Frost 22a, HC-22a, Maxi-Fridge, MX-22a, OZ-Chill 22a, Priority Cool, and RED TEK22a.</td>
<td>2–120</td>
<td>0</td>
<td>Yes 3</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>R-404a, R-407a, R-407c, R-407f, R-421a, R-427a, R-507a.</td>
<td>2–120</td>
<td>0</td>
<td>Yes 3</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>Hot Shot 2, R-125/R-134a/R-600a (28.1/70.0/1.9), R-125/R-290/R-134a/R-600a (55.0/1.0/42.5/1.5), R-417a, R-422b, R-422c, R-422d, R-424a, R-427a, R-434a, R-437a, R-438a, RS-44 (2003 formulation).</td>
<td>1,770–3,990</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>1,810–3,390</td>
<td>0</td>
<td>Yes 4</td>
<td>No change.</td>
<td></td>
</tr>
</tbody>
</table>

1 The table does not include not-in-kind technologies listed as acceptable for the stated end-use.
2 HFC-C22 and several blends containing HFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production and consumption.
3 The entire refrigerant or most of the constituents are VOC.
4 One or more constituents of the refrigerant are VOC.

Both the currently acceptable refrigerants and those proposed to be unacceptable are non-ozone depleting. The refrigerants proposed to be unacceptable would result in higher VOC emissions than the acceptable refrigerants, with the saturated HCs (e.g., propane, isobutane) having a low impact and unsaturated HCs (e.g., propylene) having a significant impact (see section VI.A.1.b.i above). The refrigerants proposed to be unacceptable have significantly lower GWPs than the refrigerants that would remain acceptable.

(b) Flammability

All refrigerants currently listed as acceptable in this end-use are nonflammable, resulting in no risk of fire or explosion from flammability of the refrigerant. In comparison, ASHRAE Class 3 refrigerants are highly flammable. As discussed further below in section VI.A.3.b.iii(b), EPA analyzed the flammability impacts of one ASHRAE Class 3 refrigerant, R-443A, and found that a release of the entire refrigerant charge inside a building from a unitary split AC system or heat pump could result in surpassing the LFL. 72 Because of the large charge sizes required for this type of equipment and the similar LFLs for other ASHRAE Class 3 refrigerants, it is likely the LFL would be surpassed for other ASHRAE Class 3 refrigerants. Fires and harm to Risk Screen on Substitutes in Residential and Light Commercial Air Conditioning and Heat Pumps. Substitute: R-443A.

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72 ICF, 2016f. Significant New Alternatives Policy Program. Refrigeration and Air Conditioning Sector
people and property have already occurred in multiple cases due to retrofit or drop-in use of R-22a and similar products in existing unitary split AC systems.

(c) Toxicity

The HFC components of acceptable substitutes in this end-use, as well as the HFC components of the unacceptable refrigerant blends have exposure limits, such as WELs from the AIHA or manufacturer acceptable exposure limits, of 1,000 ppm on an 8-hr TWA and the HC components of both the acceptable refrigerants and those proposed unacceptable have exposure limits ranging from 500 to 1,000 ppm (8-hr TWA for TLVs from ACGIH and 10-hr TWA for recommended exposure limits (RELs) from NIOSH). Both the acceptable refrigerants and the proposed unacceptable refrigerants are able to be used be used in this end-use in accordance with their respective 8-hr or 10-hr workplace exposure limits. Acute exposure may also be of concern during use in unitary split AC systems and heat pumps because of possible exposure to consumers in the event of a sudden release. The currently acceptable refrigerants typically have high acute exposure limits for their components based upon cardiotoxic effects of halocarbons over 10,000 ppm (e.g., 350,000 cardiotoxic no-observed adverse effect level for HFC-32 over 5 minutes) or have components with STELs or AEGLs (e.g., 8,000 ppm 10-minute AEGL-1 for HFC-134a component). Acute exposure limits for components of the ASHRAE Class 3 refrigerants are comparable or lower, ranging from 1,500 ppm (e.g., excursion limit for propylene) to 6,900 ppm (AEGL-1 over 30 minutes for propane). Because of the large charge sizes required for this type of equipment and somewhat lower acute exposure limits for the hydrocarbon components of ASHRAE Class 3 refrigerants, acute exposure could be a concern for specific refrigerants. For example, as discussed further below in section VI.A.3.b.iii.(c), EPA analyzed the toxicity impacts of the propylene component of R-443A, and found that a catastrophic leak of that refrigerant inside a building from a unitary split AC system or heat pump resulted in estimated exposure levels at least four-fold that of the 1,500 ppm acute exposure limit.73

At this time, the potential reduced climate risks from using a highly flammable refrigerant with lower GWP does not outweigh the flammability risks of using these refrigerants in existing equipment that was designed for nonflammable refrigerants. In addition to flammability risk, in at least some cases, acute exposure limits of the proposed unacceptable refrigerants may be more difficult to attain than those for acceptable refrigerants in this end-use. Therefore, EPA proposes that the highly flammable refrigerants proposed to be unacceptable pose greater overall risk to human health and the environment than other substitutes for retrofit in the residential and light commercial AC and heat pumps end-use. However, the Agency may look back at these end-uses for other reasons if we receive information on how risks from the refrigerants proposed for listing as unacceptable can be sufficiently mitigated, we may reconsider any final action listing these refrigerants as unacceptable in this end use.

iv. When would the listings apply?

EPA proposes that these listings would apply 30 days after the date of publication of a final rule. To date, only one of these substitutes have been submitted to EPA for this end-use and this submission is currently incomplete. Thus, under 40 CFR 82.174, manufacturers are prohibited from introducing them into interstate commerce for this end-use. Thus, manufacturers and service technicians should not be currently using these substitutes in the manner that would be prohibited by this proposed listing decision. Further, a date or 30 days after the date of publication of a final rule, the same as the proposed effective date of this regulation, would protect technicians and consumers from the risks of these substitutes at the earliest opportunity.

v. What is the relationship between this proposed SNAP rule and other federal rules?

EPA is not aware of other federal rules that would apply to the use of these flammable refrigerants for retrofits in existing unitary split AC systems and heat pumps.

vi. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on our proposal to list as unacceptable for retrofit use in existing unitary split AC systems and heat pumps all refrigerants identified as flammability Class 3 in ANSI/ASHRAE Standard 34–2013 and all refrigerants meeting the criteria for flammability Class 3 in ANSI/ASHRAE Standard 34–2013, including, but not limited to, refrigerant products sold under the names R-22a, 22a, Blue Sky 22a refrigerant, Coolant Express 22a, DURACOOL-22a, EC-22, Ecofreeze 22a, EF-22a, Envirosafe 22a, ES-22a, Frost 22a, HC-22a, Maxi-Fridge, MX-22a, Oz-Chill 22a, Priority Cool, and RED TEK 22a. The agency also requests comment on the proposed decision to list these substitutes as unacceptable 30 days after the date of publication of a final rule, and any additional technical information on how risks from the refrigerants proposed for listing as unacceptable can be sufficiently mitigated.


EPA is proposing to list the refrigerants propylene (R-1270) and R-443A as unacceptable in new equipment in residential and light commercial AC and heat pumps, cold storage warehouses, and centrifugal and positive displacement chillers for commercial comfort AC.

i. What are the affected end-uses?

The refrigeration and AC end-uses addressed in this action include:

○ Centrifugal and positive displacement chillers;
○ residential and light commercial AC and heat pumps, including both self-contained units (e.g., window air conditioners, PTACs and PTHPs, portable AC units) and split systems; and
○ cold storage warehouses.

EPA has received a submission for R-443A in new residential and light commercial AC and heat pumps and for new window air conditioners, a subset of that end-use. We have also received a submission for propylene for use in new chillers for commercial comfort AC (centrifugal and positive displacement chillers) and for cold storage warehouses. Because the two refrigerants, R-443A and propylene, have similar properties and risk profiles, we reviewed both refrigerants for all four end-uses.

ii. Which refrigerants is EPA proposing to list as unacceptable?

Propylene, also known as propene or R-1270, is a HC with three carbons, the chemical formula C6H12, and the CAS Reg. No. 115–17–1. R-443A is a HC blend74 consisting of 55 percent

74 EPA notes that under the SNAP program, we review and list refrigerants with specific compositions (59 FR 13,044; March 18, 1994). To
propylene, 40 percent propane, and five percent isobutane by weight.

iii. How do these proposed unacceptable refrigerants compare to other refrigerants for these end-uses with respect to SNAP criteria?

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks (e.g., flammability, exposure, and toxicity) are discussed below. In addition, a technical support document\(^75\) that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives in the relevant end-uses may be found in the docket for this remaking (EPA–HQ–OAR–2015–0663).

(a) Environmental Impacts

Propylene and R-443A have an ODP of zero. Many acceptable substitutes in the refrigeration and AC end-uses addressed in this proposed rule also have an ODP of zero (e.g., HFCs, HFOs, CO\(_2\), ammonia, HCgs, and not-in-kind technologies).\(^76\) Of the acceptable refrigerants having an ODP, they have ODPs ranging from 0.00024 to 0.047.\(^77\)\(^78\)

Thus, propylene and R-443A have ODPs comparable to or less than the ODPs of other alternatives in the end-uses proposed in this rule. Propylene and the components of R-443A have relatively low GWP of less than ten. As shown in Table 4, GWPs of acceptable refrigerants in these end-uses range from zero to 3,990, depending on the specific end-use. (Elsewhere in this proposal, we propose to find unacceptable a number of higher GWP blends for use in new chillers and new cold storage warehouses; if that portion of this proposed rule was finalized as proposed, the highest GWP for any acceptable refrigerant in new chillers would be 630 and in new cold storage warehouses would be approximately 1,830.) The GWPs of propylene and R-443A are comparable to or higher than those of CO\(_2\), propane, isobutane, R-441A, ammonia, HFO-1234ze(E), trans-1-chloro-3,3,3-trifluoroprop-1-ene, and not-in-kind technologies such as Stirling cycle, water/lithium bromide absorption, desiccant cooling, or evaporative cooling, each of which is acceptable in new equipment for one or more of the four proposed end-uses. In addition, propylene and R-443A have lower GWPs than those of ODS historically used in these end-uses, CFC-12 (GWP = 10,900); HCFC-22 (GWP = 1,810); and R-502 (GWP = 4,660).\(^79\)

### TABLE 4—GWP, ODP, AND VOC STATUS OF PROPYLENE AND R-443A COMPARED TO OTHER REFRIGERANTS IN NEW EQUIPMENT FOR RESIDENTIAL AND LIGHT COMMERCIAL AC AND HEAT PUMPS, COLD STORAGE WAREHOUSES, CENTRIFUGAL CHILLERS AND POSITIVE DISPLACEMENT CHILLERS\(^1\)\(^2\)\(^3\)\(^4\)

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
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<tbody>
<tr>
<td>Propylene, R-443A</td>
<td>2–3</td>
<td>0</td>
<td>Yes</td>
<td>Unacceptable.</td>
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</table>

**New Residential and Light Commercial AC and Heat Pumps**

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<tr>
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<th>VOC</th>
<th>Proposal</th>
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**New Cold Storage Warehouses**

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<tr>
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**New Centrifugal Chillers**

<table>
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<tr>
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<th>Proposal</th>
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<tbody>
<tr>
<td>Ammonia, HFO-1234ze(E), trans-1-chloro-3,3,3-trifluoroprop-1-ene, R-450A, R-513A, IKON A, IKON B, THR-02</td>
<td>0–630</td>
<td>0–0.00034</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>Ammonia, HFO-1234ze(E), R-450A, R-513A, IKON A, IKON B, THR-02</td>
<td>30–920</td>
<td>Not public</td>
<td>Yes</td>
<td>No change.</td>
</tr>
</tbody>
</table>

**New Positive Displacement Chillers**

<table>
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<tr>
<th>Refrigerants</th>
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<th>VOC</th>
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</thead>
<tbody>
<tr>
<td>Ammonia, HFO-1234ze(E), R-450A, R-513A</td>
<td>0–631</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
</tbody>
</table>

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\(^{76}\) We assume that substitutes containing no chlorine, bromine, or iodine have an ODP of zero.


\(^{78}\) Under EPA’s phaseout regulations, virgin HCFC-22, HCFC-142b, and blends containing HCFC-22 or HCFC-142b may only be used to service existing appliances. Consequently, virgin HCFC-22, HCFC-142b and blends containing HCFC-22 or HCFC-142b may not be used to manufacture new pre-charged appliances or appliance components or to charge new appliances assembled onsite. Substitutes containing these HCFCs have ODPs ranging from 0.01 to 1.0.


In addition to global impacts on the atmosphere, EPA evaluated potential impacts of propylene and the components of R-443A on local air quality. Propylene and the three components of R-443A, propylene, propane and isobutane are not excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS.

However, there is a significant difference in the photochemical reactivity between propylene and the other two HCs. Propylene, because it has an unsaturated double bond between two carbons, is significantly more reactive in the atmosphere than propane, the saturated HC with the same number of carbon atoms, and isobutane. For example, the Maximum Incremental Reactivity (MIR) of propylene, in gram ozone per gram of the substance, is 11.57 while the MIR of propane is 0.56 g O_3/g and the MIR of isobutane is 1.34 g O_3/g. Thus, propylene is roughly 21 times more reactive than propane and roughly nine times more reactive than isobutane for the same mass. Propylene is also more than 100 times more reactive than HFC-134a (MIR < 0.1) and a number of other HCs acceptable for these end-uses and is significantly more reactive than unsaturated halogenated substitutes in these end-uses, such as HFO-1234yf (MIR = 0.28), HFO-1234ze(E) (MIR = 0.998), or trans-1-chloro-3,3,3-trifluoroprop-1-ene (Solstice™ 1233zd(E)) (MIR = 0.040).

Based on analyses described below, EPA estimates that potential emissions of saturated HCs if used as refrigerant substitutes in all end-uses in the refrigeration and AC sector would have little impact on local air quality, while emissions of propylene, including propylene from R-443A, could have a significant negative impact.

EPA analyzed a number of scenarios to consider the potential impacts on local air quality if HC refrigerants were used widely. We used EPA’s Vintaging Model to estimate the HC emissions from these scenarios and EPA’s Community Multiscale Air Quality (CMAQ) model to assess their potential incremental contributions to ground-level ozone concentrations. The first analysis assumed that all refrigerant used was emitted to the atmosphere, as it could be if refrigerants were exempted from the venting prohibition of CAA section 608. In that highly conservative scenario, the model predicted that the maximum increase in the 8-hour average ground-level ozone concentration would be 0.72 parts per billion (ppb) in Los Angeles if the most reactive saturated HC, isobutane, were the only refrigerant and it was all emitted to the atmosphere. If the unsaturated HC propylene was assumed to be the only refrigerant used in equipment and it was all emitted (if it were to be exempted from the venting prohibition under CAA section 608), the model predicted that the maximum increase in the 8-hour average ground-level ozone concentration would be 6.61 ppb in Los Angeles, which is the area with the highest level of ozone pollution in the United States. For purposes of comparison, the ground-level ozone limit under the NAAQS has been 75 ppb since 2008.

We have concerns that widespread emissions of propylene from use as a refrigerant could interfere with the ability of some nonattainment areas to reach attainment, both with the 2008 NAAQS and the new, more stringent standard.

EPA also performed less conservative analyses that considered the end-uses where these refrigerants would more likely be used, based upon submissions received and upon end-uses where there are industry standards addressing the use of flammable refrigerants. Propylene was previously listed as an acceptable substitute in industrial process refrigeration. EPA has received submissions for use of R-443A in residential and light commercial AC and heat pumps and window air conditioners. We have received a SNAP submission for use of propylene in cold storage warehouses and in commercial comfort AC in chillers, and have received inquiries about using propylene in retail food refrigeration. In addition, EPA is aware that UL has developed standards addressing use of flammable refrigerants in stand-alone retail food refrigeration equipment and coolers; vending machines; water coolers; commercial ice machines; household refrigerators and freezers; and room air conditioners; and is currently developing revisions to UL 995 for residential AC equipment.

Thus, we considered scenarios where propylene would be used and emitted (1) in all stationary AC and refrigeration end-uses, but excluding MVAC, (2) in all refrigeration end-uses and all AC end-uses except for MVAC and chillers for commercial comfort AC. For further details on the scenarios and end-uses in the analysis, see the docket for this rulemaking.

Based on this still conservative assessment of refrigerator use, we found that if all the refrigerator in appliances in the end-uses analyzed were to be emitted, there would be a worst-case impact of 4.47 ppb ozone in the Los Angeles area. In the other cities examined in the analysis, Houston and Atlanta, which have also had historically high levels of ambient ozone, impacts were smaller (as much as 0.67 and 0.39 ppb, respectively).

Approximately 72–73 percent of the emissions were estimated to come from the residential and light commercial AC and heat pumps end-use in those less conservative analyses, indicating that emissions from this end-use could have a particularly large impact. Both the

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2. Ibid.
3. Ibid.
4. Ibid.
5. Ibid.
most conservative as well as the less conservative but more probable assessments indicated there could be significant air quality impacts of these refrigerants if they are released to the atmosphere.

A more recent analysis specifically examining use of R-443A and propylene in residential and light commercial AC and heat pumps, cold storage warehouses, and commercial comfort AC (centrifugal and positive displacement chillers) found noticeable impacts from these end-uses. If propylene were the only refrigerant in these end-uses and it was emitted from residential and light commercial AC and heat pumps and cold storage warehouses, the analysis indicated there would be a worst-case impact of 4.45 ppb ozone in the Los Angeles area, 1.21 ppb in Houston, and 0.65 in Atlanta, respectively. Assuming that propylene were used in all cold storage warehouses and centrifugal and positive displacement chillers; room air conditioners could use either R-443A or the currently listed VOC refrigerants propane or R-441A; other residential and light commercial AC and heat pumps all used R-443A; and these refrigerants were all emitted from cold storage warehouses and residential and light commercial AC and heat pumps, there would be a worst-case impact of 2.57 ppm ozone in the Los Angeles area, 0.77 ppb in Houston, and 0.44 ppb in Atlanta, respectively.

Propylene and R-443A in the proposed end-uses would be subject to the CAA section 608 venting prohibition unless EPA were to issue a final rule specifically exempting them: EPA is not proposing such an exemption in this rulemaking. While potential air quality impacts of propylene and R-443A would likely be reduced through the CAA section 608 venting prohibition, we do not consider this sufficient to mitigate the risks of these refrigerants in the proposed end-uses, particularly in light of their photochemical reactivity and toxicity. EPA is not aware of commercially available recovery equipment for flammable refrigerants (e.g., built with spark-proof components and other features to reduce flammability risks), and without such equipment, emissions could occur. Further, other emissions could occur that are not subject to the venting prohibition and no equipment is free of refrigerant emissions. Because of the reactivity of these refrigerants, those emissions could interfere with the ability of some nonattainment areas to reach attainment, both with the 2008 NAAQS and the new, more stringent standard.

Ecosystem effects, primarily effects on aquatic life, of the substitutes are expected to be small as are the effects of other acceptable substitutes. Propylene, propane and isobutane are all highly volatile and would evaporate or partition to air, rather than contaminate surface waters. Neither propylene nor R-443A pose a greater risk of aquatic or ecosystem effects than those of other substitutes for these uses.

(b) Flammability

Propylene and R-443A are both designated as A3 refrigerants according to ASHRAE 34–2013 and subsequent addenda. Thus, their flammability is comparable to that of ethane, propane, isobutane, and R-441A, other refrigerants that EPA has listed as acceptable, subject to use conditions, in a number of end-uses (76 FR 78832, December 20, 2011; 80 FR 19454, April 10, 2015). Due to their flammable nature, propylene and R-443A could pose a significant safety concern for workers and consumers if they are not properly handled. In the presence of an ignition source (e.g., static electricity spark resulting from closing a door, using a torch during service, or a short circuit in wiring that controls the motor of a compressor), an explosion or a fire could occur when the concentration of refrigerant exceeds its LFL. The LFLs of the substitutes are: 2.03 percent for R-443A and 2.0 percent for propylene.

To determine whether flammability would be a concern for manufacturing and service personnel or for consumers, EPA analyzed a plausible worst-case scenario to model a catastrophic release of the refrigerants. The worst-case scenario analysis for each refrigerator revealed that even if the full charge of a window AC unit is emitted within one minute, neither of these refrigerants reached their respective LFLs. However, for larger residential AC systems, such as for a unitary split AC system, charges are significantly higher, and a catastrophic leak of refrigerant inside a building could result in surpassing the LFL.93 For chillers, our risk screen found that an instantaneous release of the entire charge of propylene from a small chiller (charge size of around 12 kg) would not exceed the LFL, but release of larger charge sizes (e.g., 315 kg) would result in exceeding the LFL by ten-fold or more. Thus, flammability would be a concern for equipment with large charge sizes.

EPA also reviewed the submitters’ detailed assessments of the probability of events that might create a fire and engineering risk and approaches to avoid sparking from the refrigeration equipment. Further information on these analyses and EPA’s risk assessments are available in public docket EPA—HQ–OAR–2015–0063. Manufacturing and service personnel or consumers may not be familiar with refrigeration or AC equipment containing a flammable refrigerant. Thus, additional risk mitigation would be appropriate. Use conditions such as those recently finalized for ethane, isobutane, propane, and R-441A could potentially be adopted by regulation as use conditions to mitigate flammability concerns from propylene and R-443A in end-uses for self-contained refrigeration and AC equipment such as stand-alone retail food refrigeration units, household refrigerators and freezers, vending machines, and room air conditioners for residential and light commercial AC and heat pumps. We further note that refrigerant handling equipment designed to be used safely with flammable refrigerants are not commercially available in the United States nor are standards to test and certify such equipment in place. Assuming these substitutes would not be exempted from the venting prohibition under CAA section 608 due to potential local air quality impacts, the lack of such equipment and standards for refrigerant recovery calls into

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question whether flammability risks could be adequately addressed through use conditions at this time.

(c) Toxicity

In evaluating potential toxicity impacts of propylene and R-443A on human health, EPA considered both occupational risk, and for end-uses in the household or in retail establishments, also consumer risks. EPA investigated the risk of asphyxiation and of exposure to toxic levels of refrigerant for a plausible worst-case scenario and a typical use scenario for each refrigerant. In the worst-case scenario of a catastrophic leak, we modeled release of the unit’s full charge within one minute into a confined space to estimate concentrations that might result. We considered a conservatively small space appropriate to each end-use, such as a small utility room of 18 m³ for a room air conditioner. EPA used the same assumptions when evaluating other substitutes, such as CO₂, HFC-32, propane and R-441A.

To evaluate toxicity of both refrigerants, EPA estimated the maximum TWA exposure both for a short-term exposure scenario, with a 30-minute TWA exposure, and for an 8-hour TWA that would be more typical of occupational exposure for a technician servicing the equipment. We compared these short-term and long-term exposure values to relevant industry and government workplace exposure limits for propylene and the components of R-443A (including potential impurities). The modeling results indicate that both the short-term (30-minute) and long-term (8-hour) worker exposure concentrations would be below the relevant workplace exposure limits, such as the OSHA PEL, the NIOSH REL, or the ACGIH’s TLV in cold storage warehouses, commercial comfort AC equipment, and residential and light commercial AC and heat pumps.69 Because there is not an established short-term exposure limit (STEL) for propylene, propane, or isobutane, we considered information on short-term exposure such as a short-term excursion limit based on the TLV or the National Research Council’s AEGL. The respective workplace exposure limits we considered for the various compounds, including components of the refrigerant blend R-443A, are as follows:

- Isobutane: 800 ppm REL on 10-hour TWA; 6,900 ppm over 30 minutes
- Propylene: 500 ppm TWA; 1,500 ppm excursion limit over 30 minutes
- Propane: 1,000 ppm PEL/TLV on 8-hour TWA; 6,900 ppm AEGL–1 over 30 minutes
- Propylene: 500 ppm TWA; 1,500 ppm excursion limit over 30 minutes

In comparison, HFCs and the HFC components of acceptable substitutes in these end-uses, have exposure limits, such as WEELs from the AIHA or manufacturer acceptable exposure limits, of 1,000 ppm on an 8-hour TWA and the HC components of both the acceptable refrigerants and those proposed unacceptable have exposure limits ranging from 500 to 1,000 ppm (8-hour TWA) for TLVs from ACGIH and 10-hour TWA for recommended exposure limits (RELs) from NIOSH. HFOs acceptable in centrifugal and positive displacement chillers have WEELs of 800 ppm. Both the acceptable refrigerants and the proposed unacceptable refrigerants are able to be used in these end-uses in accordance with their respective workplace exposure limits.

For equipment with which consumers might come into contact, such as residential air conditioners and heat pumps, EPA also performed a consumer exposure analysis. In this analysis, we examined potential catastrophic release of the entire charge of the substitute in one minute under a worst-case scenario. We did not examine exposure to consumers in cold storage warehouses and commercial comfort AC (chillers), since such equipment is typically used in workplaces where access is controlled and not in homes or public spaces. The analysis was undertaken to determine the 30-minute TWA exposure levels for the substitute, which were then compared to the toxicity limits to assess the risk to consumers.

EPA considered toxicity limits for consumer exposure that reflect a short-term exposure such as might occur at home or in a store or other public setting where a member of the general public could be exposed and could then escape. Specific toxicity limits that we used in our analysis of consumer exposure include:

- Isobutane: 6,900 ppm over 30 minutes
- Propane: 6,900 ppm AEGL–1 over 30 minutes

Under the conservative assumptions used in the consumer exposure modeling, the estimated 30-minute consumer exposures to the refrigerants exceed the toxicity limits for the propylene component of R-443A in all cases but the least conservative. The least conservative scenario assumed the highest ventilation rate and the lowest charge size (160 g) evaluated, as well as assuming complete mixing of the refrigerant rather than stratification (i.e., refrigerant pooling near the floor). All of the other estimates of exposure exceeded the 1,500 ppm excursion limit for propylene, with estimates ranging from approximately 1,500 ppm to 9,700 ppm. This occurred for lower or higher charge sizes ranging from 160 g to 1,500 g; lower or higher ventilation levels of 0.11 or 0.67 ACH; and, except for the smallest charge size, whether stratification was assumed to occur or not. In comparison, EPA previously found that a charge of 180 g of propane a substance for five exposure periods (10 and 30 minutes, 1 hour, 4 hours and 8 hours). For each exposure period, three different AEGL values are developed to address different levels of toxicological impacts. Of relevance for the modeled scenario is the AEGL–1, which is defined as: "the airborne concentration, expressed as parts per million or milligrams per cubic meter (ppm or mg/m³) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure." While permanent toxicological effects are not expected up to the AEGL–2 value, this limit is not relevant for this analysis because at that level, flammability would be a greater concern.

69 There are no short term exposure limits available for propylene (e.g., AEGL–1, NIOSH STEL, ACGIH STEL). This compound is sufficiently different chemically from propane (e.g., contains a double bond) that we could not select an analogous AEGL. Therefore, EPA developed a short-term excursion limit based upon ACGIH recommendations. The ACGIH recommends that short-term exposures of chemicals not surpass three times the 8-hour TWA TLV over 15 minutes and at no time surpass five times the 8-hour TWA TLV. For propylene, this equates to 1,500 to 2,500 ppm.
in a room air conditioner could meet its AEGl–1 and a charge of 195 g of R-441A in a room air conditioner could meet the various short-term exposure limits for its components under the same assumptions of ventilation, stratification, and room size. Therefore, EPA has concern about the exposure levels and toxicity of propylene and R-443A in residential and light commercial AC and heat pumps. In comparison, the currently acceptable refrigerants typically have high acute exposure limits for their components based upon cardiotoxic effects of halocarbons over 10,000 ppm (e.g., 350,000 cardiotoxic no-observed adverse effect level for HFC-32 over 5 minutes) or have components with STEls or AEGls (e.g., 8,000 ppm 10-minute AEGl–1 for HCFC-134a component). Acute exposure limits for propylene and R-443A’s components range from 1,500 ppm for propylene to 6,900 ppm (AEGl–1 over 30 minutes for propane). Because of the relatively low acute exposure limit for propylene, acute exposure is a greater concern than for other acceptable refrigerants in residential and light commercial AC systems and heat pumps. In summary, EPA’s concerns about propylene and R-443A encompass both toxicity and exposure and impacts of these refrigerants on local air quality. Other acceptable refrigerants are available in the same end-uses that offer lower toxicity and air quality impacts, and similar flammability, GWP, and ODP when compared to R-443A and propylene. Thus, we are proposing to list propylene and R-443A as unacceptable in these end-uses because they pose significantly more risk than other available refrigerants. For further information, including EPA’s risk screens and risk assessments as well as information from the submitters of the substitutes, see docket EPA–HQ–OAR–2015–0663.

iv. When would the listings apply?
EPA proposes that this listing would apply 30 days after the date of publication of a final rule. To our knowledge, manufacturers and service technicians are not currently using these substitutes in the proposed end-uses. We note that EPA has only recently found submissions complete for these substitutes, and under the SNAP program regulations, a substitute may not be introduced into interstate commerce prior to 90 days after EPA receives a complete submission. Further, a date of 30 days after the date of publication of a final rule, the same as the proposed effective date of this regulation, would protect against the risks of these substitutes at the earliest opportunity.

v. What is the relationship between this proposed SNAP rule and other federal rules?
DOE has indicated its intent to issue a proposed energy conservation standard for portable air conditioners, a subset of the residential and light commercial air conditioning and heat pumps end-use. For information on DOE’s 2015 Fall Regulatory Agenda, see http://www.reginfo.gov/public/do/ eAgendaViewRule?pubId=201510&RIN=1904–AD02. Information on other federal rules that may apply to centrifugal chillers, positive displacement chillers, and cold storage warehouses is available in sections VI.A.4.a.vi, VI.A.4.b.vi, and VI.A.4.c.v below. We note that since these two refrigerants are currently not being used in these types of equipment in the United States, we expect this regulation, if finalized as proposed, would have no impact on compliance with federal energy conservation standards.

vi. On which topics is EPA specifically requesting comment?
EPA requests comment on all aspects of this proposal. In particular, we request comment on our proposal to list the refrigerants propylene (R-1270) and R-443A as unacceptable in new equipment in residential and light commercial AC and heat pumps, cold storage warehouses, and centrifugal and positive displacement chillers for commercial comfort AC. EPA specifically requests comment on the proposed decision to list these refrigerants as unacceptable 30 days after the date of publication of a final rule, and the end-uses proposed here.

4. Proposed Changes in Listing Status

a. Proposed Change of Status for Certain HCFC Refrigerants for New Centrifugal Chillers
As provided in the following table, EPA is proposing to change the status of numerous refrigerants from acceptable to unacceptable for new centrifugal chillers:

| Table 5—Proposed Change of Status Decisions for New Centrifugal Chillers |
|-----------------------------|-------------------------------------------------------------------|
| End-use                     | Substitutes                                                       |
| Unacceptable as of January 1, 2024, except where allowed under a narrowed use limit. |
| Centrifugal Chillers (new only). | HFC-134a, R-404A                                                    |
| Acceptable, subject to narrowed use limits, for military marine vessels, as of January 1, 2024. |
| Centrifugal Chillers (new only). | HFC-134a and R-404A                                               |
| Acceptable, subject to narrowed use limits, for human-rated spacecraft and related support equipment, as of January 1, 2024. |

i. What is the affected end-use?
(a) Overview of Equipment Covered
In the initial rule establishing the SNAP program (59 FR 13044; March 18, 1994), EPA included within the refrigeration and AC sector the end-use “commercial comfort air conditioning” and then elaborated on that end-use saying that “CFCs are used in several different types of mechanical commercial comfort AC systems, known as chillers.” EPA indicated “that over time, existing cooling capacity [from chillers] will be either retrofitted or replaced by systems using non-CFC refrigerants in a vapor compression cycle or by alternative technologies.”

101 ICF, 2014b. Risk Screen on Substitutes for HCFC-22 in Residential and Light Commercial Air Conditioning and Heat Pumps; Substitute: Propane (R-290).

102 ICF, 2014c. Risk Screen on Substitutes for HCFC-22 in Residential and Light Commercial Air Conditioning and Heat Pumps; Substitute: R-441A.
We also explained in that rule that vapor compression chillers can be categorized by the types of compressor used, including centrifugal, rotary, screw, scroll and reciprocating compressors. These compressor types are also divided into centrifugal and positive displacement chillers, the latter of which includes those with reciprocating, screw, scroll or rotary compressors. This section of the proposed rule covers centrifugal chillers.

Centrifugal chillers are equipment that utilize a centrifugal compressor in a vapor-compression refrigeration cycle. Centrifugal chillers are typically used for commercial comfort AC although other uses do exist. Centrifugal chillers can be found in office buildings, hotels, arenas, convention halls, airport terminals and other buildings. Centrifugal chillers tend to be used in larger buildings.

For commercial comfort and some other applications, centrifugal chillers typically cool water that is then pumped to fan coil units or other air handlers to cool the air that is supplied to the occupied spaces transferring the heat to the water. The heat absorbed by the water can then be used for heating purposes, and/or can be transferred directly to the air (“air-cooled”), to a cooling tower or body of water (“water-cooled”) or through evaporative coolers (“evaporative-cooled”). A centrifugal chiller or a group of centrifugal chillers could similarly be used for district cooling where the chiller plant cools water or another fluid that is then pumped to multiple locations being served such as several different buildings within the same complex. All such centrifugal chillers are covered by this section of the proposed rule.

Centrifugal chillers are used for other applications besides commercial comfort AC and are covered under this section of the proposed rule. For instance, centrifugal chillers used to cool equipment, such as in data centers, are covered under this section of the proposed rule.

(b) What other types of equipment are used for similar applications but are not covered by this section of the proposed rule?

Other equipment including packaged rooftop units and split system air conditioners, both of which fall under the SNAP end-use “household and light commercial air conditioning,” can also be used for commercial comfort AC, typically for smaller capacity needs. These equipment types are not centrifugal chillers and hence are not covered under this section of the proposed rule.

(c) What refrigerants are used in centrifugal chillers?

Centrifugal chillers historically employed either CFC-11 (called “low pressure chillers”) or CFC-12 (“high pressure chillers”), although other CFCs have been used, including CFC-114 and R-500 (a blend of CFC-12 and HFC-152a). When the production and consumption of CFCs were phased out in the United States in the 1990s, centrifugal chillers was one of the first end-uses to be redesigned for alternative refrigerants and HCFC-123 and HCFC-134a became the primary refrigerants used in centrifugal chillers. HCFC-123 was used in low pressure chillers while HCFC-134a was used in high pressure chillers. Both of these alternatives continue to be used today. HCFC-22 was also used in some centrifugal chillers, primarily only in equipment produced before approximately the year 2000. HCFC-245fa was also identified as a possible refrigerant for low pressure centrifugal chillers, but has found only limited use.

More recently, centrifugal chillers that use alternatives listed as acceptable have been demonstrated or announced. For instance, one manufacturer has introduced centrifugal chillers using trans-1-chloro-3,3,3-trifluoroprop-1-ene, a nonflammable low-GWP refrigerant.104 ii. Which refrigerants is EPA proposing to list as unacceptable?

For new centrifugal chillers, EPA is proposing to change the status of the following refrigerants from acceptable to unacceptable: FOR12A, FOR12B, HFC-134a, HFC-227ea, HFC-236fa, HFC-245fa, R-125/134a/600a (28.1/70/1.9), R-125/290/134a/600a (55.0/0.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-423A, R-424A, R-434A, R-438A, R-507A, RS-44 (2003 composition), and THR-03.

iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?

For new centrifugal chillers, acceptable refrigerants for which we are not proposing a change of status in this end-use include: HFC-1234ze(E), IKON A, IKON B, R-450A, R-513A, R-717 (ammonia), THR-02, and trans-1-chloro-3,3,3-trifluoroprop-1-ene.104

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP, climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; and ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below. In addition, a technical support document that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives for new centrifugal chillers may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

(a) Environmental Impacts

The refrigerants for which we are proposing a change of status have an ODP of zero. Other alternatives also with an ODP of zero that we are not proposing a change of status for new centrifugal chillers include HFO-1234ze(E), IKON A, IKON B, R-450A, R-513A, R-717, and THR-02. Also, the alternative refrigerant trans-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP of 0.00024 to 0.00034.106 107 Estimates of this compound’s potential to deplete the ozone layer indicate that even with worst-case estimates of emissions, which assume that this compound would substitute for all compounds it could replace, the impact on global atmospheric ozone abundance would be statistically insignificant.108 Thus, the acceptable alternatives not subject to the proposed status change have ODPs lower than or of the same practical effect to the ODPs of other alternatives for which EPA is proposing a change of status, and lower than the ODPs of ODS historically used in this end-use. The refrigerants we are proposing to find unacceptable through this action have GWPs ranging from about 920 to 9,810. As shown in Table 6, other alternatives

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acceptable for this end-use have GWPs ranging from zero to 630.

### Table 6—GWP, ODP, and VOC Status of Refrigerants in New Centrifugal Chillers

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonia, HCFC-123, HCFC-124, HFO-1234ze(E), R-450A, R-513A, trans-1-chloro-3,3,3-trifluoroprop-1-ene</td>
<td>0–630</td>
<td>0–0.022</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>IKON A, IKON B, THR-02</td>
<td>30–560</td>
<td>0</td>
<td>Yes</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-134a, HFC-245fa</td>
<td>1,030–1,430</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>FOR12A, FOR12B, THR-03</td>
<td>920–1,220</td>
<td>0</td>
<td>Yes</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>HFC-236fa, R-404A, R-507A</td>
<td>3,920–9,810</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
</tbody>
</table>

1 The table does not include not-in-kind technologies listed as acceptable for the stated end-use.
2 HCFC-22, HCFC-123, HCFC-124, and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production and consumption.
3 One or more constituents of the refrigerant are VOC.

One of the refrigerant blends not subject to the proposed status change (THR-02), as well as several of the substitutes subject to the proposed status change, include small amounts of R-290 (propane), R-600 (butane) or other substances that are VOCs. These amounts are small and for this end-use are not expected to contribute significantly to ground level ozone formation.

In the actions where EPA listed these refrigerants as unacceptable, EPA concluded none of these refrigerants in this end-use pose significantly greater risk to ground-level ozone formation than other alternative refrigerants that are not VOCs or that are specifically excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS.

The refrigerants not subject to the proposed status change are highly volatile and typically evaporate or partition to air, rather than contaminating surface waters. Their effects on aquatic life are expected to be small and pose no greater risk of aquatic or ecosystem effects than those of other refrigerants that are subject to the proposed status change for this end-use.

(b) Flammability

For the centrifugal chillers end-use, with the exceptions of HFO-1234ze(E) and R-717, all other refrigerants listed as acceptable, including those for which we are proposing to change the status to unacceptable, are not flammable. HFO-1234ze(E) is non-flammable at standard temperature and pressure using the standard test method ASTM E681; however, at higher temperatures it is mildly flammable. It is classified as a Class 2L (lower flammability, low burning velocity) refrigerant under the standard ASHRAE 34 (2013). Our assessment and listing decision (77 FR 47768; August 10, 2012) found that the overall risk, including the risk due to this mild flammability at elevated temperature, is not significantly greater than for other refrigerants or for the refrigerants we are proposing to list as unacceptable.

R-717 is slightly flammable with a low flame speed; it is classified as a 2L refrigerant under ASHRAE 34 (2013). R-717 has a long history of use in cold storage warehouses and other applications, but it is not believed to be used extensively in centrifugal chillers. In the original SNAP rule, EPA noted “[a]mmonia has been used as a medium to low temperature refrigerant in vapor compression cycles for more than 100 years. Ammonia has excellent refrigerant properties, a characteristic pungent odor, no long-term atmospheric risks, and low cost. It is, however, slightly flammable and toxic, although it is not a cumulative poison. OSHA standards specify a 15 minute short-term exposure limit of 35 ppm for ammonia.” (53 FR 13072; March 18, 1994). We further noted its use in various food and beverage processing and storage applications as well as other industrial applications. In that rule, we found R-717 acceptable for use in new centrifugal chillers, concluding that its overall risk to human health and the environment was not significantly greater than the other alternatives found acceptable. This conclusion was based on the assumption that the regulated community adheres to OSHA regulations on such use as well as standard refrigeration practices, such as the adherence to ASHRAE Standard 15, which is often utilized by local authorities when setting their own building and safety requirements.

For further information, including EPA’s risk screens and risk assessments as well as information from the submitters of the substitutes, see docket EPA–HQ–OAR–2015–0663.

(c) Toxicity

The toxicity of the refrigerants we are proposing to list as unacceptable is comparable to that of other alternatives that are acceptable in this end-use, with the exception of R-717. R-717, for which we are not proposing a change of status, is of a higher toxicity than some other refrigerants and is classified as a B refrigerant under ASHRAE 34 (2013). See section VI.A.4.a.iii.(b) for a discussion on the long history of use of R-717 and our original decision finding it acceptable in new centrifugal chillers. The other acceptable alternatives listed above that are included in ASHRAE 34 (2013) are classified as A (lower toxicity) refrigerants.

For all refrigerants, the relatively large charge sizes employed in centrifugal chillers, and the fact that some such chillers are placed in an enclosed mechanical room, raise a concern regarding oxygen displacement. This concern has been addressed over the long history of the use of centrifugal chillers, including the use of HCFC-123, another B refrigerant as classified by ASHRAE 34 (2013), by providing adequate ventilation, reducing leaks to small levels, and other techniques such as employing refrigerant sensors and automatic air movement. Commonly followed standards and practices have reduced toxicity concerns equally for historically used ODS, the alternatives for which we are proposing a status...
change, and the alternatives for which we are not proposing a status change.

(d) Summary

EPA has listed as acceptable several alternatives that pose lower overall risk to human health and the environment than the refrigerants whose status we are proposing to change to unacceptable. The risks other than GWP are not significantly different for the alternatives than for the refrigerants we are proposing to list as unacceptable, and the GWPs for the refrigerants we are proposing to list as unacceptable are significantly higher and thus pose significantly greater risk.

iv. What narrowed use limits for military marine vessels and human-rated spacecraft and related support equipment, are the EPA proposing?

EPA is proposing a narrowed use limit that would allow continued use of HFC-134a in centrifugal compressor chillers for military marine vessels after the change of status date where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. Under the narrowed use limit, the end user for this military application would need to ascertain that the alternatives are not technically feasible and document the results of their analysis. See 40 CFR 82.180(b)(3). For the military, there are several unique performance requirements related to marine vessel air conditioning systems that require extensive testing prior to qualifying alternatives for HFC-134a. The lower-GWP alternatives available or potentially available for use in commercial chillers either do not meet the military-unique requirements or will require longer testing, based on available program funding for testing, for military suitability. It will also then take additional time to redesign, qualify, and procure new chillers for military shipbuilding programs.

We anticipate that most centrifugal compressor chillers in military applications will be able to transition to acceptable alternatives by the proposed January 1, 2024 date. However, HFC-134a chillers are mission-critical equipment on ships and submarines, primarily in cooling of electronics, sensors, and weapon systems, but also cooling of ship spaces for personnel. Failure of the chillers would disable the ship. The equipment is not the same as commercial equipment and it is located in confined engineering spaces near other high-temperature, including conventional and nuclear propulsion plants. All major components are designed, tested and certified for military use (including the compressor, motor, evaporator, condenser, and electronic controls) and must meet military-unique requirements: Weapons effect shock resistance, stringent electromagnetic interference resistance, ship vibration resistance, all weather pitch and roll operation, low acoustic signature, arctic to tropical operations (at temperatures from 28°F to 105°F), compact to fit in confined warship spaces, 40 to 50 year service life, and very high reliability due to extended at-sea missions. Further challenges include installation on submarines with the inherent risk of refrigerant leakage and need for the refrigerant to be compatible with the submarine life support systems. Production for these equipment for naval ships and submarines is low volume with only one certified manufacturer, limited test facilities, and prototype hardware and designs shared among platforms for affordability and commonality. Another significant challenge lies in the fact that the testing program for the use of alternatives for ships has not yet been funded. Once funding is in place, the completion timeline to fund, test, qualify, and begin procurement on all Navy-unique surface ship chiller designs is estimated to be about ten years. Due to the unique challenges associated with submarines, including potential refrigerant incompatibility with life support systems, it may not be feasible to implement currently available alternatives being evaluated for surface ships. Given the limited population of submarine chillers, the resulting greenhouse gas emissions from refrigerant leakage in this application is not expected to be significant.

EPA is proposing a narrowed use limit that would allow continued use of HFC-134a and R-404A in centrifugal compressor chillers for human-rated spacecraft and related support equipment applications after the change of status date where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. Under the narrowed use limit, the end user for this human-rated spacecraft and related support equipment application would need to ascertain that other alternatives are not technically feasible and document the results of their analysis. See 40 CFR 82.180(b)(3). HFC-134a and R-404A chillers are used to provide cooling to human-rated spacecraft and related support equipment during ground-based assembly, integration and test operations, and launch. The cooling of sensitive human-rated electrical equipment is critical to the spacecraft technical performance and crew safety. EPA understands that such programs use specialized ground coolant systems to provide heat transfer during certain ground operations. These coolant circulation systems use HFC-134a and R-404A chillers to meet the program’s stringent performance and material compatibility requirements. Other alternatives currently listed as acceptable under the SNAP program have not yet been proven to provide appropriate heat transfer, material compatibility, stability in the test environment, and other critical properties necessary for use in human-rated spacecraft and related support equipment applications. Considering that identification, testing, and implementation of materials to be used in human-rated-spacecraft programs routinely take several years due to the challenging operational environment, lengthy qualification process associated with human rating, and the federal budgetary cycle, it may not be feasible to deploy centrifugal chillers using other alternatives in the proposed timeframe. Given the limited population of chillers used in human-rated spacecraft and related support equipment applications, the resulting greenhouse gas emissions from refrigerant leakage in this application is not expected to be significant.

Users of a restricted agent within the narrowed use limits category must make a reasonable effort to ascertain that other substitutes or alternatives are not technically feasible. Users are expected to undertake a thorough technical investigation of alternatives to the otherwise restricted substitute. Although users are not required to report the results of their investigations to EPA, users must document these results, and retain them in their files for the purpose of demonstrating compliance. This information includes descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

v. When would the status change?

The Agency understands that relevant building standards and codes are likely to change in 2021. These include ASHRAE 13, UL 1901, UL 60335–2–40, and the International Building Code. The Agency believes some amount of
time will be needed to meet the technical challenges for a safe and smooth transition to alternatives particularly considering the complexity of chiller designs and the need to ensure energy efficiency levels are met. EPA is considering a range of dates from January 1, 2022, through January 1, 2025, as the change of status date for new centrifugal chillers. Our lead proposal is a status change date of January 1, 2024, which we believe would allow development of designs of new centrifugal chillers using an acceptable alternative. We are aware that some equipment has been introduced with acceptable alternatives and that additional research and development is underway with these and other possible alternatives. In addition, EPA has received communication from representatives of AHRI and NRDC requesting a change of status date of January 1, 2025, for HFC-134a, R-407C and R-410A, in all types of chillers.110 We are encouraged that the major trade organization representing manufacturers of chillers worked with the environmental non-governmental group to develop this consensus agreement that all chillers could transition to lower-GWP alternatives by or before this date and that during this time period more and more models of such equipment would be released from individual manufacturers. While the letter did not provide detailed technical analysis or timelines of why this date but not an earlier date was offered, it did indicate that their recommendation “allows eight years from the publication of the final rule for industry to finish designing and bringing to market chillers using alternative refrigerants.” The authors pointed out that “this conversion [in all types of chillers] is anticipated to involve use of new 2L flammable refrigerants, which are severely restricted by current safety and building codes” and added that a 2025 date “provides time to amend model building codes to accommodate these new refrigerants and for adoption by state and local jurisdictions.” AHRI and NRDC held that a January 1, 2025 change of status date “provides adequate time for industry to launch products that have been tested and certified by the existing laboratories and certification agencies . . . globally” and emphasized that time was required to complete revisions to ASHRAE Standard 15, recertify the chillers with safety standards, and qualify materials and components to ensure low-leak, high-reliability products. They also said their recommended schedule provides time for manufacturers to optimize the energy efficiency of their products.

vi. What is the relationship between this proposed SNAP rule and other federal rules?

DOE has established efficiency requirements, based on ANSI/ASHRAE/IES Standard 90.1–2010, for chillers used in federal buildings.111 EPA is not aware of any DOE energy efficiency requirements for chillers used in non-federal buildings. Although EPA is not aware of any federal standards that apply, EPA recognizes, however, that state and local building codes may place certain requirements that affect the desired efficiency of chillers. Many state and local codes reference ASHRAE Standard 90.1. EPA’s understanding of ASHRAE Standard 90.1 is that it provides both a prescriptive and performance-based measures to achieve compliance. Under the prescriptive approach, depending on the version of the standard, one or two “paths” exist setting specific energy efficiency requirements based on the type and capacity of the chiller. Under a performance-based approach, the energy consumption of the chiller may exceed the prescriptive requirements provided that the building as a whole meets or exceeds the applicable reference building.

vi. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on a range of dates from January 1, 2022, through January 1, 2025, for the change of status of the identified substitutes. EPA requests comment and information on any potential environmental or other impacts of EPA adopting a date other than January 1, 2024, which is our lead option. In particular, EPA requests comment on whether other alternatives that reduce overall risk would be available prior to January 1, 2024 and for comment on any technical or other reasons that NRDC and AHRI proposed January 1, 2025 in their joint letter. EPA requests comment on the specific steps that must be undertaken to commercialize centrifugal chillers with alternative refrigerants, including the time each such step would take, which steps must occur in sequence, and which steps could occur in parallel. EPA requests comments on if and how this timing might vary based on the characteristics of the chiller, such as but not limited to, compressor type, capacity range, evaporator design, condenser design (e.g., air cooled or water cooled), and refrigerant currently used and potentially used.

EPA requests comment on the current use of four refrigerants not subject to the proposed change of status, trans-1-chloro-3,3,3-trifluoroprop-1-ene, HFO-1234ze(E), R-450A and R-513A, in centrifugal chillers, including the status of product availability and the capacity range covered by such products. We also request comment on the on-going research, development, deployment and expected increased market penetration of centrifugal chillers using refrigerants such as trans-1-chloro-3,3,3-

trifluoroprop-1-ene, HFO-1234ze(E), R-290, R-450A, R-513A, DR-55,112 R-718 and R-744.

Additionally, EPA requests comment on any energy efficiency performance impacts of using the refrigerants not subject to the change of status proposed today that could affect the ability of manufacturers to meet current energy efficiency requirements or standards for centrifugal chillers in the United States. Also, EPA requests comment on the ability of centrifugal chillers using refrigerants other than those for which we are proposing a status change to meet those energy efficiency requirements or standards. In particular, we request comment on the specific steps and timing of such steps required to design and develop centrifugal chillers to meet applicable federal energy efficiency requirements.

EPA is also requesting comment on the proposed narrowed use limitation for chillers on military marine vessels and human-rated spacecraft and related support equipment where the unique requirements would limit the availability and feasible use of alternatives not subject to the proposed status change.

b. Proposed Change of Status for Certain HFC Refrigerants for New Positive Displacement Chillers

As provided in the following table, EPA is proposing to change the status of numerous refrigerants from acceptable to unacceptable for new positive displacement chillers:

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110 Doniger, David (NRDC) and Stephen Yurek (AHRI), February 1, 2016. AHRI/NRDC Letter Regarding Chiller Actions Under SNAP.


112 DR-55 is a temporary name identifying a specific HFC/HFO blend.
TABLE 7—PROPOSED CHANGE OF STATUS DECISIONS FOR NEW POSITIVE DISPLACEMENT CHILLERS

<table>
<thead>
<tr>
<th>Positive Displacement Chillers (new only).</th>
<th>Substitutes</th>
<th>Proposed decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFC-134a</td>
<td>Acceptable, subject to narrowed use limits, for military marine vessels, as of January 1, 2024.</td>
<td></td>
</tr>
<tr>
<td>HFC-134a and R-404A</td>
<td>Acceptable, subject to narrowed use limits, for human-rated spacecraft and related support equipment, as of January 1, 2024.</td>
<td></td>
</tr>
</tbody>
</table>

i. What is the affected end-use?
(a) Overview of Equipment Covered
As discussed in section VI.A.4.a.i, vapor compression cycle chillers are divided into centrifugal chillers and positive displacement chillers. This section deals with positive displacement chillers, which are those that utilize positive displacement compressors such as reciprocating, screw, scroll or rotary types. Positive displacement chillers are applied in similar situations as centrifugal chillers, again primarily for commercial comfort AC, except that positive displacement chillers tend to be used for smaller capacity needs such as in mid- and low-rise buildings.

For commercial comfort and some other applications, positive displacement chillers typically cool water that is then pumped to fan coil units or other air handlers to cool the air that is supplied to the occupied spaces transferring the heat to the water. The heat absorbed by the water can then be used for heating purposes, and/or can be transferred directly to the air (“air-cooled”), to a cooling tower or body of water (“water-cooled”) or through evaporative coolers (“evaporative-cooled”).

Positive displacement chillers are used for other applications besides commercial comfort AC and are covered under this section of the proposed rule. For instance, positive displacement chillers used to cool equipment, such as in data centers, are covered under this section of the proposed rule.

(b) What other types of equipment are used for similar applications but are not covered by this section of the proposed rule?
Other equipment including packaged rooftop units and split system air conditioners, both of which fall under the SNAP end-use “household and light commercial air conditioning,” can also be used for commercial comfort AC, typically for even smaller capacity needs than positive displacement chillers. These equipment types are not positive displacement chillers and hence are not covered under this section of the proposed rule.

(c) What refrigerants are used in positive displacement chillers?
Positive displacement chillers historically used CFC-12, although HCFC-22 was also used and became more common after the production and consumption of CFC-12 were phased out. In accordance with CAA 605(a) and the implementing regulations codified at 40 CFR part 82, subpart A, in the United States, the use of newly manufactured HCFC-22 for new positive displacement chillers (and other new equipment) ceased as of January 1, 2010. Both R-407C and to a larger extent R-410A are used in new positive displacement chillers primarily in lower capacity ranges previously served by HCFC-22 chillers. HFC-134a is also used for new positive-displacement chillers, including some mid-level capacity water-cooled screw chillers.

More recently, positive displacement chillers that use alternatives listed as acceptable including HFO-1234ze(E) and R-513A (a blend of HFC-134a and HFO-1234yf) have been demonstrated or announced. EPA is aware of air-cooled rotary chillers in the 115 to 500 refrigeration ton (400 to 1,750 kW) range using R-513A.113 Other chiller models using low-GWP refrigerants have also been introduced; for instance an air-cooled chiller using DR-55 at the IIR International Conference of Refrigeration.114 EPA also notes that a water-cooled screw chiller using HFO-1234ze 115 has been installed in Europe.116

ii. Which refrigerants is EPA proposing to list as unacceptable?
For new positive displacement chillers, EPA is proposing to change the status of the following refrigerants from acceptable to unacceptable: FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/134a/600a (28.1/0.1/1.9), R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-424A, R-434A, R-437A, R-438A, R-507A, RS-44 (2003 composition), SP34E, and THR-03.

iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?
For new positive displacement chillers, acceptable refrigerants for which we are not proposing a change of status in this end-use include: HFO-1234ze(E), IKON B, R-450A, R-513A, R-717, and THR-03.

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; and ecosystem impacts, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below. In addition, a technical support document that provides the Federal Register citations concerning data on the SNAP criteria

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115 EPA assumes the refrigerant used is the stereoisomer HFO-1234ze(E) but requests comment on this assumption.
(e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives for new positive displacement chillers may be found in the docket for this rulemaking (EPA-HQ-OAR-2015-0663).

(a) Environmental Impacts

The refrigerants for which we are proposing to change the status to unacceptable have zero ODP and GWPs ranging from about 920 to 3,990. As shown in Table 8, other alternatives for which we are not proposing a change of status in this end-use have GWPs ranging from zero to 630.

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonia, HFO-1234ze(E), R-450a, R-513A</td>
<td>0–630</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>IKON B, THR-02</td>
<td>30–560</td>
<td>0</td>
<td>Yes²</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-134a</td>
<td>1,430</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>FOR12A, FOR12B, SP34E, THR-03</td>
<td>920–1,410</td>
<td>0</td>
<td>Yes²</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>HFC-227ea, R-407c, R-410a, R-410b, R-421a</td>
<td>1,770–3,220</td>
<td>0</td>
<td>Yes²</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>KRD6, R-125/134a/600a (28.1/70/1.9), R-125/290/134a/600a (55/42/5/1.5), R-417a, R-422b, R-422c, R-422d, R-424a, R-434a, R-437a, R-438a, RS-44 (2003 composition)</td>
<td>1,810–3,250</td>
<td>0</td>
<td>Yes²</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>R-404A, R-507A</td>
<td>3,920–3,990</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
</tbody>
</table>

1 The table does not include not-in-kind technologies listed as acceptable for the stated end-uses.
2 HCFC-22 and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production and consumption.
3 One or more constituents of the refrigerant are VOC.

Table 8—GWP, ODP, and VOC Status of Refrigerants in New Positive Displacement Chillers

One of the refrigerant blends not subject to the proposed status change (THR-02), as well as several of the substitutes subject to the proposed status change, include small amounts of R-290 (propane), R-600 (butane), or other substances that are VOCs. These amounts are small and for this end-use are not expected to contribute significantly to ground level ozone formation.

In the actions where EPA listed these refrigerants as acceptable, EPA concluded none of these refrigerants in this end-use pose significantly greater risk to ground-level ozone formation than other alternative refrigerants that are not VOCs or that are specifically excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS.

The refrigerants not subject to the proposed status change are highly volatile and typically evaporate or partition to air, rather than contaminating surface waters. Their effects on aquatic life are expected to be small and pose no greater risk of aquatic or ecosystem effects than those of other refrigerants that are subject to the proposed status change for this end-use.

(b) Flammability

For the positive displacement chillers end-use, with the exception of HFO-1234ze(E) and R-717, all other refrigerants listed as acceptable, including those for which we are proposing to change the status to unacceptable, are not flammable. HFO-1234ze(E) is non-flammable at standard temperature and pressure using the standard test method ASTM E681; however, at higher temperatures it is mildly flammable. It is classified as a Class 2L (lower flammability, low burning velocity) refrigerant under the standard ASHRAE 34 (2013). Our assessment and listing decision (77 FR 47768; August 10, 2012) found that the overall risk, including the risk due to this mild flammability at elevated temperature, is not significantly greater than for other refrigerants or for the refrigerants we are proposing to list as unacceptable. As noted above, a positive displacement chiller using this refrigerant has already been installed.

R-717 is slightly flammable with a low flame speed; it is classified as a 2L refrigerant under ASHRAE 34 (2013). R-717 has a long history of use as a refrigerant in positive displacement chillers, especially in water-cooled screw chillers, and other applications.

In our evaluation finding R-717 acceptable in this end-use, EPA noted “Ammonia has been used as a medium to low temperature refrigerant in vapor compression cycles for more than 100 years. Ammonia has excellent refrigerant properties, a characteristic pungent odor, no long-term atmospheric risks, and low cost. It is, however, slightly flammable and toxic, although it is not a cumulative poison. Ammonia may be used safely if existing OSHA and ASHRAE standards are followed” (61 FR 47015).

(c) Toxicity

With the exception of R-717, the toxicity of the refrigerants we are proposing to list as unacceptable is comparable to that of other alternatives that are acceptable in this end-use. R-717, for which we are not proposing a change of status, is of a higher toxicity than some other refrigerants and is classified as a B refrigerant under ASHRAE 34 (2013). See section VI.A.4.b.iii.(b) for a discussion on the long history of use of R-717 and our original decision finding it acceptable in new positive displacement chillers.

For all refrigerants, the possible relatively large charge sizes of some positive displacement chillers, and the fact that some such chillers are place in an enclosed mechanical room, raise a concern regarding oxygen displacement. This concern has been addressed over the long history of the use of positive displacement chillers by providing adequate ventilation, reducing leaks to small levels, and other techniques such as employing refrigerant sensors and automatic air movement. Commonly followed standards and practices have reduced toxicity concerns equally for histologically used ODS, the alternatives subject to the proposed status change, and the alternatives not subject to the proposed status change.

(d) Summary

EPA has listed as acceptable several alternatives that pose lower overall risk to human health and the environment than the refrigerants whose status we are proposing to change to unacceptable. The risks other than GWP are not significantly different for the

188 HCFC-22 and several blends containing HCFCs are also listed as acceptable, but their use is severely restricted by the phasedown in HCFC production and consumption.

189 One or more constituents of the refrigerant are VOC.
alternatives than for the refrigerants we are proposing to list as unacceptable, and the GWP's for the refrigerants we are proposing to list as unacceptable are significantly higher and thus pose significantly greater risk.

iv. What narrowed use limits for military marine vessels and human-rated spacecraft and related support equipment is EPA proposing?

EPA is proposing a narrowed use limit that would allow continued use of HFC-134a in positive displacement compressor chillers for military marine vessels after the change of status date where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. Under the narrowed use limit, the end user for this military application would need to ascertain that other alternatives are not technically feasible and document the results of their analysis. See 40 CFR 82.180(b)(3). For the military, there are several unique performance requirements related to marine vessel air conditioning systems that require extensive testing prior to qualifying alternatives for HFC-134a. The lower-GWP alternatives available or potentially available for use in commercial chillers either do not meet the military-unique requirements or will require longer timeframes to test, based on available program funding for testing, for military suitability. It will also then take additional time to redesign, qualify, and procure new chillers for military shipbuilding programs. See additional information in section VI.A.4.a.iv above on centrifugal chillers.

EPA is proposing a narrowed use limit that would allow continued use of HFC-134a and R-404A in positive displacement compressor chillers for human-rated spacecraft and related support equipment applications after the change of status date where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. Under the narrowed use limit, the end user for this human-rated spacecraft and related support equipment application would need to ascertain that other alternatives are not technically feasible and document the results of their analysis. See 40 CFR 82.180(b)(3). HFC-134a and R-404A chillers are used to provide cooling to human-rated spacecraft and related support equipment during ground-based assembly, integration and test operations. The cost of sensitive human-rated electrical equipment is critical to the spacecraft technical performance and crew safety. EPA understands that such programs use specialized ground coolant systems to provide heat transfer during certain ground operations. These coolant circulation systems use HFC-134a and R-404A chillers to meet the program's stringent performance and material compatibility requirements. Other alternatives currently listed as acceptable under the SNAP program have not yet been proven to provide appropriate heat transfer, material compatibility, stability in the test environment, and other critical properties necessary for use in human-rated spacecraft and related support equipment applications. Considering that identification, testing, and implementation of materials to be used in human-rated spacecraft programs routinely take several years due to the challenging operational environment, lengthy qualification processes associated with human rating, and the federal budgetary cycle, it may not be feasible to deploy positive displacement chillers using other alternatives in the proposed timeframe. Given the limited population of chillers used in human-rated spacecraft and related support equipment applications, the resulting greenhouse gas emissions from refrigerant leakage in this application is not expected to be significant.

Users of a restricted agent within the narrowed use limits category must make a reasonable effort to ascertain that other substitutes or alternatives are not technically feasible. Users are expected to undertake a thorough technical investigation of alternatives to the otherwise restricted substitute. Although users are not required to report the results of their investigations to EPA, users must document these results, and retain them in their files for the purpose of demonstrating compliance. This information includes descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

v. When would the status change?

The Agency understands that relevant building standards and codes are likely to change in 2021. These include ASHRAE 15, UL 995, UL 60335-2-40, and the International Building Code. The Agency believes some amount of time will be needed to meet the technical challenges for a safe and smooth transition to alternatives particularly considering the complexity of chiller designs and the need to ensure energy efficiency levels are met. EPA is considering a range of dates from January 1, 2022, through January 1, 2025, as the change of status date for new positive displacement chillers. Our lead proposal is a status change date of January 1, 2024, which we believe would allow development of designs of new positive displacement chillers using an acceptable alternative. We are aware that some equipment has been introduced with acceptable alternatives and that additional research and development is underway with these and other possible alternatives.

In addition, EPA has received communication from representatives of AHRI and NRDC requesting a change of status date of January 1, 2025, for HFC-134a, R-407C and R-410A, in all types of chillers. See section VI.A.4.a.v.

vi. What is the relationship between this proposed SNAP rule and other federal rules?

DOE has established efficiency requirements, based on ANSI/ASHRAE/IIES Standard 90.1–2010, for chillers used in federal buildings. See section VI.A.4.a.vi for more information.

vii. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on a range of dates from January 1, 2022, through January 1, 2025, for the change of status of the identified substitutes. EPA requests comment and information on any potential environmental or other impacts of EPA adopting a date other than January 1, 2024, which is our lead option. In particular, EPA requests comment on whether other alternatives that reduce overall risk would be available prior to January 1, 2024 and for comment on any technical or other reasons that NRDC and AHRI proposed January 1, 2025 in their joint letter. EPA requests comment on the specific steps that must be undertaken to commercialize positive displacement chillers with alternative refrigerants, including the time each such step would take, which steps must occur in sequence, and which steps could occur in parallel. EPA requests comments on if and how this timing might vary based on the characteristics of the chiller, such as but not limited to, compressor type.
capacity range, evaporator design, condenser design (e.g., air cooled or water cooled), and refrigerant currently used and potentially used. EPA requests comment on the current use of three refrigerants, HFO-1234ze(E), R-450A and R-513A, in positive displacement chillers, including the status of product availability and the capacity range covered by such products. We also request comment on the on-going research, development, deployment and expected increased market penetration of positive displacement chillers using refrigerants such as HFO-1234ze(E), R-290, R-450A, R-513A, DR-55, R-718 and R-744.

Additionally, EPA requests comment on any energy efficiency performance impacts of using the refrigerants not subject to the change of status proposed today that could affect the ability of manufacturers to meet current energy efficiency requirements or standards for positive displacement chillers in the United States. Also, EPA requests comment on the ability of positive displacement chillers using refrigerants other than those for which we are proposing a status change to meet those energy efficiency requirements or standards. In particular, we request comment on the specific steps and timing of such steps required to design and develop positive displacement chillers to meet federal energy efficiency requirements.

EPA is also requesting comment on the proposed narrowed use limitation for chillers on military marine vessels and human-rated spacecraft and related support equipment where the unique requirements would limit the availability and feasible use of alternatives not subject to the proposed status change.

c. Proposed Change of Status for Certain HFC Refrigerants for New Cold Storage Warehouses

As provided in the following table, EPA is proposing to change the status of numerous refrigerants from acceptable to unacceptable for new cold storage warehouses.

### Table 9—Proposed Change of Status Decisions for Cold Storage Warehouses

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitutes</th>
<th>Proposed decision</th>
</tr>
</thead>
</table>

### i. What is the affected end-use?

Cold storage warehouses are temperature-controlled facilities used to store meat, produce, dairy and other products that are delivered to other locations for sale to the ultimate consumer. This end-use within the SNAP program describes an application of refrigeration equipment for an intended purpose, and hence the listings of acceptable and unacceptable refrigerants for this end-use apply regardless of the type of refrigeration system used. In addition to traditional vapor-compression cycle systems, EPA has found several not-in-kind systems acceptable for this end-use, including ammonia absorption, evaporative cooling, desiccant cooling, and Stirling cycle systems, which are not subject to the proposed status change.

Cold storage warehouses are usually termed “private” or “public,” describing the relationship between the owner or operator of the cold storage warehouse and the owner of the products stored within. Private cold storage warehouses are ones owned by a company for the purpose of storing its products; for instance, a food producer, processor or shipper may own and operate a facility as a distribution point for its products. Likewise, a supermarket chain may own and operate a facility to control the distribution of a variety of products to multiple stores in a given region. A public cold storage warehouse provides storage for lease and hence may receive and hold products from multiple producers and for multiple supermarkets or other vendors. Some cold storage warehouses may be both public and private, with one part dedicated to the owner’s products and another part available for lease. All such types of cold storage warehouses are included within the SNAP end-use.

Cold storage warehouses are also often divided into two general uses: Those storing products at temperatures above 32 °F (0 °C) and those storing products below this temperature. The former is referred to as a “cooler” while the term “freezer” is used for the latter. The 2014 ASHRAE Handbook of Refrigeration provides an additional cooler application called “controlled atmosphere for long-term fruit and vegetable storage” and the ability to subdivide freezers; “high-temperature freezers” storing goods at 27 to 28 °F (−2.8 to −2.2 °C), “low-temperature storage rooms for general frozen products, usually maintained at −5 to −20 °F (−21 to −29 °C), and low-temperature storage at the same temperature range as before but “with a surplus of refrigeration for freezing products received at above 0 °F” (−18 °C).

Several other end-uses under the SNAP program cover other parts of the food (and product) cold chain, and are distinct from the cold storage warehouse end-use. These are discussed here as examples of what EPA considers to be part of or separate from the “cold storage warehouse” end-use for which we are proposing changes of status.

Many food products require refrigeration during the production process. The application of refrigeration equipment used during the production of food and beverages falls within the SNAP end-use “industrial process refrigeration.” The industrial process refrigeration end-use would include all equipment and operations (that use a refrigerant) used to make and prepare food that is not immediately available for sale to the ultimate consumer and would require shipping it, possibly through intermediate points, to the point where such sale would occur. The industrial process refrigeration end-use could be applied at facilities where food is processed and packaged by the food producer. An example could be a meat processor that prepares and packages individual cuts of meat within a single facility or building while maintaining the required temperatures within that facility or building. Although such facilities may be designed in a fashion similar to a cold storage warehouse, the fact that items are being processed by the food producer indicates that the application falls in the industrial process refrigeration end-use. However, if a food producer operates a refrigerated storage area solely for the holding of already packaged products, and possibly packing such products in larger containers or bundles for shipment, that application would fall under the cold-storage warehouse end-use. In the...
example above, such a cold storage warehouse might be a facility, separate from the industrial process refrigeration system in a different facility, where the individually-packaged cuts of meat are packed in a larger container that is placed on a pallet and then shipped.

Another example of an industrial process refrigeration system is a “blast cooler” or “blast freezer.” As described previously in a separate SNAP rulemaking “[a] ‘blast chiller’ or ‘blast freezer’ is a type of equipment in which cold air is supplied and circulated rapidly to a food product, generally to quickly cool or freeze a product before damage or spoilage can occur.” (80 FR 42901; July 20, 2015). Such devices might be used as part of a food production line in an industrial setting. They also can be placed separately at public facilities including hospitals, schools, restaurants and supermarkets. These public facilities might use the blast chiller on products that they will store for later use after they receive products from a vendor or that they cook or prepare as a part of their operations. Such units might also be placed near entrances or to cold storage warehouses, for instance to receive food shipped refrigerated at one temperature and bring it down to a lower temperature for storage. EPA does not consider a separate blast chiller or blast freezer (i.e., one with its own refrigerant-containing circuit, including the compressor, evaporator and the condenser or heat exchanger) to be part of a cold storage warehouse. Another design however, could consist of a refrigeration system that is used to provide refrigerant (or a secondary fluid in an indirect system) to the evaporators extracting heat from the cold storage warehouse as well as to the evaporators used by a blast chiller or blast freezer that is installed at the facility. In this situation, EPA expects that the majority of the load and intended use of the combination system is for the cold storage of products, including those that undergo the blast cooling or freezing, and hence we consider the system to be a cold storage. For such systems, certain refrigerants would be subject to the proposed change of status as explained below.

As discussed in section VI.A.4.d, because products from refrigerated food processing and dispensing equipment are generally available for sale to the ultimate consumer, that end-use category, part of the retail food refrigeration end-use, is distinct from industrial process refrigeration. Another application in the food cold chain is the use of a “cold room” at a retail facility where refrigerated food is kept generally for short periods of time. In the July 20, 2015, final rule (80 FR 42870), EPA changed the status of certain refrigerants used in “remote condensing units” and “stand-alone systems,” two categories within the “retail food refrigeration” end-use that include equipment that can be used for such cold rooms. Remote condensing units may include a dedicated one- or two-compressor system with condensers located on a roof or the side of a building providing cooling through unit coolers to an insulated room, for instance in a restaurant or supermarket, that are built and charged with refrigerant at the site. Also, some cold rooms are stand-alone systems that are pre-charged at the factory and ready to use once placed at the retailer’s facility and provided with electrical and possibly plumbing connections, and are accessed via a door to store refrigerated products. In general, both types of applications are often called “walk-in coolers” or “walk-in freezers,” depending on the design temperature.

Such cold rooms might be used as part of a food establishment and hence is part of the retail food establishment. For these applications, even if this equipment is not accessible to the public—for instance, it is in the back of a supermarket and holds products that are later brought to display cases from which customers obtain the products; or in the back of a restaurant where a cook takes and prepares the food that is brought to the diner by a waiter—it is considered part of the retail establishment and hence is part of the “retail food refrigeration” end-use and is not included in the “cold storage warehouse” end-use. The changes of status proposed in this action would not apply to such systems, “walk-in coolers,” or “walk-in freezers.” However, EPA refers the reader to a previous rulemaking that does apply (80 FR 42870; July 20, 2015).

R-717 is believed to be the most common refrigerant used in cold storage warehouses. While R-717 is not used extensively in many other types of refrigeration and air-conditioning equipment, certain characteristics of cold storage warehouses have facilitated the widespread use of R-717 as a refrigerant in this end-use. For example, because cold storage warehouses are often large in size for economies of scale reason and require a large amount of land use—as opposed to other systems that might be located on a building roof or a small slab next to the building—they are typically located away from population centers where land costs and taxes may be higher. Also, because they often service multiple retail locations and may receive goods from multiple producers, cold storage warehouses are often sited where major transportation services (i.e., highways and rail lines) are available and are less prone to high traffic delays and similar disruptions that are more common in population centers. In addition, the transportation of goods is typically done in large volumes—by truck or train—to reduce costs, which in turn reduces the workforce needed and the number of people at the warehouse and in particular near the refrigeration equipment. These factors allow for more consideration of the use of refrigerants that do pose toxicity and flammability risks, such as R-717, than in other applications where more people might be at risk, such as an office building.

Limitations on the use of R-717 do exist. For example, it is reported that charge sizes exceeding 10,000 pounds of R-717 “may require government-mandated process safety management (PSM) and [a] risk management plan (RMP)” (80 FR 42870; July 20, 2015). Such cold rooms are used to store products at required temperatures until sale to the ultimate consumer, such as a shopper in a supermarket or a diner in a restaurant. In some cases, one side of the room is fitted with glass doors and racks where the owner stacks products on the racks and the consumer obtains the product from the rack. In other cases, the cold room is only accessible by employees of the retail food establishment. For these applications, even if this equipment is not accessible to the public—for instance, it is in the back of a supermarket and holds products that are later brought to display cases from which customers obtain the products; or in the back of a restaurant where a cook takes and prepares the food that is brought to the diner by a waiter—it is considered part of the retail establishment and hence is part of the “retail food refrigeration” end-use and is not included in the “cold storage warehouse” end-use. The changes of status proposed in this action would not apply to such systems, “walk-in coolers,” or “walk-in freezers.”

Likewise, regulations may require employing operators with special levels of expertise, reporting of use or accidental releases, and other actions not typically required for other alternatives, increasing the operating cost compared to facilities using other refrigerants. These increased costs however are often offset given the high energy efficiencies typically achieved with ammonia systems.

Some of the limitations on the use of R-717 in cold storage warehouses may be overcome with system designs that have been introduced or have been more fully explored recently. These include low charge packaged R-717 systems, R-717/R-744 cascade systems, and indirect secondary-loop systems using R-717 as the primary refrigerant in a machine room separated from the cooled interior. These systems are described in market characterizations found in the docket to 120 ASHRAE, 2014. 2014 Handbook—Refrigeration. The American Society of Heating, Refrigerating, and Air-conditioning Engineers, Inc. Atlanta, Georgia, USA. ISBN 978-1–936504–71–8; ISSN 1930–7195.
this proposed rule (EPA–HQ–OAR–2015–0663).\textsuperscript{121}

Where R-717 was not used, cold storage warehouses traditionally used CFC-12, R-502 and HCFC-22. With the 1996 CFC phaseout, and the restriction on the use of newly manufactured HCFC-22 in new equipment that took effect January 1, 2010, R-404A or R-507A are generally used when R-717 is not chosen. Two nonflammable HFC/ HFO blends, R-448A and R-449A, are designed to perform similarly to R-404A and R-507A and are under investigation for this use. EPA also notes that a major retailer recently announced progress on implementing HFC-free food distribution centers.\textsuperscript{122}

\textbf{ii. Which refrigerants is EPA proposing to list as unacceptable?}


EPA understands that existing cold storage warehouses may undergo expansion to handle needs such as increased production, consolidation of distribution points, or increased population or other reasons for increased demands of the products stored. Such expansions could include a physical expansion of the storage space or using racking techniques to increase the amount of product within a given facility. The owner of cold storage warehouses undergoing such expansions (or the owner’s designer) may determine that a new system needs to be added. That new system could be a completely newly manufactured system separate from the existing system, or it could be equipment and refrigerant added to the existing system increasing the capacity of the existing system. In both cases, EPA considers these actions as the manufacturing of a new system and hence that equipment could be affected by the proposed changes of status, as explained further below.

EPA addressed the difference between a “new” and “retrofit” system as used in the SNAP program in a previous rule (80 FR 42902–42903; July 20, 2015). As used in the SNAP program, “new” refers to the manufacture and often installation of a refrigeration system, which may occur on a newly manufactured or an existing cold storage warehouse. This proposed action would apply to expansion of the refrigeration system in an existing cold storage warehouse as being designated a “new” system if the capacity of that existing refrigeration system is increased to handle the expansion. On the other hand, if an existing refrigeration system is extended (for instance, by adding additional refrigerant lines and evaporators to a newly manufactured or newly commissioned building, to a portion of the existing facility previously not used for cold storage, or to an extension of the previous building), without requiring an increase in capacity, the system is not considered “new” and hence may continue its operations with the existing refrigerant. Likewise, a facility may increase the amount of products it handles while at the same time providing better sealing around infiltration points and/or increasing the insulation on walls and roofs, and thereby avoid the need to increase the refrigeration capacity of the equipment serving the cold storage warehouse. EPA requests comment on the definition of “new” and how it applies to cold storage warehouses. In particular, EPA requests comments on the likelihood and frequency that existing cold storage warehouses are expanded and whether it is typical to utilize or expand the existing refrigeration system to address the increased load from the facility expansion or whether it is typical to install a new system specifically to handle that expansion.

iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?

For new cold storage warehouses, acceptable refrigerants for which we are not proposing a change of status in this end-use include: FOR12A, FOR12B, HFC-134a, Ikon A, Ikon B, KDD6, R-407C, R-407F, R-437A, R-450A, R-513A, R-717, R-744, RS-24 (2002 composition), SP34E, THR-02, and THR-03.

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; and ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below. In addition, a technical support document\textsuperscript{123} that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives for new cold storage warehouses may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

\textbf{(a) Environmental Impacts}

The refrigerants we are proposing to find unacceptable through this action have zero ODPs, but they have GWPs ranging from 2,090 to 3,990. As shown in Table 10, acceptable alternatives have GWPs ranging from zero to 1,820.

\begin{table}[h]
\centering
\begin{tabular}{|l|l|l|l|}
\hline
Refrigerant & GWP & ODP & VOC & Proposal  \\
\hline
Ammonia, CO\textsubscript{2}, R-450A, R-513A & 0–630 & 0 & No & No change.  \\
IKON A, Ikon B, THR-02 & 30–560 & 0 & Yes\textsuperscript{3} & No change.  \\
HFC-134a, R-407C, R-407F & 1,430–1,820 & 0 & No & No change.  \\
FOR12A, FOR12B, KDD6, R-437A, RS-24 (2002 composition), SP34E, THR-03 & 920–1,810 & 0 & Yes\textsuperscript{3} & No change.  \\
R-717, R-744, RS-24 (2002 composition), SP34E, THR-02, and THR-03 & 2,260–2,730 & 0 & Yes\textsuperscript{3} & Unacceptable.  \\
R-125/290/134a/600a (55/1/42.5/1.5), R-417A, R-422B, R-422D, R-424A, R-424A, R-434A, R-438A, R-507A & 3,190–3,990 & 0 & No & Unacceptable.  \\
HFC-227ea, R-421B, R-404A, R-507A & 0 & Yes & No change.  \\
\hline
\end{tabular}
\caption{GWP, ODP, and VOC Status of Refrigerants in New Cold Storage Warehouses\textsuperscript{123}}
\end{table}

Some of the refrigerant blends not subject to the proposed status change, as well as several of the substitutes subject to the proposed status change, include small amounts of R-290, R-600, or other substances that are VOCs. These amounts are small and for this end-use, are not expected to contribute significantly to ground-level ozone formation. In the actions where EPA listed these refrigerants as acceptable or acceptable subject to use conditions, EPA concluded none of these refrigerants in this end-use pose significantly greater risk to ground-level ozone formation than other alternative refrigerants that are not VOCs or that are specifically excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. The refrigerants not subject to the proposed status change are highly volatile and typically evaporate or partition to air, rather than contaminating surface waters. Their effects on aquatic life are expected to be small and pose no greater risk of aquatic or ecosystem effects than those of other refrigerants that are subject to the proposed status change for this end-use.

(b) Flammability

For the cold storage warehouse end-use, with the exception of R-717, the acceptable refrigerants not subject to proposed changes of status, as well as those that are subject to proposed changes of status, are not flammable. R-717 is slightly flammable with a low flame speed; it is classified as a 2L refrigerant under ASHRAE 34 (2013). R-717 has a long history of use as a refrigerant in cold storage warehouses and other applications. In the original SNAP rule, EPA noted “ammonia has been used as a medium to low temperature refrigerant in vapor compression cycles for more than 100 years. Ammonia has excellent refrigerant properties, a characteristic pungent odor, no long-term atmospheric risks, and low cost. It is, however, slightly flammable and toxic, although it is not a cumulative poison. OSHA standards specify a 15 minute short-term exposure limit of 35 ppm for ammonia.” (53 FR 13072; March 18, 1994). We further noted its use in various food and beverage processing and storage applications as well as other industrial applications. In that rule, we found R-717 acceptable for use in new cold storage warehouses, concluding that its overall risk to human health and the environment was not significantly greater than the other alternatives found acceptable. This conclusion was based on the assumption that the regulated community adheres to OSHA regulations on such use as well as standard refrigeration practices, such as the adherence to ASHRAE Standard 15, which is often utilized by local authorities when setting their own building and safety requirements.

(c) Toxicity

For the cold storage warehouse end-use, with the exception of R-717, the acceptable refrigerants not subject to the proposed status change, as well as those that are subject to the proposed status change, are of low toxicity (e.g., those listed under ASHRAE Standard 34–2013 are class A toxicity). R-717, for which we are not proposing a change of status, is of a higher toxicity than some other refrigerants and is classified as a B refrigerant under ASHRAE 34 (2013). See section VI.A.4.c.iii.(b) for a discussion on the long history of use of R-717 and our original decision finding it acceptable in new cold storage warehouses.

(d) Summary

EPA has listed as acceptable several alternatives that pose lower overall risk to human health and the environment than the refrigerants whose status we are proposing to change to unacceptable. The risks other than GWP are not significantly different for the alternatives than for the refrigerants we are proposing to list as unacceptable, and the GWP for the refrigerants we are proposing to list as unacceptable are significantly higher and thus pose significantly greater risk.

iv. When would the status change?

EPA is proposing a change of status date for new cold storage warehouses of January 1, 2023, which the Agency believes is the earliest date by which the technical challenges can be met for a safe and smooth transition to alternatives, particularly considering the various equipment types that could be employed to provide the cooling necessary for new cold storage warehouses and the requirement for many of these equipment types to meet energy conservation standards while undergoing such a transition. Given the widespread use of other acceptable alternatives, particularly R-717, EPA expects that only a limited number of new cold storage warehouses, including expansions at existing facilities, would otherwise have been designed to use one of the alternatives for which we are proposing a change of status. Nonetheless, because of the restrictions that may apply on the use of ammonia at the local level, and the variety of equipment that could be applied at a cold storage warehouse, EPA expects that this period of time is necessary until acceptable alternatives will become available for cold storage warehouses. HFC blends, primarily R-404A and R-507A, like CFCs and HCFCs in the past, may have been used where R-717 was deemed by the owner as impractical, costly, onerous and/or too risky to use, given the restrictions that might exist in certain locations or for certain applications. For such locations and applications, the cold storage warehouse industry may need the time proposed to develop equipment with other alternative refrigerants or address the issues that exist with R-717.

v. What is the relationship between this proposed SNAP rule and other federal rules?

EPA is not aware of other federal rules applying to efficiency of cold storage warehouses (i.e., the buildings), but we find that some federal rules apply to equipment that could be used in this specified end-use. Specifically, EPA notes that air-cooled commercial unitary air conditioners and heat pumps (“CUACs” and “CUHPs”) might be applied at cold storage warehouses, and such equipment is subject to DOE energy conservation standards.

DOE recently issued a pre-publication version of a direct final rule affecting CUACs and CUHPs (see docket numbers EEERE–2013–BT–STD–0007 and EEERE–2013–BT–STD–0021). DOE’s standards require that energy efficiency levels be met by January 1, 2018 and that a second phase of minimum energy efficiency levels be met by January 1, 2023. The 2023 date was chosen by the Appliance Standards and Rulemaking Federal Advisory Committee Working Group as a time when alternative refrigerants could be adopted during design modifications for the second phase of DOE’s minimum energy efficiency levels. In adopting a 2023 date, DOE stated “In recognition of the issues related to alternative refrigerants, members of the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC) Working Group agreed as part of the Term Sheet to delay implementation of the second phase of increased energy conservation standard levels until January 1, 2023, in part to align dates with potential refrigerant phase-outs and to provide sufficient development lead time after safety requirements for acceptable alternatives have been established.” (http://energy.gov/sites/prod/files/2015/12/f27/CUAC-CUHP%20GWA%20Direct%20Final%20Rule.pdf). Further, DOE indicated that “Delaying the implementation of the second phase of standards in the manner recommended and agreed to by the Working Group will provide manufacturers with flexibility and additional time to comply with both energy conservation standards and potential refrigerant changes, allowing manufacturers to better coordinate equipment redesign to reduce the cumulative regulatory burden.”

DOE issued a final rulemaking on June 3, 2014 (79 FR 32049) that set nineteen energy conservation standards for walk-in coolers and walk-in freezers with a compliance date of June 5, 2017. Due to litigation regarding this rulemaking, DOE vacated six of those standards for refrigeration systems and is currently engaged in a negotiated rulemaking to address the standards as referenced in the agency’s technical amendments final rulemaking (80 FR 69837, November 12, 2015). For purposes of the DOE regulations, the Energy Conservation Act 42 U.S.C. 6311(20) defines walk-in coolers and walk-in freezers as having a total chilled storage area of less than 3,000 square feet. EPA considers the vast majority of such equipment to fit within the retail food refrigeration end-use, rather than the cold storage warehouse end-use. As described in the July 20, 2015 SNAP final rule, walk-in coolers and walk-in freezers as pertaining to DOE regulations could fall in the SNAP retail food refrigeration end-use category “supermarket system” (i.e., where refrigerant from a multi-compressor rack was supplied to the evaporator(s) in the walk-in enclosed storage space), “remote condensing unit” (where a dedicated one- or two-compressor system installed in the field supplied the refrigerant to the walk-in enclosed storage space) or “stand-alone equipment” (where the enclosed storage space is manufactured and delivered with all components including the refrigerant). Thus, we consider there to be no regulatory overlap between the vast majority of equipment to provide cooling to cold storage warehouses, which is addressed by this proposed rule and the DOE energy conservation standards for walk-in coolers and freezers. One exception might be where a refrigeration system (that does not otherwise fit SNAP end-use categories of supermarket system or remote condensing units) supplied refrigerant to an enclosed storage space with an area less than 3,000 square foot. This enclosed storage space would be required to meet both this proposed rule and the DOE requirements. On the other hand, if this refrigeration system supplied refrigerant to two enclosed storage spaces, one with an area greater than 3,000 square foot and one with an area less than that amount, both spaces would be counted under this proposed rule as cold storage warehouses while only the smaller room is covered by the DOE requirements.

vi. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on the types and subdivisions of cold storage warehouses explained here and whether other subdivisions of the end-use should be considered for this action. In particular, EPA requests comments on whether different alternatives are used or are otherwise available for different types of cold storage warehouses, why such differences exist, and whether the proposed change of status decisions, including the date such changes occur, might be affected considering such differences.

EPA requests comment on the proposed decision to change the status of the identified substitutes to unacceptable on January 1, 2023, and on the specific steps that must be undertaken to commercialize cold storage warehouse refrigeration equipment with alternative refrigerants, including the time each such step would take, which steps must occur in sequence, and which steps could occur in parallel. EPA requests comments on if and how this timing might vary based on the characteristics of the cold storage warehouse and application of the equipment. Such characteristics could include but are not limited to the equipment and system design (i.e., direct or indirect, central or unitary/packaged equipment), the required temperatures, jurisdictional limitations (e.g., at State or local levels), and considerations of risk and safety (e.g., to workers, those transporting goods to/from the facility, and the local public depending on the location). EPA requests comment on how these different distinctions may affect any federal rules that apply to the equipment or subsets thereof, for instance DOE energy conservation standards for walk-in coolers and walk-in freezers.

Additionally, EPA requests comment on any energy efficiency performance impacts of using the refrigerants not subject to the change of status proposed today that could affect the ability of manufacturers to meet current energy efficiency requirements or standards for cold storage warehouses in the United States. Also, EPA requests comment on the ability of cold storage warehouses using refrigerants other than those for which we are proposing a status change to meet those energy efficiency requirements or standards. In particular, we request comment on the specific steps and timing of such steps required to design and develop cold storage warehouses to meet applicable federal energy efficiency requirements.

EPA requests comment on the distinctions made here between cold storage warehouses and other SNAP end-uses. In particular, EPA requests comments on whether such distinctions are clear and if not, comments on how to make such distinctions clear so that they are understood by the regulated community.
EPA requests comment on the definition of “new” and how it applies to cold storage warehouses. In particular, EPA requests comments on the likelihood and frequency that existing cold storage warehouses are expanded and whether it is typical to utilize or expand the existing refrigeration system to address the increased load from the facility expansion or whether it is typical to install a new system specifically to handle that expansion.

EPA also requests comment on the current and expected use of refrigerants in cold storage warehouses. In particular, we request comment on the continued use of ODS and on the use of the HFCs for which we propose a change of status. We request comment on the factors that led to the decision to use those refrigerants as opposed to other refrigerants for which we are not proposing a change of status, including especially R-717, which as explained above has been used widely in this end-use. We request comment on the use of other alternatives, including the ones for which we are not proposing a change of status and others that may be in development, and the expected availability and penetration into the cold storage warehouse market for such alternatives. Two nonflammable HFC/ HFO blends, R-448A and R-449A, are designed to perform similarly to R-404A and R-507A and are under investigation for this use. EPA requests comment on the status of such investigations and results seen to date.

We request comment on our interpretation that there may be some overlap between EPA’s proposed status change in cold storage warehouses and DOE’s regulatory activity on walk-in coolers and walk-in freezers, as discussed in section VI.A.4.c.v above.

d. Proposed Change of Status for Certain HFC Refrigerants for New Retail Food Refrigeration (Refrigerated Food Processing and Dispensing Equipment)

As provided in the following table, EPA is proposing to change the status of numerous refrigerants from acceptable to unacceptable for new retail food refrigeration (refrigerated food processing and dispensing equipment):

| TABLE 11—PROPOSED CHANGE OF STATUS DECISIONS FOR RETAIL FOOD REFRIGERATION |
|-------------------|-----------------|-----------------|
| End-use                        | Substitutes                                      | Proposed decision |

i. What is the affected end-use?

In the SNAP July 20, 2015, final rule (80 FR 42870), EPA clarified in the response to comments that “equipment designed to make or process cold food and beverages that are dispensed via a nozzle, including soft-serve ice cream machines, ‘slushy’ iced beverage dispensers, and soft-drink dispensers” was not included as part of the retail food refrigeration end-use categories specifically identified in that final rule. In the July 20, 2015, final rule, EPA clarified that this equipment is part of a separate end-use category within the retail food refrigeration end-use—“refrigerated food processing and dispensing equipment.” A variety of food and beverage products are dispensed and often processed by equipment within this end-use category, including but not limited to: Chilled and frozen beverages (carbonated and uncarbonated, alcoholic and nonalcoholic); frozen custards, gelato, ice cream, Italian ice, sorbets and yogurts; milkshakes, “slushies” and smoothies, and whipped cream. For instance, some such equipment will process the product by combining ingredients, mixing and preparing it at the proper temperature, while others function mainly as a holding tank to deliver the product at the desired temperature or to deliver chilled ingredients for the processing, mixing and preparation. Some may use a refrigerant in a heat pump, or utilize waste heat from the cooling system, to provide hot beverages. Some may also provide heating functions to melt or dislodge ice or for sanitation purposes.

We noted in the July 20, 2015, final rule that refrigerated food processing and dispensing equipment “can be self-contained or can be connected via piping to a dedicated condensing unit located elsewhere” (80 FR 42902) and clarify here that both types fall within this end-use category. The equipment can be air-cooled although in some cases where multiple units are together and/or other space constraints exist (and hence air movement to the condenser would be compromised), a separate water line could be used to remove heat. This end-use category does not include certain types of refrigeration equipment. For example, units designed solely to cool and dispense water, including those that feature detachable containers of water as well as those that are supplied directly from a shared water supply, fall under the separate “Water Coolers” end-use within the SNAP program. In addition, this end-use category does not include the preparation of chilled products in factory situations; such equipment falls under the SNAP end-use “Industrial Process Refrigeration” and are characterized as being those that do not provide products to the ultimate consumer for immediate or near-immediate consumption. Also included in the industrial process refrigeration end-use are blast chillers and freezers, including those that may be used at consumer settings such as schools, hotels, supermarkets, hospitals, restaurants, etc. Further, this end-use category does not include the equipment used to transport food products between distinct points of production and storage, such as refrigerated trucks that may transport products from a factory to a cold storage warehouse or from that warehouse to a supermarket or restaurant. That type of equipment falls under the SNAP end-use “Refrigerated Transport.”

As part of the retail food refrigeration end-use, any alternative that has been listed broadly acceptable for the retail food refrigeration end-use, as opposed to being listed for only an individual end-use category within the retail food end-use, is likewise acceptable for this end-use category. For example, because R-744 was found acceptable for the retail food refrigeration end-use (74 FR 50129; September 30, 2009), it is acceptable for the refrigerated food processing and dispensing equipment category within the retail food refrigeration end-use. Those alternatives that have been found broadly...
unacceptable for this end-use, or those that have been found acceptable only for other specific end-use categories in this end-use, would not be acceptable alternatives under current regulations. For example, propane has been listed specifically for certain end-use categories such as stand-alone reach in coolers indicating it is not necessarily acceptable for all other end-use categories within the retail food end-use. Hence, the following alternatives are currently acceptable for new refrigerated food process and dispensing equipment: FOR12A, FOR12B, HFC-134a, HFC-227ea, IKON A, IKON B, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-428A, R-434A, R-437A, R-507A, RS-44 (2003 formulation), RS-44 (2002 formulation), SP34E, THR-02, and THR-03. On the other hand, because in our December 2011 and April 2015 final rules we found R-290, R-600a and R-441A acceptable only for stand-alone units, those alternatives are not currently acceptable for equipment in this end-use category.

ii. Which refrigerants is EPA proposing to list as unacceptable?


iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?

For new retail food refrigeration (refrigerated food processing and dispensing equipment), acceptable refrigerants for which we are not proposing a change of status in this end-use category include: FOR12A, FOR12B, HFC-134a, IKON A, IKON B, R-426A, RS-24 (2002 formulation), R-450A, R-744, SP34E, THR-02 and THR-03.

### TABLE 12—GWP, ODP, AND VOC STATUS OF REFRIGERANTS IN NEW RETAIL FOOD REFRIGERATION

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO₂, HFC-134a, R-450A</td>
<td>1–1,430</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>FOR12A, FOR12B, IKON A, IKON B, R-426A, RS-24 (2002 composition), SP34E, THR-02, THR-03.</td>
<td>30–1,510</td>
<td>0</td>
<td>Yes</td>
<td>No change.</td>
</tr>
<tr>
<td>KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-417A, R-422B, R-422D, R-424A, R-437A, R-438A, R-450A, RS-44 (2003 composition),</td>
<td>1,810–2,730</td>
<td>0</td>
<td>Yes</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>HFC-227ea, R-404A, R-421B, R-507A</td>
<td>3,190–3,990</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
</tbody>
</table>

1 The table does not include non-in-kind technologies listed as acceptable for the stated end-uses.
2 HFC-22 and several blends containing HFCs are also listed as acceptable but their use is severely restricted by the phaseout in HCFC production and consumption.
3 One or more constituents of the refrigerant are VOC.

Some of the refrigerant blends not subject to the proposed status change, as well as several of the substitutes subject to the proposed status change, include small amounts of VOC such as R-290 (propane) and R-600 (butane). These amounts are small, and for this end-use are not expected to contribute significantly to ground level ozone formation.126 In the actions where EPA listed these refrigerants as acceptable, EPA concluded none of these refrigerants in this end-use pose significantly greater risk to ground-level ozone formation than other alternative refrigerants that are not VOCs or that are specifically excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS.

The refrigerants not subject to the proposed status change are highly volatile and typically evaporate or partition to air, rather than contaminating surface waters. Their effects on aquatic life are expected to be small and pose no greater risk of aquatic or ecosystem effects than those of other refrigerants that are subject to the proposed status change for this end-use.

(b) Flammability

For the retail food refrigeration (refrigerated food processing and dispensing equipment) end-use category, all other refrigerants, including those for which we are proposing to change the status to unacceptable, are not flammable (e.g., those listed under ASHRAE Standard 34–2013 are class 1 flammability).
(c) Toxicity

Toxicity is not a significant concern for the refrigerants we are proposing to list as unacceptable. Their toxicity is comparable to that of other alternatives that are acceptable in this end-use. For the retail food refrigeration (refrigerated food processing and dispensing equipment) end-use category, all other refrigerants, including those for which we are proposing to change the status to unacceptable, are of lower toxicity (e.g., those listed under ASHRAE Standard 34–2013 are class A toxicity).

(d) Summary

EPA has listed as acceptable several alternatives that pose lower overall risk to human health and the environment than the refrigerants whose status we are proposing to change to unacceptable. The risks other than GWP are not significantly different for the alternatives than for the refrigerants we are proposing to list as unacceptable, and the GWP's for the refrigerants we are proposing to list as unacceptable are significantly higher and thus pose significantly greater risk.

iv. When would the status change?

EPA is proposing a change of status date for new retail food refrigeration (refrigerated food processing and dispensing equipment) of January 1, 2021, which the Agency believes is the earliest date by which the technical challenges can be met for a safe and smooth transition to alternatives particularly considering the need for equipment to comply with any sanitation, safety and energy conservation standards while continuing to maintain the properties, characteristics and quality of the food or beverage provided by the equipment. EPA recognizes that some manufacturers will need time to test alternative refrigerants and develop equipment to use them while meeting other standards that may apply. We find however that components for some refrigerants, such as HFC-134a, are in wide supply. Further, as noted in our July 2015 rule, at least one major beverage retailer has chosen R-744 as its alternative refrigerant for stand-alone equipment and vending machines. Given the change of status dates established for such products in that rule (from January 1, 2018 to January 1, 2020) precede the change of status date we are proposing here, we expect an increasing supply of R-744 components that could be utilized in refrigerated food processing and dispensing equipment. We note that two substitutes are currently awaiting SNAP review for this end-use. These two substitutes, R-448A and R-449A, are designed to mimic R-404A and could be readily adapted to those refrigerants if they are listed as acceptable in the future. As discussed below, there are other relevant requirements that mean that newly designed equipment will need to be certified as complying with sanitation and safety standards, and some may be required to meet energy conservation standards issued by DOE. These standards apply to similar equipment that falls within other end-use categories of the retail food refrigeration end-use, and changes of status for those end-use categories take effect January 1, 2020, or before. Those requirements will provide additional incentive for refrigerant producers to increase low-GWP refrigerant supply, for component manufacturers to test and qualify components for such low-GWP refrigerants, and for manufacturers to gain the technical knowledge necessary to successfully implement those refrigerants. Hence, we foresee that additional equipment using similar low-GWP refrigerants, and using components that are expected to become available, could be similarly transitioned in a similar amount of time as finalized for those other end-use categories.

v. What is the relationship between this proposed SNAP rule and other federal rules?

EPA is not aware of any energy conservation standards issued by DOE that apply to refrigerated food processing and dispensing equipment. EPA also understands that food safety and sanitation standards, such as those from the U.S. Food and Drug Administration and the National Sanitation Foundation (NSF), as well as product safety standards, such as those from UL, apply.

vi. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on the refrigerant(s) used for equipment in this end-use category, and detailed descriptions of the functions and why a particular refrigerant is used. We also seek comment on the applicability, technical feasibility, research, development and use of HCs, HFC/HFO blends, R-744 or other low-GWP alternatives for equipment within this end-use category. Additionally, we request comment on applicable standards for equipment used in the United States as well as those that apply to products that are pre-charged with refrigerant and exported to other countries and specifically request comment on how those standards may affect when equipment can be transitioned away from the alternatives we are proposing to list as unacceptable. Likewise, we request comment on DOE energy conservation standards and other federal requirements that apply to this equipment.

Additionally, EPA requests comment on any energy efficiency performance impacts of using the refrigerants not subject to the change of status proposed today that could affect the ability of manufacturers to meet current energy efficiency requirements or standards for refrigerated food processing and dispensing equipment in the United States. Also, EPA requests comment on the ability of refrigerated food processing and dispensing equipment using refrigerants other than those for which we are proposing a status change to meet those energy efficiency requirements or standards. In particular, we request comment on the specific steps and timing of such steps required to design and develop refrigerated food processing and dispensing equipment to meet applicable federal energy efficiency requirements.

EPA requests detailed comment on the proposed decision to change the status of the identified substitutes to unacceptable on January 1, 2021, and on the specific steps that must be undertaken for refrigerated food processing and dispensing equipment with alternative refrigerants to be available, including the time each such step would take, which steps must occur in sequence, and which steps could occur in parallel. EPA requests comments on if and how this timing might vary based on the characteristics of the equipment. Such characteristics could include, but are not limited to, compressor type, condenser design (e.g., air cooled or water cooled), refrigeration capacity, intended dispensing rate (e.g., short-term rush dispensing or steady dispensing over longer time), and refrigerant currently used and potentially used.

Additionally, EPA requests comment on our description of this end-use category to ensure it is sufficiently understood particularly by those in the equipment manufacturing and equipment servicing industry. For example, are there other technical factors that should be used to describe this end-use category? In particular, do such factors describe equipment types that are sufficiently distinct such that they are better described as two separate end-use categories (e.g., processing dispensing and dispensing-only).
e. Proposed Change of Status for Certain HFC Refrigerants for New Household Refrigerators and Freezers

As provided in the following table, EPA is proposing to change the status of numerous refrigerants from acceptable to unacceptable for new household refrigerators and freezers:

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitutes</th>
<th>Proposed decision</th>
</tr>
</thead>
</table>

i. What is the affected end-use?

Household refrigerators, freezers and combination refrigerator/freezers are intended primarily for residential use, although they may be used outside the home. The designs and refrigeration capacities of equipment vary widely. Household refrigerators and freezers are composed of three main categories of equipment. Household freezers only offer storage space at freezing temperatures, while household refrigerators only offer storage space at non-freezing temperatures. Products with both a refrigerator and freezer in a single unit are most common. In addition to the most common types, other small refrigerated household appliances exist (i.e., chilled kitchen drawers, wine coolers, and mini-fridges). Household refrigerators and freezers have all refrigeration components integrated, and for the smallest types, the refrigeration circuit is entirely brazed or welded. These systems are charged with refrigerant at the factory and typically require only an electricity supply to begin operation.

The 2014 ASHRAE Handbook of Refrigeration provides an overview of food preservation in regards to household refrigerators and freezers. Generally, a storage temperature between 32 and 39 °F (0 to 3.9 °C) is desirable for preserving fresh food. Humidity and higher or lower temperatures are more suitable for certain foods and beverages. Wine chillers, for example, are frequently used for storing wine, and have slightly higher optimal temperatures from 45 to 65 °F (7.2 to 18.3 °C). Freezers and combination refrigerator-freezers that are designed to store food for long durations have temperatures below 8 °F (−13.3 °C) and are designed to hold temperatures near 0 to 5 °F (−17.2 to −15 °C). In single-door refrigerators, the optimum conditions for food preservation are typically warmer than this due to the fact that food storage is not intended for long-term storage.


Currently, the most commonly used refrigerant in the United States for household refrigerators and freezers is R-134a, a HFC with a GWP of 1.430. However, throughout many parts of the world, R-600a with a GWP of 8 is the most commonly used refrigerant and there are ongoing efforts to help facilitate the adoption and continued use of R-600a in this industry.227 The European Union (EU) banned the use of HFCs with a GWP greater than 150 (which includes R-134a) for household refrigerators and freezers as of January 1, 2015.126 R-600a has been in use in Europe for approximately two decades. Throughout parts of Asia, Africa, and South America, R-600a is the dominant refrigerant for this end-use. In its 2014 assessment report,129 the TEAP’s RTOC projects that by 2020 about 75 percent of new household refrigerators globally will use R-600a, a small percentage will use HFOs, and the rest will use HFC-134a. There are other alternatives that can be considered too. EPA also listed R-450A and R-513A as acceptable for use in this end-use (79 FR 62863, October 21, 2014; 80 FR 42053, July 16, 2015, respectively). As noted in the preamble to those Notices of Acceptability, both R-450A and R-513A were designed to match the characteristics and performance of HFC-134a and therefore we conclude that they may be under consideration by manufacturers as well.

EPA previously found a number of flammable HC refrigerants including R-290, R-441A and R-600a as acceptable, subject to use conditions in household refrigerators and freezers (76 FR 78832, December 20, 2011; 80 FR 19454, April 10, 2015). Hydrocarbon refrigerants have been in use for over 20 years in countries such as Germany, the United Kingdom, Australia, and Japan.130

ii. Which refrigerants is EPA proposing to list as unacceptable?


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iii. How do these proposed unacceptable refrigerants compare to other refrigerants for this end-use with respect to SNAP criteria?

For new household refrigerators and freezers, acceptable refrigerants for which we are not proposing a change of status in this end-use include: HFC-152a, IKON A, IKON B, and THR-02; two HFC/HFO blends R-513A and R-450A; and HC refrigerants R-290, R-441A and R-600a.

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; and ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below. In addition, a technical support document that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives for new household refrigerators and freezers may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

(a) Environmental Impacts

The refrigerants we are finding unacceptable through this action also have zero ODP, but they have GWPs ranging from 920 to 3,990. As shown in Table 14, other alternatives, some of which are acceptable subject to use conditions, have GWP ranging from three to 630.

### TABLE 14—GWP, ODP, AND VOC STATUS OF REFRIGERANTS IN NEW HOUSEHOLD REFRIGERATORS AND FREEZERS

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>IKON A, IKON B, R-290, R-441A, R-600a, THR-02</td>
<td>3–560</td>
<td>0</td>
<td>Yes</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>R-450A, R-513A</td>
<td>124</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>HFC-134a</td>
<td>600–630</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>R-404A, R-421B, R-507A</td>
<td>3,190–3,990</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
</tbody>
</table>

1 The table does not include not-in-kind technologies listed as acceptable for the stated end-uses.
2 HCFC-22 and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production and consumption.
3 One or more constituents of the refrigerant are VOC.

Three substitutes that remain acceptable subject to use conditions, R-290, R-600a, and R-441A, are or are composed primarily of VOC. EPA’s analysis indicates that their use as refrigerants in this end-use are not expected to contribute significantly to ground level ozone formation. In the actions where EPA listed these refrigerants as acceptable subject to use conditions, EPA concluded none of these refrigerants in this end-use pose significantly greater risk to ground-level ozone formation than other alternative refrigerants that are not VOCs or that are specifically excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS.

The refrigerants not subject to the proposed status change are highly volatile and typically evaporate or partition to air, rather than contaminating surface waters. Their effects on aquatic life are expected to be small and pose no greater risk of aquatic or ecosystem effects than those of other refrigerants that are subject to the proposed status change for this end-use.

(b) Flammability

For household refrigerators and freezers, with the exception of HFC-134a, R-290, R-600a and R-441A, all other refrigerants listed as acceptable, including those for which we are proposing to change the status to unacceptable, are not flammable. The HCs R-290 and R-600a are classified as Class A3 (lower toxicity, higher flammability) refrigerants under the standard ASHRAE 34 (2013) while HFC-152a is classified as Class A2 (lower toxicity, lower flammability). To address flammability, EPA listed these HCs as acceptable, subject to use conditions. The use conditions include conditions consistent with industry standards, limits on charge size, and requirements for warnings and markings on equipment to inform consumers and technicians of potential flammability hazards. Our assessment and listing decisions (76 FR 78832; December 20, 2011 and FR 80 1954; April 10, 2015) found that the overall risk, including the risk due to flammability with the use conditions, is not significantly greater than for other refrigerants at that time and likewise are not significantly greater than for the refrigerants we are proposing to list as unacceptable. EPA found HFC-152a acceptable for new household refrigerators and freezers in the original SNAP rule indicating “[a]lthough HFC-152a is flammable, a risk assessment demonstrated it could be used safely in this end-use” (59 FR 13081; March 18, 1994).

(c) Toxicity

Toxicity is not a significant concern for the refrigerants we are proposing to list as unacceptable. Their toxicity is comparable to that of other alternatives that are acceptable in this end-use. The refrigerants subject to the proposed status change and the refrigerants not subject to the proposed status change, if listed under ASHRAE 34 (2013), are classified as A refrigerants (lower toxicity).

(d) Summary

EPA has listed as acceptable several alternatives that pose lower overall risk to human health and the environment than the refrigerants whose status we are proposing to change to unacceptable. The risks other than GWP are not significantly different for the alternatives than for the refrigerants we


are proposing to list as unacceptable, and the GWPs for the refrigerants we are proposing to list as unacceptable are significantly higher and thus pose significantly greater risk.

iv. When would the status change?

EPA is proposing a change of status date for new household refrigerators and freezers of January 1, 2021, by this date the Agency believes the technical challenges can be met for a safe and smooth transition to alternatives, particularly considering the likely use of alternatives that are acceptable subject to use conditions such as isobutane or propane. As noted above, most experts, including the TEAP, anticipate the majority of the household refrigeration market will use HC refrigerants globally and EPA does not have information suggesting anything different for the United States. Although some models may be able to transition in compliance with use conditions required for alternatives earlier, the Agency believes that most can transition by 2021.

EPA recognizes that manufacturers will need time to continue product design work for alternative refrigerants, drawing from current models used both in the United States and elsewhere. Household refrigerators are subject to DOE energy conservation standards and will need to be tested to demonstrate compliance with those standards. We understand that there may be limitations with regards to the availability of testing facilities. If the proposed change of status date was exceedingly ahead of the next anticipated DOE energy conservation standard date, it could affect the availability of testing facilities. DOE’s previous energy conservation rulemaking for this end-use was finalized in 2011 with a compliance date of September 15, 2014 (76 FR 57516; September 15, 2011). EPA anticipates that any amended standard set by DOE for these products in an upcoming rulemaking will, consistent with prior rulemakings, have a compliance date several years following issuance of the standard and thus we expect that the compliance date would be no earlier than 2020. As a result, EPA’s proposed change of status in 2021 likely would occur at approximately the same time as a compliance date for the next future DOE energy conservation standard for these products.

v. What is the relationship between this proposed SNAP rule and other federal rules?

DOE energy conservation standards apply to household refrigerators and freezers, as discussed in section VI.A.4.e.iv.

vi. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on the proposed change of status date of January 1, 2021. In particular, EPA requests comments on the specific steps that must be undertaken to commercialize household refrigerators and freezers with alternative refrigerants in the United States, including the time each step would take, which steps must occur in sequence, and which steps could occur in parallel. EPA requests comments on how and if this timing might vary based on the characteristics of the household refrigerator and freezer. Such characteristics could include, but are not limited to, capacity range, internal volume, design (e.g., refrigerator-only, freezer-only, or both) and refrigerator currently used and potentially used. EPA also requests comment on the expected availability of alternatives for such equipment, including when products using such alternatives would be available. EPA requests comments on how such timing is expected to be affected by other federal rules in the future, including the availability of testing laboratories to analyze the performance of products with alternatives while meeting any applicable federal rules. Additionally, EPA requests comment on any energy efficiency performance impacts of using the refrigerants not subject to the change of status proposed today that could affect the ability of manufacturers to meet current energy efficiency requirements or standards for household refrigerators and freezers in the United States. Also, EPA requests comment on the ability of household refrigerators and freezers using refrigerants other than those for which we are proposing a status change to meet those energy efficiency requirements or standards. In particular, we request comment on the specific steps and timing of such steps required to design and develop household refrigerators and freezers to meet applicable federal energy efficiency requirements.

B. Motor Vehicle Air Conditioning

1. Proposed Listing of HFO-1234yf as Acceptable, Subject to Use Conditions, for Newly Manufactured MVAC Systems

EPA is proposing to list HFO-1234yf as acceptable, subject to use conditions, in MVAC systems for newly manufactured MDPVs, HD pickup trucks, and complete HD vans. EPA is proposing to list HFO-1234yf as acceptable, subject to use conditions, for use in complete HD vans; we also are requesting comment and information on listing HFO-1234yf as acceptable subject, to use conditions for some incomplete HD vans. At this time, our proposal only includes complete HD vans because we do not have sufficient information on the potential for modifications to OEM-installed MVAC systems of incomplete HD vans by secondary and tertiary manufacturers and the impact of those modifications on safe use of HFO-1234yf. The use conditions are detailed below in section V.B.1.c., “What are the proposed use conditions?”

2. What is the affected end-use?

The vehicle types within the MVAC end-use that are addressed in today’s proposal include limited types of heavy-duty (HD) vehicles, specifically, MDPVs,133 HD trucks, and complete HD vans.134 EPA has previously listed HFO-1234yf as acceptable subject to use conditions in light-duty (LD) motor vehicles and trucks (76 FR 17490; March 29, 2011).

HD vehicles are often subdivided by vehicle weight classifications, as defined by the vehicle’s gross vehicle weight rating (GVWR), which is a measure of the combined curb (empty) weight and cargo carrying capacity of the vehicle. HD vehicles have GVWRs above 8,500. Table 15 outlines the HD vehicle weight classifications commonly used. MDPVs,135 HD pickup trucks, and HD vans are Class 2b and 3 vehicles with GVWRs between 8,501 and 14,000 pounds.

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133 Defined at 40 CFR 86.1801–03.
134 MVAC systems provide passenger comfort cooling for light-duty cars and trucks, heavy-duty vehicles (large pick-ups, delivery trucks, recreational vehicles, and semi-trucks), off-road vehicles, buses, and rail vehicles. EPA is not addressing other types of HD vehicles, off-road vehicles, buses, or trains in the proposed listing decision.
135 MDPVs are classified as HD vehicles based on their GVWR, but due to their similarities to LD vehicles they are subject to the GHG emissions standards established for LD trucks.
The types of HD vehicles for which EPA is proposing to list HFO-1234yf as acceptable, subject to use conditions, are in many ways more similar to LD vehicles, for which HFO-1234yf has already been approved under SNAP.136 than they are to the HD vehicles with a higher GVWR classification. These vehicle types are similar to LD vehicles technologically and most are manufactured by companies with major light-duty markets in the United States and in a similar manner to LD vehicles.137 Ford, General Motors, and Fiat Chrysler Automobiles (FCA) produce approximately 100 percent of HD pickup trucks and approximately 95 percent of HD vans, with Daimler and Nissan producing the remaining approximately five percent of HD vans.138 In many cases, these types of HD vehicles are versions of their LD counterparts.139 For example, the Silverado 1500, Ram 1500, and Ford F–150 are the LD counterparts of the HD Silverado 2500/3500, Ram 2500/3500, and Ford F–250/F–350/F–450 pickup trucks.140 The primary difference between HD pickup trucks and vans and their LD counterpart vehicles is that HD pickups and vans are occupational or work vehicles that are designed for much higher towing and payload capabilities than are LD pickup trucks and vans.141 All types of HD vehicles can be sold as “complete” or “incomplete” vehicles (76 FR 57259–60; September 15, 2011). Complete vehicles are sold by vehicle manufacturers to end-users with no secondary manufacturer making substantial modifications prior to registration and use. Incomplete vehicles are sold by vehicle manufacturers to secondary manufacturers without the primary load-carrying device or container attached. With regard to HD pickup trucks and vans, 90 percent are sold as complete vehicles while only 10 percent are sold as incomplete (80 FR 40331; July 13, 2015). Of the 10 percent of HD pickups and vans that are sold as incomplete vehicles to secondary manufacturers, about half are HD pickup trucks and half are HD vans. Examples of modifications by secondary manufacturers to HD pickup trucks are installing a flatbed platform or tool storage bins. EPA is not aware of any equipment added by a secondary manufacturer to an incomplete HD pickup truck that would result in a secondary manufacturer modifying or adjusting the already installed MVAC system to provide cooling capacity. Incomplete vans are typically sold with no enclosed cabin area behind the driver’s seat, and secondary manufacturer modifications could include applications such as conversion to ambulances, shuttle vans, and motor homes. Incomplete vans may include OEM MVAC systems that are identical to those installed in the complete van on which the incomplete model is based. In some cases these systems are designed solely for cooling the front driver area, while other systems are manufactured by the OEM with additional capability to provide cooling behind the driver area to the cabin. Some, but not all, secondary manufacturers use the OEM MVAC system with no modification to the contained refrigerant system (hoses, connections, heat exchangers, compressor, etc.).

3. How does HFO-1234yf compare to other refrigerants for these MVAC applications with respect to SNAP criteria? The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; and ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below. In addition, a technical support document144 that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives in the relevant end-uses may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

Available refrigerants in the end-uses subject to this proposal include HFC-134a, HFC-152a,142 and CO2.143 There are also several blend refrigerants that are listed as acceptable for new HD MVAC systems, subject to use conditions, including the HFC blends SP34E and R-426A (also known as RS-24) and the HCFC blends, R-416A (also known as HCFC Blend Beta or FRGC FR12), R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP). EPA is not aware of the use or development of any of these blend refrigerants in newly manufactured MDPVs, HD pickup trucks, or HD vans. HFC-134a is the refrigerant most widely used today in HD MVAC systems. All MVAC refrigerants are subject to use conditions requiring labeling and the use of unique fittings, and the two lower-GWP alternatives (HFC-152a, CO2) currently approved for use in HD vehicles are subject to additional use conditions mitigating flammability and toxicity as appropriate to the alternative.

As explained more fully below, to evaluate environmental, flammability, and toxicity risks resulting from the use of HFO-1234yf in new MDPVs, HD pickup trucks, and complete HD vans, the Agency is relying on EPA’s analysis conducted in support of the 2011 listing decision for HFO-1234yf for LD

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**TABLE 15—VEHICLE WEIGHT CLASSIFICATION**

<table>
<thead>
<tr>
<th>Class</th>
<th>2b</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>GVWR (lb)</td>
<td>8,501–10,000</td>
<td>10,001–14,000</td>
<td>14,001–16,000</td>
<td>16,001–19,500</td>
<td>19,501–26,000</td>
<td>26,001–33,000</td>
<td>&gt;33,000</td>
</tr>
</tbody>
</table>

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136 HFO-1234yf is listed as acceptable, subject to use conditions for newly manufactured passenger cars and light-duty trucks only (40 CFR part 82 subpart G).
137 This is more broadly true for heavy-duty pickup trucks than vans because every manufacturer of heavy-duty pickup trucks also makes light-duty pickup trucks, while only some heavy-duty van manufacturers also make light-duty vans (80 FR 40418; July 13, 2015).
142 HFC-152a is listed as acceptable, subject to use conditions, for new vehicles only at 40 CFR part 82 subpart G; final rule published June 12, 2008 (73 FR 33304).
143 CO2 is listed as acceptable, subject to use conditions, for new vehicles only at 40 CFR part 82 subpart G; final rule published June 6, 2012 (77 FR 33315).
vehicles. In addition, we considered risk assessments performed by OEMs and independent consultants on the use of HFO-1234yf in LD vehicles through SAE Cooperative Research Programs (CRPs) and found these were consistent with our analysis. Based on that analysis, in 2011 EPA concluded that for LD vehicles HFO-1234yf did not pose significantly greater risk to human health and the environment than the other alternatives when used in accordance with use conditions established as part of the listing decision. The refrigerants to which HFO-1234yf was compared in the 2011 action for LD vehicles are the same refrigerants available for use in the vehicle types included in today’s proposal.

EPA is able to rely on the 2011 analysis of HFO-1234yf in LD vehicles in support of this proposal because the MVAC systems, vehicle designs, and the potential for exposure for the HD vehicle types for which EPA is proposing to list HFO-1234yf as acceptable, subject to use conditions, in today’s action are identical or very similar to those of LD vehicles. As discussed in more detail below, EPA has determined that the analyses conducted on HFO-1234yf in LD vehicles are sufficiently conservative to support today’s proposal, and, in turn, that the use of HFO-1234yf in the MVAC systems of MDPVs, HD pickup trucks, and complete HD vans does not pose greater risk to human health or the environment than other alternatives, when used in accordance with use conditions.

### a. Environmental Impacts

HFO-1234yf has a GWP of one to four. HFO-1234yf has a GWP similar to or lower than the GWP of other alternatives for the HD vehicle types addressed in today’s proposal. For example, its GWP is significantly lower than that of HFC-134a, the refrigerant most widely used in these vehicles today, which has a GWP of 1,430. As shown in Table 16, two other alternatives, HFC-152a, and CO2, have GWPs of 1,430, 124, and one, respectively. Other acceptable refrigerants for the HD vehicle types addressed in today’s proposal have GWPs ranging from 1 to 2,340.

### Table 16—GWP, ODP, and VOC Status of HFO-1234yf Compared to Other Refrigerants in MVAC Systems of Newly Manufactured MDPVs, HD Pickup Trucks, and Complete HD Vans

<table>
<thead>
<tr>
<th>Refrigerants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC status</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFO-1234yf</td>
<td>1–4</td>
<td>0</td>
<td>No</td>
<td>Acceptable, subject to use conditions.</td>
</tr>
<tr>
<td>CO2, HFC-152a, HFC-134a</td>
<td>1–1,430</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>IKON A, R-416A, R-426A, SP34E</td>
<td>30–1,510</td>
<td>0–0.009</td>
<td>Yes 3</td>
<td>No change.</td>
</tr>
</tbody>
</table>

1 The table does not include not-in-kind technologies listed as acceptable for the stated end-use.

2 HCFC-22 and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production and consumption.

3 One or more constituents of the blend are VOC.

HFO-1234yf does not deplete the ozone layer. Like HFO-1234yf, HFC-134a, HFC-152a, CO2 and the HFC blends SP3AE and R-426 Ado not deplete the ozone layer; however, the HCFC blends have ODVs ranging from 0.012 to 0.056.

HFO-1234yf, HFC-134a, HFC-152a, and CO2 are exempt from the definition of VOC under CAA regulations (see 40 CFR 51.100(c)) addressing the development of SIPs to attain and maintain the NAAQS. The HFC blends and some of the HCFC blends have one or more components that are VOCs.

Another potential environmental impact of HFO-1234yf is its atmospheric decomposition to trifluoroacetic acid (TFA, CF,COOH). TFA is a strong acid that may accumulate on soil, on plants, and in aquatic ecosystems over time and that may have the potential to adversely impact plants, animals, and ecosystems. Simulations have found that the amount of TFA in rainfall produced from a transition of all mobile air conditioners in the continental United States to HFO-1234yf has been estimated to be double or more than the values observed in the United States in 2009 from all sources, natural and artificial (i.e., HFC-134a) sources.

In comparison, the amount of TFA produced from HFO-1234yf is expected to be higher than that of other fluorinated refrigerants in this end-use.

In support of the 2011 listing decision for HFO-1234yf in LD vehicles, EPA analyzed potential TFA concentrations from a full transition to HFO-1234yf in all MVAC applications, not limited to LD vehicles. The analysis found a maximum projected concentration of TFA in rainfall of approximately 1,700 ng/L. This maximum projected concentration identified in EPA’s analysis, 1700 ng/L, was roughly 34 percent higher than that projected in a 2009 peer reviewed article. The differences in projected TFA concentrations in water to be higher than that of other fluorinated refrigerants in this end-use.

123 HFO-1234yf is expected to have GWPs ranging from 1 to 2,340.

144 HFC-152a is listed as acceptable, subject to use conditions, for new vehicles only at 40 CFR part 82 subpart G; final rule published June 6, 2012 (77 FR 33315).

145 CO2 is listed as acceptable, subject to use conditions, for new vehicles only at 40 CFR part 82 subpart G; final rule published June 12, 2008 (73 FR 33304).

146 Other fluorinated compounds also decompose into TFA, including HFC-134a.


153 ICF, 2010d. Sensitivity Analysis CMAQ results on projected maximum TFA rainwater concentrations and maximum 8-hr ozone concentrations.

is a reflection of EPA’s reliance on higher emission estimates. Even when relying on more conservative emission estimates, a concentration of 1700 ng/L corresponds to roughly 1/600th of the No-Observed-Adverse-Effect-Level (NOAEL) for the most sensitive algae species, which is also well below the NOAEL for the most sensitive aquatic animal species.

Since the 2011 final rule listing HFCO-1234yf as acceptable for LD vehicles, additional research on TFA has been conducted. The UNEP Ozone Secretariat provided a summary of key information pertaining to TFA based on the 2014 Assessment Reports of the Environmental Effects Assessment Panel (EEAP) and the Scientific Assessment Panel (SAP) of the Montreal Protocol. The brief states, “While it is well established that TFA is a ubiquitous natural component in rivers, lakes, and other surface water bodies, uncertainties remain regarding anthropogenic sources, long-term fate and abundances as these are linked to current and future use and emissions of HFCs, HCFCs, and HFOs. Based on estimates to 2040, increases are predicted to remain relatively low and are therefore not expected to be a significant risk to human health or detrimental to the environment. Projected future increased loadings of TFA to playas, land-locked lakes, and the oceans due to continued use of HCFCs, HFCs, and replacement products such as HFOs are still judged to present negligible risks for aquatic organisms and humans.” The UNEP background document also states that TFA and its salts “do not bioconcentrate in aquatic organisms, and do not biomagnify in the food chain. Thus they present negligible risk to organisms higher on the food chain, including humans.”

A 2014 study by Kazil, et al. analyzed TFA deposition in the United States assuming 100 percent of all MVAC systems use HFCO-1234yf. The results indicated that rainwater TFA concentrations, while varying strongly geographically, will on average be low compared to the levels at which toxic effects are observed in aquatic systems. The additional information available since our 2011 listing decision shows no greater risk than our earlier analysis. Taking into consideration the analysis conducted in support of the 2011 listing decision, which was based on conservative emissions assumptions and a transition from HFC-134a to HFC-1234yf for all MVAC systems (not limited to LD vehicles), and the research that has been conducted since, EPA concludes that the use of HFCO-1234yf in the HD vehicle types addressed in this action will not pose a significant risk to the environment from atmospheric decomposition to TFA.

Based on the consideration of all of these environmental impacts, EPA concludes that HFCO-1234yf does not pose significantly greater risk to the environment than the other alternatives for use in newly manufactured MDVPs, HD pickup trucks, and complete HD vans, and it poses significantly less risk than several of the alternatives with high-GWPs and ODPs.

b. Flammability

HFCO-1234yf is a flammable refrigerant classified as A2L under ASHRAE 34-2013. HFC-134a and CO2 are nonflammable refrigerants, while HFC-152a is slightly more flammable than HFCO-1234yf with an ASHRAE classification of A2. To evaluate human health and safety impacts, including flammability risks, of the use of HFCO-1234yf in MDVPs, HD pickup trucks, and complete HD vans, the Agency is relying on EPA’s analysis conducted in support of the 2011 listing decision for HFCO-1234yf for LD vehicles and information submitted during the public comment period of the proposal for the 2011 final decision (October 19, 2009; 74 FR 53445), including the SAE CRP risk assessments. With regards to occupational exposure, EPA’s risk screen on the use of HFCO-1234yf in LD vehicles evaluated flammability risks (e.g., potential for a fire from release and ignition) in workplace situations, such as during equipment manufacture and disposal or recycling of vehicle end-of-life. Modeling of concentrations of HFCO-1234yf in the workplace scenarios found short-term, 15-minute concentrations of 28 ppm or less—far below the lower LFL of 6.2 percent by volume (62,000 ppm).

The SAE CRP’s risk assessments also evaluated flammability risks to technicians. The SAE CRP conducted Computational Fluid Dynamics (CFD) modeling of exposure levels in case of a leak in a system in a service shop. The SAE CRP found that a leaked concentration of HFCO-1234yf could exceed the LFL of 6.2%, but only within ten centimeters or less of the leak. The SAE CRP risk assessment concluded that the risk of this occupational exposure scenario is “inconsequential” because ignition sources would not be located within ten centimeters of the MVAC system given technicians’ familiarity with precautions necessary to avoid flammability risks due to the presence of other flammable materials in the engine compartment. EPA notes that HFCO-1234yf is less flammable and results in a less energetic flame than a number of fluids that motor vehicle service technicians and recyclers or disposers deal with on a regular basis, such as oil, anti-freeze, transmission fluid, and gasoline. The results of the CRP indicate that HFCO-1234yf does not pose a greater risk in occupational settings than nonflammable alternatives, or HFC-152a, which is more flammable than HFCO-1234yf and already approved for use in the HD vehicle types being addressed in this action.

Regarding the flammability risks of HFCO-1234yf to passengers inside LD vehicle, in support of the 2011 listing decision, EPA determined the following (76 FR 17490; March 29, 2011):

Depending on the charge size of an HFCO-1234yf MVAC system, which may range from as little as 400 grams to as much as 1600 grams, it is possible in a worst case scenario to reach a flammable concentration of HFCO-1234yf inside the passenger compartment. This could occur in the case of a collision that ruptures the evaporator in the absence of a switch or other engineering mitigation device to prevent flow of high concentrations of the refrigerant into the passenger compartment, provided that the windows and windshield remain intact. As stated in the SAE CRP, ignition of the refrigerant once in the passenger cabin is unlikely (probability on the order of 10^-14 occurrences per operating hour) because the only causes of ignition within the passenger cabin with sufficient energy to ignite the refrigerant would be use of a butane lighter (EPA–OAR–2008–0664–0056.2). If a passenger were in a collision, or in an emergency situation, it is unlikely that they would choose to operate a butane lighter in the passenger cabin. Additionally, it is unlikely ignition would occur from a flame from another part of the vehicle because...
automobiles are constructed to seal off the passenger compartment with a firewall. If a collision breached the passenger compartment such that a flame from another part of the vehicle could reach it, that breach would also create ventilation that would lower the refrigerant concentration below the lower flammability limit. Similarly, if either a window or the windshield were broken in the collision, the ventilation created would lower the refrigerant concentration below the lower flammability limit. Therefore, EPA finds that flammability risks of HFO-1234yf to passengers inside a vehicle will be low. Further, these risks are likely to be less than those from HFC-152a, another flammable refrigerant that EPA has previously found acceptable subject to use conditions, because HFC-152a has a lower LFL and a lower minimum ignition energy than HFO-1234yf (EPA–HQ–OAR–2008–0064–0008, –0013.4, –0056.2).

Since that time additional analysis has been conducted under more recent SAE CRPs.

The fourth and most recent SAE CRP, SAE CRP1234–4, was established in October 2012 in response to a press release issued by the German OEM Daimler “suggesting that new testing conducted by the company had shown R-1234yf to pose greater risk of vehicle fire than was estimated by the prior CRP1234 analysis.” The final report for SAE CRP1234–4 was released on July 24, 2013, and concluded that the “refrigerant release testing completed by Daimler was unrealistic.” And, “their testing created extreme conditions that favored ignition while ignoring many mitigating factors that would be present in an actual real-world collision.”

The OEM members of CRP1234–4 included FCA, Ford, General Motors, Honda, Hyundai, Jaguar Land Rover, Mazda, PSA, Renault, and Toyota.

To fully assess the newly raised concerns, CRP1234–4 completed two new fault tree scenarios as refinements to the original fault tree analysis (FTA). “The two new fault tree scenarios consider the possibility of an individual being unable to exit the vehicle due to a collision or a non-collision event that involves a refrigerant/oil release, the refrigerant/oil being ignited and the fire propagating. The FTA examined average risks across the entire global fleet of light-duty vehicles and used a number of conservative assumptions to ensure that the final risk estimate would be more likely to overestimate rather than underestimate actual risks.”

Based on the updated analysis, the estimated overall risk of vehicle fire exposure attributed to use of R-1234yf is conservatively estimated at $3 \times 10^{-12}$ events per vehicle operating hour. This is nearly six orders of magnitude less than the current risk of vehicle fires due to all causes (approximately $1 \times 10^{-6}$ per vehicle operating hour) and also well below other risks accepted by the general public. The current overall risk of occupant exposure to adverse events based on R-1234yf usage is on the same order of magnitude as those estimated in the prior work of CRP1234. Therefore, the conclusions of the former CRP risk assessment are still valid: Risks are still very small compared to the risks of a vehicle fire from all causes and well below risks that are commonly viewed as acceptable by the general public.

The findings of CRP1234–4 provide additional support for the conclusions of prior CRPs, and the EPA’s analysis for its 2011 rule listing HFO-1234yf as acceptable, subject to use conditions, for use in LD vehicles. These findings in conjunction with EPA’s earlier evaluation for LD vehicles support this proposal to list HFO-1234yf as acceptable, subject to use conditions, for the identified HD vehicle types.

To determine the appropriateness of relying on the conclusions of the extensive risk assessments conducted on flammability risks to passengers from HFO-1234yf in LD vehicles to support today’s proposed SNAP listing of the same alternative in MDPVs, HD pickup trucks, and complete HD vans, we conducted an analysis of refrigerant charge size as compared to vehicle cabin size. Specifically, we evaluated whether the charge size and vehicle cabin size used for the worst case scenario for LD vehicles would be sufficiently conservative to also represent a worst case scenario for the HD vehicle types addressed in this proposal. EPA analyzed the charge to vehicle cabin size ratios for 38 vehicle models of MDPVs, HD pickup trucks, and HD vans and found that the highest ratio of charge size to compartment area, which represents the most conservative exposure scenario (smallest passenger compartment with largest refrigerant charge), for the types of HD vehicles included in this proposal, is 410 g/m³. This ratio is significantly lower than the highest ratio identified for LD vehicles, 641 g/m³, which was identified as the most conservative value and used to conduct the risk screen supporting for LD listing. Thus, the assessment used for the LD vehicles is sufficiently conservative to also represent a worst case scenario for the HD vehicle types subject to this proposal.

EPA considered the results of our examination of the ratio of charge size to compartment area and our understanding of these vehicle types and their HVAC systems being very similar to LD vehicles in determining it was appropriate to rely on the currently available analyses on light-duty vehicles. In addition, EPA has considered the characteristics of MDPVs, HD pickup trucks, and HD vans that could be different from LD vehicles, such as differences in the engine compartment size, passenger cabins, and operating conditions, and how those might impact EPA’s reliance on the LD analyses. CRP1234–4 considered the temperature and conditions of a hot surface that would be necessary to ignite HFO-1234yf released into the engine compartment as part of the FTA. The risk assessment conservatively analyzed a refrigerant and oil mixture contacting a hot surface, at or above 700 degrees Fahrenheit, in a stagnant zone condition such as might occur if the hot surface were covered with a heat shield with limited ventilation. EPA considered whether the engine temperatures and configurations of MDPVs, and HD pickup trucks and vans would reach higher temperatures (above 700 degrees) more regularly due to workload and towing capabilities, and if this would increase the likelihood of a fire under the hood of the vehicle. EPA does not believe this is the case. Despite their use as occupational vehicles and their towing capabilities, EPA does not expect any engine compartment surfaces to reach temperatures above those conservatively assumed for LD vehicles. The engine materials in these vehicles are the same as their LD counterparts, or in some cases a different material may be used to ensure consistent operating conditions. Also, in many cases the engine compartments for these vehicle types are larger than a LD engine compartment, allowing for additional space between hot parts and refrigeration lines, as well as increased airflow in the engine, decreasing the likelihood that refrigerant would be released onto a hot surface and that
contact, if it occurs, would occur in a stagnant zone condition.

EPA also considered whether the MVAC systems in diesel vehicles require additional analysis, since only gasoline vehicles have been used in the existing risk assessments. Unlike the LD fleet, where few vehicles have diesel engines, about half of HD pickup trucks and vans use diesel engines (July 13, 2015; 80 FR 40137). Based on EPA’s understanding that MVAC systems and passenger compartments will be the same in gasoline and diesel engines, and surface temperatures within a diesel engine are typically lower than those in a gasoline vehicle because of the lean combustion and more complete utilization of thermal energy inherent to diesel engines, EPA has determined that additional analysis on vehicles with diesel engines is not necessary.

For these reasons, EPA concludes that the currently available assessments on the use of HFO-1234yf in LD vehicles are sufficiently conservative to account for all possible flammability risks from the use of HFO-1234yf in MDVPs, HD pickup trucks, and complete HD vans. Relying on the same analysis considered in support of the 2011 SNAP listing of HFO-1234yf as acceptable, subject to use conditions, for MVAC in new LD vehicles, verifying that more recent information is consistent with that analysis, and considering unique factors for these vehicle types, EPA concludes that the use of HFO-1234yf in new MVAC systems for MDVPs, HD pickup trucks, and complete HD vans does not pose greater flammability risk than the other alternatives when used in accordance with the proposed use conditions.

c. Toxicity

To evaluate human health and safety impacts, including toxicity risks, from the use of HFO-1234yf in MDVPs, HD pickup trucks, and complete HD vans, the Agency is relying on EPA’s analysis conducted in support of the 2011 listing decision for HFO-1234yf for LD vehicles and information submitted during the public comment period of the proposal (October 19, 2009; 74 FR 53445) for the 2011 final decision, including the SAE CRP risk assessments.

In our analysis supporting the 2011 final decision, EPA compared worker exposures to a workplace exposure limit of 250 ppm over an 8-hour time-weighted average for long-term occupational exposure to HFO-1234yf. For short-term occupational exposure to HFO-1234yf, we compared worker exposure to an acute exposure limit of 98,211 ppm, divided by a margin of exposure of 30, for a value of 3,270 ppm over 30 minutes.166 167 Concerning workplace exposure, we expect that professional technicians have proper training and certification and have the proper equipment and knowledge to minimize their risks due to exposure to refrigerant from an MVAC system. Thus, worker exposure to HFO-1234yf is expected to be low. If workers service MVAC systems using certified refrigerant recovery equipment after receiving training and testing, exposure levels to HFO-1234yf are estimated to be on the order of 4 to 8.5 ppm on an 8-hour time-weighted average (as compared with a 250 ppm workplace exposure limit)168 and 122 ppm on a 30-minute average (as compared with a short-term exposure level of 98,211 ppm divided by a margin of exposure of 30, for a value of 3270 ppm over 30 minutes).169 170 171 172 We also analyzed exposure levels during manufacture and final disposition at vehicle end-of-life, and found that they would be no higher than 28 ppm on a 15-minute average or 8.5 ppm on an 8-hour time-weighted average.173 The manufacture, use, and disposal or recycling of HFO-1234yf MVAC systems are not expected to present a risk to workers. Other alternatives such as HFC-134a and HFC-152a also do not present a toxicity risk to workers in the same scenarios; therefore, HFO-1234yf poses the same or less risk than other alternatives.

EPA’s review of consumer risks from toxicity of HFO-1234yf indicated that

collective uncertainty factor of 30. Uncertainty factors of 3 were assigned for animal to human extrapolation, and 10 for variability within the human population. The long-term workplace exposure limit was calculated as follows: 4000 ppm (animal exposure) × 1.9 (ratio of estimated human exposure/animal exposure) × 1/3 (UF for animal to human extrapolation) × 1/10 (UF for variability within the human population) = 250 ppm. This value was compared against 8-hour average concentrations. See EPA–HQ–OAR–2008–0664–0036 and EPA–HQ–OAR–2008–0664–0038.166 167

This was based on a NOAEL of 51,690 ppm from the study. “Sub-acute (2-week) Inhalation Toxicity Study with HFO-1234yf in rats,” EPA–HQ–OAR–2008–0664–0020 through–0020.4, a factor of 1.9 to account for differences in blood concentrations between animals and humans and a margin of exposure or collective uncertainty factor of 30. Uncertainty factors of 3 were assigned for animal to human extrapolation, and 10 for variability within the human population. The short-term workplace exposure value was calculated as follows: 51,690 ppm (animal exposure) × 1.9 (ratio of estimated human exposure/animal exposure) × 98,211 ppm This value was then divided by the expected exposure in each scenario, and compared against the target margin of exposure of 30. See EPA–HQ–OAR–2008–0664–0036 and EPA–HQ–OAR–2008–0664–0038.167 172 For comparison, the SAE CRP used exposure limits of 500 ppm over 8 hours and 115,000 ppm over 30 minutes to evaluate risks for these same time periods. These are based on the 8-hr Workplace Environmental Exposure Limit (WEEL) for HFO-1234yf and for short-term exposure, assuming a NOAEL of approximately 405,800 ppm from the study. “Acute (4-hour) inhalation toxicity study with HFO-1234yf in rats,” Note that EPA disagrees with the finding that the acute inhalation toxicity study found a NOAEL. We consider this study to show adverse effects at all levels because of the presence of grey discoloration in the lungs of the test animals. In order to ensure sufficient protection, EPA’s risk assessment used a NOAEL from a subacute study instead of a LOAEL from an acute study.171 172

166For comparison, the SAE CRP used exposure limits of 500 ppm over 8 hours and 115,000 ppm over 30 minutes to evaluate risks for these same time periods. These are based on the 8-hr Workplace Environmental Exposure Limit (WEEL) for HFO-1234yf and for short-term exposure, assuming a NOAEL of approximately 405,800 ppm from the study. “Acute (4-hour) inhalation toxicity study with HFO-1234yf in rats,” Note that EPA disagrees with the finding that the acute inhalation toxicity study found a NOAEL. We consider this study to show adverse effects at all levels because of the presence of grey discoloration in the lungs of the test animals. In order to ensure sufficient protection, EPA’s risk assessment used a NOAEL from a subacute study instead of a LOAEL from an acute study.171 172

165This was based on a NOAEL of 4000 ppm from the study, “An Inhalation Prenatal Developmental Toxicity Study of HFO-1234yf (2,3,3,3-Tetrafluoropropene) in Rats,” EPA–HQ–OAR–2008–0664–0041. We used a factor of 1.9 to account for differences in blood concentrations between animals and humans, and a margin of exposure or

166This was based on a NOAEL of 51,690 ppm from the study, “Sub-acute (2-week) Inhalation Toxicity Study with HFO-1234yf in rats,” EPA–HQ–OAR–2008–0664–0020 through–0020.4, a factor of 1.9 to account for differences in blood concentrations between animals and humans and a margin of exposure or collective uncertainty factor of 30. Uncertainty factors of 3 were assigned for animal to human extrapolation, and 10 for variability within the human population. The short-term workplace exposure value was calculated as follows: 51,690 ppm (animal exposure) × 1.9 (ratio of estimated human exposure/animal exposure) × 98,211 ppm This value was then divided by the expected exposure in each scenario, and compared against the target margin of exposure of 30. See EPA–HQ–OAR–2008–0664–0036 and EPA–HQ–OAR–2008–0664–0038.

167For comparison, the SAE CRP used exposure limits of 500 ppm over 8 hours and 115,000 ppm over 30 minutes to evaluate risks for these same time periods. These are based on the 8-hr Workplace Environmental Exposure Limit (WEEL) for HFO-1234yf and for short-term exposure, assuming a NOAEL of approximately 405,800 ppm from the study. “Acute (4-hour) inhalation toxicity study with HFO-1234yf in rats,” Note that EPA disagrees with the finding that the acute inhalation toxicity study found a NOAEL. We consider this study to show adverse effects at all levels because of the presence of grey discoloration in the lungs of the test animals. In order to ensure sufficient protection, EPA’s risk assessment used a NOAEL from a subacute study instead of a LOAEL from an acute study.171 172

168This was based on a NOAEL of 4000 ppm from the study, “An Inhalation Prenatal Developmental Toxicity Study of HFO-1234yf (2,3,3,3-Tetrafluoropropene) in Rats,” EPA–HQ–OAR–2008–0664–0041. We used a factor of 1.9 to account for differences in blood concentrations between animals and humans, and a margin of exposure or
potential consumer (passenger) exposure from a refrigerant leak into the passenger compartment of a vehicle is not expected to present an unreasonable risk. The consumer risks due to exposure to HFC-152a and HFC-134a are comparable to those of HFO-1234yf, with exposure levels expected to be below relevant exposure limits such as their cardiotoxic NOAELs. The consumer toxicity risks due to CO₂ are mitigated by the use conditions for that refrigerant, resulting in comparable risks to other alternatives.

In addition to analyzing exposure to the refrigerant, EPA and the SAE CRPs have also considered risks of generating hydrogen fluoride (HF) from combustion of HFO-1234yf. With regards to consumer risks from the use of HFO-1234yf in MVAC systems, we have considered information concerning consumer exposure to HF from thermal decomposition or combustion of HFO-1234yf. The 2009 CRP risk assessments analyzed potential concentrations of HFO-1234yf, from leak inside the passenger compartment, and HF, from thermal decomposition or ignition, in the passenger compartment. SAE CRP members conducted testing to measure HF concentrations and to identify factors that were most likely to lead to HF formation. One test on HF concentrations inside a car cabin found maximum concentrations were in the range of zero to 35 ppm in trials both with HFO-1234yf and with HFC-134a, with concentrations dropping to 10 ppm or less after 10 minutes. In a second test of HF generated in the engine compartment, HF concentrations from thermal decomposition of HFO-1234yf reached as high as 120 ppm in the engine compartment in the worst case, with interior passenger cabin values of 40 to 80 ppm. Under the same extreme conditions (flash ignition, temperature of 700°C, closed hood), HF concentrations from thermal decomposition of HFC-134a reached 36.1 ppm in the engine compartment with interior passenger cabin values of two to eight ppm. The other trials with less extreme conditions found HF concentrations from HFO-1234yf in the engine compartment of zero to 8 ppm.

The SAE CRP selected an Acute Exposure Guideline Limit (AEGL)-2 of 95 ppm over 10 minutes as its criterion for determining toxicity risk from HF. Thus, even assuming levels inside a passenger compartment reached the highest level that occurred during the tests—80 ppm—a passenger inside a vehicle would at worst experience discomfort and irritation, rather than any permanent effects. HF levels that could result in similar effects were also observed for HFC-134a. The SAE CRP concluded that the probability of such a worst-case event is on the order of 10⁻¹² occurrences per operating hour. This level of risk is similar to the current level of risk of HF generated from HFC-134a. To date, EPA is unaware of any reports of consumer exposure affected by HF generated by HFC-134a, which has been used in automobile MVAC systems across the industry since 1993. Therefore, EPA concludes that when used in accordance with use conditions, HFO-1234yf does not pose greater risk overall to human health and the environment than other alternatives.

SAE CRP1234–4 considered the need to reevaluate HF exposure due to decomposition or ignition of HFO-1234yf and determined it was unnecessary. This decision considered that: The risks of HF evaluated in the earlier CRP were not significantly different from the risks of HF generation during use of HFO-134a; a presentation from the German automobile manufacturing industry group VDA found that thermal decomposition would not lead to significant amounts of HF and confirmed that there is not expected to be additional risk due to HF from HFO-1234yf compared to HFC-134a. In addition, the CRP1234–4 considered new scenarios where an individual might not be able to leave a car; however, it is expected that because HF is irritating, individuals will leave the area unless they are unable to do so. The CRP1234–4 also considered that mitigating factors specific to HF, such as convection of HF away from the vehicle due to the heat of a fire, mean that the factors already analyzed were likely to be very conservative. Finally, the CRP1234–4 was aware of studies conducted by the CRP for a refrigerant blend, referred to as “CRP MRB,” that found HF from HFO-1234yf along the side of a vehicle never exceeded the health-based HF limit of 95 ppm, even in the case of fire. This additional information confirms that the consumer risks from generation of HF are no greater than in EPA’s 2011 evaluation. Further, risks of generation of HF are comparable to those from HFC-134a, and likely also from HFC-152a. CO₂ contains no fluorine, and thus, there are no risks due to HF generation.

EPA did not analyze toxicity concerns from the generation of HF in the workplace. In its December 17, 2009, Risk Assessment for Alternative Refrigerants HFC-1234yf and R-744 (CO₂), the SAE CRP indicated that “service technicians will be knowledgeable about the potential for HF generation and will immediately move away from the area when they perceive the irritancy of HF prior to being exposed above a health-based limit” (EPA–HQ–OAR–2008–0664–0056.2). Because the potential to form HF from HFO-1234yf is similar to that from other MVAC refrigerants and because service technicians, recyclers, and disposers have historically handled refrigerants with the same concern, including HFC-134a which is the most commonly used refrigerant, EPA concludes that HFO-1234yf does not pose greater risk in the workplace with regard to HF generation than other available or potentially alternatives.

4. What are the proposed use conditions?

All MVAC refrigerants listed as acceptable are subject to use conditions requiring labeling and the use of unique fittings. HFC-152a and CO₂ are subject to additional use conditions mitigating flammability and toxicity as appropriate to the alternative. None of these alternative refrigerants can simply be “dropped” into existing HFC-134a AC systems because they are listed as acceptable only for newly manufactured vehicles.

EPA is proposing to list HFO-1234yf acceptable, subject to use conditions, because the use conditions are necessary to ensure that use of HFO-1234yf will not have a significantly greater overall impact on human health and the environment than other alternatives for use in MDPVs, HD pickup trucks, and complete HD vans. EPA is proposing to require the same use conditions for HFO-1234yf in the HD vehicle types included in today’s proposal that are currently required for the use of HFO-1234yf in newly manufactured LD vehicles. Because of the similarities in the MVAC systems used for these vehicles, these use conditions will be sufficiently protective to ensure use of HFO-1234yf
in MDPVs, HD pickup trucks, and complete HD vans does not pose significantly greater risk than use of other alternatives.

The first use condition requires that MVAC systems designed to use HFO-1234yf must meet the requirements of SAE J639, “Safety Standards for Motor Vehicle Refrigerant Vapor Compression Systems.” This standard sets safety standards that include unique fittings; a warning label indicating the refrigerant’s identity and that it is a flammable refrigerant; and requirements for engineering design strategies that include a high-pressure compressor cutoff switch and pressure relief devices. This use condition also requires that for connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844 (revised October 2011). SAE J639 (2011 version) which specifies quick-connect fittings that are different from those for any other refrigerant. The low-side service port and connections will have an outside diameter of 14 mm (0.551 inches) and the high-side service port will have an outside diameter of 17 mm (0.669 inches), both accurate to within 2 mm. Under SAE J2844 (revised October 2011), containers of HFO-1234yf for use in professional servicing of MVAC systems must have a left-handed screw valve with a diameter of 0.5 inches and Acme (trapezoidal) thread with 16 threads per inch. The SAE standards do not include and EPA has not received a submission for unique fittings for small containers of HFO-1234yf refrigerant.

Consistent with the conclusion EPA drew at the time of the EPA’s listing decision for HFO-1234yf in LD vehicles relied, EPA believes that the safety requirements that are included in SAE J639 sufficiently mitigate risks of both HF generation and refrigerant ignition (March 29, 2011; 76 FR 17488) for MDPVs, HD pickup trucks, and complete HD vans subject to this proposed action. HFO-1234yf is mildly flammable (2L classification) and, like other fluorinated refrigerants, can decompose to form the toxic compound HF when exposed to flame or to sufficient heat. The SAE J639 standard can also address flammability and HF risks of HFO-1234yf for MDPVs, HD pickup trucks, and complete HD vans. For example, SAE J639 provides for a pressure relief device designed to minimize direct impingement of the refrigerant and oil on hot surfaces and for design of the refrigerant circuit and connections to avoid refrigerant entering the passenger cabin. The pressure relief device ensures that pressure in the system will not reach an unsafe level that might cause an uncontrolled leak of refrigerant, such as if the AC system is overcharged. The pressure release device will reduce the likelihood that refrigerant leaks would reach hot surfaces that might lead to either ignition or formation of HF. Designing the refrigerant circuit and connections to avoid refrigerant entering the passenger cabin ensures that if there is a leak, the refrigerant is unlikely to enter the passenger cabin. Keeping refrigerant out of the passenger cabin minimizes the possibility that there would be sufficient levels of refrigerant to reach flammable concentrations or that HF would be formed and transported where passengers might be exposed.

The second use condition requires the manufacturer of MVAC systems and vehicles to conduct Failure Mode and Effects Analysis (FMEA) as provided in SAE J1739 (adopted 2009) and keep records of the FMEA on file for three years from the date of creation. SAE J1739 (adopted 2009) describes a FMEA as “a systematic group of activities intended to: (a) Recognize and evaluate the potential failure of a product/process and the effects and causes of that failure; (b) identify actions that could eliminate or reduce the chance of the potential failure occurring, and (c) document the process.” Through the FMEA, OEMs determine the appropriate protective strategies necessary to ensure the safe use of HFO-1234yf across their vehicle fleet. It is standard industry practice to perform the FMEA and to keep it on file while the vehicle is in production and for several years afterwards. As with the previous use condition, this use condition is intended to ensure that new MDPVs, HD pickup trucks, and complete HD vans manufactured with HFO-1234yf MVAC systems are specifically designed to minimize release of the refrigerant into the passenger cabin or onto hot surfaces that might result in ignition in or generation of HF.

5. When would the listing apply?

EPA proposes that this listing would apply 30 days after the date of publication of a final rule. This date, the same as the proposed effective date of this regulation, allows for the safe use of this substitute at the earliest opportunity.

6. What is the relationship between this proposed SNAP rule and other federal rules?

a. CAA Sections 608 and 609

CAA section 609 establishes standards and requirements regarding servicing of MVAC systems. Under section 609, no person repairing or servicing motor vehicles for consideration 179 may perform any service on an MVAC that involves the refrigerant without properly using approved refrigerant recovery or recovery and recycling equipment and no such person may perform such service unless such person has been properly trained and certified. Refrigerant handling equipment must be certified by EPA or an independent organization approved by EPA. EPA has issued regulations interpreting this statutory requirement and those regulations are codified at subpart B of 40 CFR part 82. The statutory and regulatory provisions regarding MVAC servicing apply to all refrigerant alternatives and application is not limited to ozone-depleting refrigerants. Today’s proposal will not have a direct impact on EPA’s regulations under section 609.

Section 608 of the CAA prohibits the intentional release (venting) of all refrigerants except those specifically exempted; because HFO-1234yf is not exempt, intentional release from MVAC systems of MDPVs, HD pickup trucks, and HD vans addressed in this action would be prohibited if the decision to list HFO-1234yf as acceptable subject to use conditions is finalized. MVAC end-of-life disposal and recycling specifications are also covered under section 608 of the CAA and our regulations issued under that section of the Act, which are codified at subpart F of 40 CFR part 82.

b. Would this action listing HFO-1234yf as acceptable, subject to use conditions, for MDPVs, HD pickup trucks, and complete HD vans affect EPA’s LD GHG standards?

Today’s proposal to list HFO-1234yf as acceptable, subject to use conditions, if finalized, will have no direct effect on the MY 2017–2025 light-duty vehicle GHG standards since today’s proposed action applies to HD vehicles, not light-duty. We raise the issue here, however, because today’s proposed action would apply to MDPVs. As noted above in section V.B.1.a., although MDPVs are classified as HD vehicles based on their GVWR, due to their similarities to LD vehicles, GHG emissions from MDPVs are regulated under the LD GHG and fuel economy standards, and they are excluded from the HD GHG and fuel economy standards.

179 Service for consideration means receiving something of worth or value to perform service, whether in money, credit, goods, or services.

180 40 CFR 1037.5(c).
Nonetheless, this proposed action would have no direct effect on the regulations on MDPVs established under the LD GHG standards. Those standards are established by rule and EPA is not reopening that rule in this action. We do note, however, that today’s proposal is relevant to one of the compliance flexibilities in that rule. As part of the MY 2017–2025 LD GHG rule, EPA established the availability of credits for the use of alternative refrigerants with lower GWPVs than that of HFC-134a. If EPA lists HFO-1234yf as acceptable for MDPVs under SNAP, as proposed, vehicle manufacturers will be able to obtain credits for the use of HFO-1234yf in these vehicles as allowed for in the MY 2017–2025 LD GHG rule. The LD GHG standards do not require any specific means of compliance, so manufacturers have the flexibility to either switch refrigerants or to comply with the standards by other means.

c. Would this action listing HFO-1234yf as acceptable, subject to use conditions, for certain HD vehicles affect EPA’s HD GHG standards?

The Phase 1 HD GHG rules divided the industry into three discrete categories—combination tractors, heavy-duty pickups and vans, and vocational vehicles. The Phase 1 rules also set separate standards for engines that power vocational vehicles and combination tractors—based on the relative degree of homogeneity among vehicles within each category (76 FR 57106; September 15, 2011). On July 13, 2015, EPA and the National Highway Traffic Safety Administration (NHTSA) proposed Phase 2 HD GHG standards that would build on existing Phase 1 HD GHG standards, and also proposed GHG standards for certain trailers used in combination with HD tractors (80 FR 40137; July 12, 2015). Today’s proposal, should EPA adopt it, will have no direct effect on the HD GHG standards, either for Phase 1 or the proposed Phase 2.

As part of today’s action, EPA is proposing to list HFO-1234yf as acceptable, subject to use conditions, for MDPVs, HD pickup trucks, and complete HD vans. HD pickup trucks and vans are one of the categories of HD vehicles regulated under the Phase 1 HD GHG standards, and proposed to be further regulated under the Phase 2 program. As part of the Phase 1 HD GHG standards, EPA finalized a low leakage requirement of 1.50 percent leakage per year for AC systems installed in HD trucks and vans and combination tractors for model years 2014 and later. EPA finalized a standard of 1.50 percent leakage per year for heavy-duty pickup trucks and vans and combination tractors. See section II.E.5 of Phase 1 HD GHG standard preamble (76 FR 57194–57195) for further discussion of the MVAC leakage standard.

As part of the NPRM for Phase 2 of the HD GHG standards (80 FR 40343; July 12, 2015), EPA proposed regulatory provisions that would be in place if and when lower-GWP alternative refrigerants are approved and adopted by manufacturers of HD vehicles. EPA proposed to adopt the same MVAC leakage standard for vocational vehicles as apply for pickups and vans, and for combination tractors. If adopted, these provisions would have the effect of easing the burden associated with complying with the lower-leakage requirements when a lower-GWP refrigerant is used instead of HFC-134a. These provisions would recognize that leakage of refrigerants would be relatively less damaging from a climate perspective if one of the lower-GWP alternatives is used. Specifically, EPA proposed to allow a manufacturer to be “deemed to comply” with the leakage standard set through the Phase 1 regulations by using a lower-GWP alternative refrigerant. EPA proposed that in order to be “deemed to comply” the vehicle manufacturer would need to use an alternative refrigerant other than HFC-134a that is listed as an acceptable alternative refrigerant for heavy-duty MVAC systems under SNAP and defined under the LD GHG regulations at 40 CFR 86.1867–12(e) (80 FR 40343–44; July 12, 2015). The lower-GWP refrigerants currently defined at 40 CFR 86.1867–12(e) are HFC-152a, HFO-1234yf, and CO2.

If HFO-1234yf is listed as acceptable under SNAP for use in HD pickup trucks and complete HD vans, as proposed, and if the incentive proposed in the Phase 2 HD NPRM is finalized, these types of HD vehicles manufactured with HFO-1234yf MVAC systems will be “deemed to comply” with the low leakage standard.

7. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposed action. EPA is particularly interested in any additional exposure scenarios or unique characteristics of the types of HD vehicles included in today’s action as compared to LD vehicles where HFO-1234yf has previously been listed as acceptable. In addition, EPA also specifically requests comment on whether the proposed use conditions are adequately protective for MDPVs, HD pickup truck, and complete HD vans, or whether more protective use conditions are necessary. If a commenter believes more protective use conditions are necessary, the commenter should identify what additional, more protective use conditions could be implemented.

With regard to incomplete HD pickup trucks and vans, EPA requests information on any modifications to incomplete HD pickup trucks by secondary manufacturers that could result in modifying the OEM-installed MVAC system. Concerning incomplete HD vans, at this time, EPA does not have information on all potential vehicle conversions that could be made by secondary manufacturers or the impact those conversions may have with regard to the SNAP criteria. Due to lack of information on potential vehicle conversions, EPA cannot assess whether or not the same risk analysis used for complete HD vans would be applicable to all incomplete HD vans. However, EPA is aware that for some incomplete HD vans, secondary manufacturers do not modify the MVAC systems. An example of an incomplete HD van that is manufactured by the OEM with cabin cooling that is not altered by the secondary manufacturer might be a HD van customized by a secondary manufacturer for transportation of persons with disabilities. In this situation, the secondary manufacturer would install wheelchair ramps, lifts, and other equipment to meet the needs of their customer in an incomplete HD van from the OEM without making any modifications to the OEM-installed MVAC system. However, some secondary manufacturers may alter the OEM MVAC system design based on their needs (e.g., alter the HVAC system to provide cooling to the back of a vehicle). We request comments on whether there is a distinction that can be made between HD vans that could not have the MVAC systems modified and those that could have the MVAC systems modified. EPA is not including these vehicle types in this proposed action but is interested in receiving information on this topic. If such information clearly indicates that necessary distinctions can be made, and EPA establishes that use of HFO-1234yf in these vehicles will not result in greater overall risk to human health and the environment, the Agency would consider taking further rulemaking action to include a subset of incomplete HD vans in the listing of HFO-1234yf instead.
Additional risk analysis would be necessary prior to considering a listing decision for HFO-1234yf in all incomplete HD vans, especially on those for which the OEM-installed MVAC system may be altered. EPA requests comment on secondary manufacturer modifications that are likely for HD vans and, we welcome information on the types of modifications that could result in altering the MVAC system installed by the OEMs and the procedures for those modifications. EPA requests information on potential exposure scenarios, and is especially interested in information relevant to risk assessment such as charge sizes, the ratio of charge size to cabin size, exposure levels, potential for leaks and for ignition events, and means of mitigating risks during system modifications by the secondary manufacturer, and subsequently during the useful life of the vehicle. This information may be used to inform a future listing.

Additionally, EPA requests information on development of HFO-1234yf MVAC systems for other HD vehicle types or off-road vehicles, or plans to develop these systems in the future. This information may be used to inform a future listing.

### C. Foam Blowing Agents

1. Proposed Change of Status for Certain HFC Foam Blowing Agents for Rigid PU Spray Foam

As provided in the following table, for rigid PU spray foam, EPA is proposing to list as acceptable, subject to narrowed use limits, numerous foam blowing agents for military or space- and aeronautics-related applications, and change the status from acceptable to unacceptable for all other uses:

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitutes</th>
<th>Proposed decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid PU: Spray foam—high-pressure two-component.</td>
<td>HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mf with seven to 13 percent HFC-227ea, and the remainder HFC-365mfc; and Formaclus.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* as of January 1, 2020. Unacceptable for all applications other than military or space- and aeronautics-related applications as of January 1, 2020. Unacceptable for all uses as of January 1, 2025. Unacceptable for all applications other than military or space- and aeronautics-related applications* as of January 1, 2021. Unacceptable for all uses as of January 1, 2025. Unacceptable as of January 1, 2020.</td>
</tr>
<tr>
<td>Rigid PU: Spray foam—low-pressure two-component.</td>
<td>HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mf with seven to 13 percent HFC-227ea, and the remainder HFC-365mfc; and Formaclus.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* as of January 1, 2020. Unacceptable for all applications other than military or space- and aeronautics-related applications as of January 1, 2020. Unacceptable for all uses as of January 1, 2025. Unacceptable for all applications other than military or space- and aeronautics-related applications* as of January 1, 2021. Unacceptable for all uses as of January 1, 2025. Unacceptable as of January 1, 2020.</td>
</tr>
<tr>
<td>Rigid PU: Spray foam—one component foam sealants.</td>
<td>HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mf with seven to 13 percent HFC-227ea, and the remainder HFC-365mfc; and Formaclus.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* as of January 1, 2020. Unacceptable for all applications other than military or space- and aeronautics-related applications as of January 1, 2020. Unacceptable for all uses as of January 1, 2025. Unacceptable for all applications other than military or space- and aeronautics-related applications* as of January 1, 2021. Unacceptable for all uses as of January 1, 2025. Unacceptable as of January 1, 2020.</td>
</tr>
</tbody>
</table>

* Under the narrowed use limit, an end user must make reasonable efforts to ascertain that other alternatives are not technically feasible due to performance or safety requirements.

EPA is proposing to change the listings from acceptable to unacceptable, for HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa; commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and the HFC blend Formaclus for in use rigid PU spray foam, with the exception of certain narrowed use limits for military, space, and aeronautics uses. See section VLC.3 for how these proposed changes would apply to imported foam products.

In the NPRM published on August 6, 2014, EPA proposed to change the listings from acceptable to unacceptable for HFC-134a and blends thereof, and the HFC blend Formaclus for spray foam as of January 1, 2017 (79 FR 41419). In that proposal, EPA stated that a number of nonflammable HFCs and HFC blends, such as HFC-245fa, blends of HFC-365mfc with at least four percent HFC-245fa by weight, and commercial blends of HFC-365mfc and HFC-227ea, with seven to 13 percent HFC-227ea and the remainder HFC-365mfc, were available and posed significantly less risk in the spray foam end-uses. We noted that these available HFC foam blowing agents provide a non-flammable alternative where there are flammability concerns associated with in situ use and use with pressurized spray pumps that meant most flammable foam blowing agents were not feasible for use based on the current state of knowledge (79 FR 46149; 46152; August 6, 2014). After considering the comments received on the proposed rule, EPA deferred taking final action on spray foam in the final rule. See sections V.D.2.a and V.D.3.b of the preamble to the final rule (80 FR 42870; July 20, 2015).

a. What is the affected end-use?

In the past, EPA combined spray foam, commercial refrigeration foam, sandwich panels, and marine flotation foam within a single end-use: rigid PU spray foam. However, because of differences in the exposure and fire safety characteristics of these uses as well as the fact that different alternatives are generally used for each of these applications, EPA more recently created separate end-use listings for each of these applications. See 80 FR 42870; July 20, 2015. Commercial refrigeration and sandwich panels include insulation for walls, pipes (including "pipe-in-pipe"), metal doors, vending machines, refrigerated and unrefrigerated coolers, refrigerated transport vehicles, and other laboratory and commercial refrigeration equipment, as well as foam for taxidermy. These foams may be injected or applied using "pour-in-place" equipment, depending on the agent used and on whether the formulation is pressurized. Marine flotation foam includes buoyancy or flotation foam used in construction of boats and ships. These foams typically are injected into a cavity in the boat wall from a two-canister (A- and B-side) system under lower pressures and they provide structure as well as buoyancy. Rigid PU
spray foam, hereafter called “spray foam,” includes insulation for roofing, walls, doors, and other construction uses, as well as foam for building breakers for pipelines. These foams are rigid with closed cells that still contain the foam blowing agent, which can contribute to the foam’s ability to insulate. Spray foam may have similar chemistry to other rigid PU end-uses, but it differs by being sprayed onto a surface in the location where it is to be used, either when constructing a new building or when adding insulation to an existing building, rather than being injected or poured or being produced in a manufacturing facility. As a result, it may be more difficult to provide engineered ventilation during application of spray foam than for other foam end-uses. The proposed action applies only to this last end-use—spray foam and we have identified three distinct and separate spray foam applications for this end-use: (1) High-pressure two-component, (2) low-pressure two-component, and (3) one-component foam sealants.

i. High-Pressure Two-Component Spray Foam

High-pressure two-component spray foam products are pressurized 800–1600 psi during manufacture, are sold in pressurized containers as two parts (i.e., A-side and B-side), and are sprayed in the field for thermal insulation and air sealing of buildings and in roofing applications. In the United States, Side A typically contains methylene diphenyl isocyanate (MDI), consisting of monomeric MDI and higher molecular weight oligomers. Side B typically contains polyols and a mixture of other chemicals, including catalysts, flame retardants, blowing agents, and surfactants. High-pressure two-component spray foam is blown and applied in situ using high-pressure pumps to propel the foam components, and thus, may use liquid blowing agents without an additional propellant. Common liquid foam blowing agents used in high-pressure two-component spray foam include HFC-245fa; blends of HFC-365mfc with at least four percent HFC-245fa; and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TQ.184

ii. Low-Pressure Two-Component Spray Foam

Low-pressure two-component spray foam products are pressurized to less than 250 psi during manufacture, are sold in pressurized containers as two parts (i.e., A-side & B-side), and are sprayed in the field for thermal insulation and air sealing of buildings. Low-pressure two-component spray foams are typically applied in situ relying upon a gaseous foam blowing agent that also serves as a propellant; pumps typically are not needed. This end-use category has primarily used the gaseous blowing agent HFC-134a; the Foams Technical Option Committee has also identified CO2 and water as options. Low-pressure two-component spray foam is usually applied by home improvement contractors to fill in cracks and gaps in a residence using kits that are available for sale.183 The amount of resin and foam blowing agent is smaller than for high-pressure two-component spray foam.

iii. One-Component Spray Foam Sealants

One-component foam sealants are packaged in aerosol cans and are applied in situ using a gaseous foam blowing agent that is also the propellant for the aerosol formulation. Because the SNAP program has not expressly identified one-component spray foam sealants in the past descriptions of the end-use, manufacturers of one-component foam sealants may have considered acceptable substitutes in the larger rigid PU: Commercial refrigeration, spray, and sandwich panel end-use to apply for this end-use or acceptable propellants in the aerosol sector to apply. This end-use category primarily uses light saturated HCs as the blowing agent, as well as HFCs such as HFC-134a and HFC-152a. This type of spray foam may be used by consumers and by home improvement contractors in order to seal cracks and leaks in a residence, as well as used for pest management. The total amount of resin and foam blowing agent is smaller than for low-pressure two-component spray foam.

183 Low-pressure two-component spray foam kits should only be used by trained professionals. The polyurethanes industry has guidance on how to use low pressure kits available at: http://spraypolyurethane.org/sfp-chemical-health-and-safety-training and at http://spraypolyurethane.org/Main-Menu-Category/Weatherization-Contractors/Installing-SPP.

184 We note that neat HFC-365mfc has never been listed as acceptable for use in spray foam.

EPA is proposing to change the status of the following HFCs and HFC blends that are currently listed as acceptable foam blowing agents for use in spray foam: HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa; commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TQ.184

c. How do the proposed unacceptable blowing agents compare to other blowing agents for these applications with respect to SNAP criteria?

HFCs have been widely used as blowing agents in spray foam in the United States since the phaseout of ODS blowing agents such as HFC-141b, particularly where insulation value and flammability have been of greater concern. Over the past ten years, the number of available alternatives has increased and the variety of uses for acceptable blowing agents has also expanded. A number of new foam blowing agents with low GWPs, both fluorinated and non-fluorinated, have been introduced during the past several years. Many end users have indicated interest in these newer alternatives, often to improve energy efficiency of the foam products manufactured with the spray blowing agent. Production volumes for some of these newer substitutes are expanding rapidly to keep pace with growing demand.

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks (e.g., flammability, exposure, and toxicity) are discussed below. In addition, a technical support document185 that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives in the relevant end-uses may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).
i. Environmental Impacts

The HFCs that we are proposing to find unacceptable have GWPs ranging from 1.030 for HFC-245fa to 1.430 for HFC-134a. The HFC blends that we are proposing to find unacceptable have GWPs that vary depending on the specific composition; the range of GWPs for blends is 740 to 1.430 for blends of HFC-365mfc with at least four percent HFC-245fa, 900 to 1.100 for commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc, and 1.330 to approximately 1.500 for Formacel TI. Alternatives for all three spray foam applications include CO₂, water, Exxsol blowing agents, ecomate™, HFC-152a, HFO-1234ze(E), and trans-1-chloro-3,3,3-trifluoroprop-1-ene. As shown in Table 18, these alternatives have GWPs ranging from zero to 1.430. In addition, for one-component foam sealants only, light saturated HCs are acceptable, with GWPs in the range of three to 15. For high-pressure two-component spray foam only, HFO-1336mzz(Z) is acceptable, with a GWP of approximately nine. These GWPs are significantly lower than the GWPs of 740 to 1.430 for the HFC and HFC blend substitutes subject to the proposed change of status.

All of the HFCs and HFC blends for which we are proposing a change of status to unacceptable consist of compounds that are non-ozone-depleting. Of all the alternatives in the three applications affected by the proposed change of status listed above, only trans-1-chloro-3,3,3-trifluoroprop-1-ene contains chlorine and thus might have an ODP. Trans-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP of 0.00024 to 0.00034 and estimates of its maximum potential impact on the ozone layer indicate a statistically insignificant impact, comparable to that of other substitutes in the same end-use that are considered to be non-ozone-depleting.¹⁸⁶ ¹⁸⁷

All of the HFCs and HFC blends for which we are proposing a change of status to unacceptable consist of compounds that are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPS to attain and maintain the NAAQS (e.g., CO₂, component of ecomate, HFO-1234ze(E), trans-1-chloro-3,3,3-trifluoroprop-1-ene). Based on the small anticipated usage of hydrocarbons and of Exxsol blowing agents, and due to existing state regulations affecting aerosol products that may include one-component foam sealants, we do not expect these alternative to have a significantly greater impact on local air quality than other available alternatives in these applications. The manufacturer of HFO-1336mzz(Z) has petitioned EPA to exempt HFO-1336mzz(Z) from the definition of VOC under those regulations. As provided in our decisions listing these substitutes as not VOC (i.e., water) or are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPS to attain and maintain the NAAQS (e.g., CO₂, component of ecomate, HFO-1234ze(E), trans-1-chloro-3,3,3-trifluoroprop-1-ene). Based on the small anticipated usage of hydrocarbons and of Exxsol blowing agents, and due to existing state regulations affecting aerosol products that may include one-component foam sealants, we do not expect these alternative to have a significantly greater impact on local air quality than other available alternatives in these applications. The manufacturer of HFO-1336mzz(Z) has petitioned EPA to exempt HFO-1336mzz(Z) from the definition of VOC under those regulations. As provided in our decisions listing these substitutes as

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acceptable, we determined that emissions of these alternatives in this end use would not pose a significantly greater risk than that posed by foam blowing agents that are not VOCs.

ii. Flammability

All of the HFCs and HFC blends for which we are proposing a change of status are nonflammable. There has been use of blends of HFC-134a and HFC-152a, composition unspecified, in the past; those blends may be flammable depending on the exact composition.

HFC-1234ze(E), HFC-1336mzz(Z), and trans-1-chloro-3,3,3-trifluoroprop-1-ene are nonflammable blowing agents that have recently been listed as acceptable. The manufacturers of the flammable alternatives Exxsol blowing agents and ecomate™ have developed training to assist users of high-pressure two-component spray foam users in addressing the flammability hazards of these flammable foam blowing agents in this end-use and thereby minimize flammability risks.¹⁸⁸ ¹⁸⁹

Use of flammable blowing agents in spray foam can be an issue. Spray foam is frequently used in situ in commercial and residential buildings and it is not practical to make all electrical fixtures explosion proof or to add engineered ventilation when applying spray foam in place in many circumstances. As mentioned above, flammability is a major issue for high-pressure and low-pressure two-component spray foam. Thus, all acceptable substitutes in these applications either are nonflammable or else are flammable but information in EPA’s possession indicates there are measures available to mitigate flammability risk.

iii. Toxicity

Both the HFC substitutes for which we are proposing a change of status and other alternatives have workplace exposure limits, either as regulatory requirements (i.e., OSHA PEL) or as a recommendation (e.g., AIIA WEEL, AGCH TLV or manufacturer recommended workplace exposure limits). Proper training, use of PPE, and use of ventilation should be adhered to when applying spray foam. As we determined at the time that we listed both the substitutes for which we are proposing a status change and the other available alternatives, they can be used consistent with the relevant workplace exposure limits in spray foam.

iv. Summary

EPA is proposing to find HFC-134a, HFC-245fa, and blends thereof; commercial blends of HFC-365mfc and HFC-227ea, containing seven to 13 percent HFC-227ea and the remainder HFC-365mfc; blends of HFC-365mfc and at least four percent HFC-245fa; and Formacel TI unacceptable in spray foam because there are other available or potentially available alternatives that reduce risk overall compared to these foam blowing agents. EPA has listed as acceptable several alternatives that pose lower overall risk to human health and the environment than the blowing agents whose status we are proposing to change to unacceptable. The risks other than GWP are not significantly different for the alternatives than for the blowing agents we are proposing to list as unacceptable, and the GWP’s for the blowing agents we are proposing to list as unacceptable are significantly higher and thus pose significantly greater risk.

d. What narrowed use limits for military or space- and aeronautics-related applications is EPA proposing?

EPA is proposing an time-limited exception to the proposed unacceptable determination for HFC and HFC blend foam blowing agents for military or space- and aeronautics-related applications when used in low pressure two-component and high pressure two-component spray foam. Specifically, EPA is proposing a narrowed use limit that would expire on January 1, 2025. As provided in section e below, the vast majority of applications for spray foams are anticipated to be able to transition to acceptable alternatives by January 1, 2020, for high-pressure two-component spray foam and as of January 1, 2021, for low-pressure two-component spray foam. However, for the military, there are several unique performance requirements related to weapon systems that require extensive testing and qualification prior to qualifying alternatives for HFC-containing foams. In addition, some of the lower-GWP alternatives may not be available by 2020 or 2021 in certain specialty applications with unique military requirements such as underwater; aerospace; and chemical, biological, and radiological warfare systems. In the case of space- and aeronautics-related applications, past experience indicates that transitions away from the foam blowing agents in current use took several years due to the challenging operational environment and the lengthy requalification process associated with human-rated space flight systems.

Users of a restricted agent within the narrowed use limits category must make a reasonable effort to ascertain that other substitutes or alternatives are not technically feasible. Users are expected to undertake a thorough technical investigation of alternatives to the otherwise restricted substitute. Although users are not required to report the results of their investigations to EPA, users must document these results, and retain them in their files for the purpose of demonstrating compliance.

Users should include the following additional documentation to demonstrate compliance with the narrowed use applications. This information includes descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

e. When would the status change?

Except for the proposed narrow use limits addressed above, EPA is proposing to change the listings from acceptable to unacceptable (1) in high-pressure two-component spray foam and in one-component foam sealants as of January 1, 2020, and (2) in low-pressure two-component spray foam as of January 1, 2021. The change of status would apply to the following blowing agents: HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc and Formacel TI. The Agency is aware of several companies transitioning between now and 2017.¹⁹⁰ However, a transition date of January 1, 2020, is necessary for high-pressure two-component spray foam to allow sufficient opportunity for affected entities to redesign to address the technical issues associated with using a different foam blowing agent, including the time required for reformulation (about one year), and the time required for testing and certification of the final product.

commercial product (one to one and a half years). Similarly, a transition date of January 1, 2021, is necessary for low-pressure two-component to address the technical issues associated with using a different foam blowing agent. Based on information from several companies developing low-pressure two-component spray foam products, the process of reformulation has been more difficult than for high-pressure two-component spray foam, because it must have a significantly longer shelf life and requires significant reformulation to achieve an acceptable shelf-life. These products are then sold to an end user many months after they are formulated. Thus, at least two years are expected to be needed for reformulation after issuance of a final rule and another one to one and a half years for testing for low-pressure two-component spray foam, resulting in a change of status date of January 1, 2021.

For high-pressure two-component and low-pressure two-component spray foam a certain insulation value may be required to meet building code requirements. Some studies have indicated that CO₂ may provide less insulation value to an insulation foam, pound for pound, than HFCs. Recent information on some of the newer fluorinated foam blowing agents with low GWPVs, such as HFO-1234ze(E), HFO-1336mzz(Z), and trans-1-chloro-3,3,3-trifluoroprop-1-ene, ecomate® component spray foam. Although alternatives for high-pressure two-component spray foam because testing is required only for a final formulation in an aerosol can for one-component foam sealants, rather than testing both the formulation in separate containers (A- and B-side) and ensuring the long-term stability of the final blown foam once the two parts are mixed to blow the foam. Also, no certification testing would be required for the one-component foam sealant, unlike for high-pressure two-component foam. In Europe, one-component foam sealants have already converted away from using HFCs and predominantly use HCs or HFO-1234ze(E), which are available substitutes for this end-use under SNAP. Allowing for one year for reformulation and one to two years for testing of products and to allow existing stock of one-component foams to be purchased and used, we are proposing a change of status date of January 1, 2020, after which date, no more one-component foam sealants (cans) could be manufactured using the specified HFC blowing agents, but the end user could continue to use cans that had already been manufactured. In the July 20, 2015, final rule, EPA took such an approach for aerosol propellants, which are used in similar packages for consumer use as well as manufacturing use, and similarly, may be in distribution for a year or more before they are purchased and eventually used by the end user. Under the proposed approach, we would limit the applicability of the use prohibition on closed cell foam products (discussed in section VLC.3), so that it would not apply to closed cell foam products produced through the use of a one-component spray foam manufactured prior to the status change date.

For low-pressure two-component spray foam, commenters on the August 6, 2014, proposal with a change of status date of January 1, 2017, expressed concern about the feasibility of alternatives by that date. Specifically, two manufacturers mentioned the heightened challenges of shelf-life and stability for a product using HFO-1234ze(E), and suggested change of status dates of January 1, 2020 or 2021. One manufacturer of alternative foam blowing agents suggested that HFC-134a and Formacel® TI should remain listed as acceptable for use in low-pressure foam systems until multiple low-GWP alternatives with appropriate technical performance qualities would become commercially available, while another foam blowing agent manufacturer claimed that multiple options are available for this use but would require a couple of years to be optimized. Since that time, some of these same companies have provided additional information indicating that many of the technical challenges with use of HFO-1234ze(E) have been worked through and that this is expected to be a viable option given sufficient time to address the technical challenges of a transition. To allow sufficient time for manufacturers of low-pressure two-component spray foam kits to complete working through the technical challenges of alternatives, as well as time for existing kits to be distributed, purchased, and used by the end user, we are proposing as our lead option, a change of status date of January 1, 2021. Alternatively, similar to an approach proposed above for one-component foam sealants, EPA proposing as an alternative option a change of status date of January 1, 2020, for low-pressure two-component spray foam kits, after which date no more kits could be manufactured using the specified HFC blowing agents, but the end user could continue to use kits that had already been manufactured. Although low-pressure two-part spray foam kits would typically be used by a professional (e.g., home improvement contractor) rather than by a consumer, there are similar issues with an extended chain manufacture, distribution, and use for these kits that are more similar to aerosol canisters and

one-component spray foam sealants than to high-pressure two-component spray foam or other foam blowing end-uses (e.g., rigid PU appliance, rigid PU commercial refrigeration and sandwich panel). Under this alternative proposal, as under the proposed approach for one-component spray foams, we would limit the applicability of the use prohibition on closed cell foam products (discussed in section VLC.3) so that it would not apply to closed cell foam products produced through the use of a low-pressure two-component spray foam kit manufactured prior to the status change date.

f. What is the relationship between this proposed SNAP rule and other federal rules?

Over the past several years, to address potential exposure to workers and consumers, the Federal Partnership and each of its member agencies, including EPA, CPSC, OSHA, and NIOSH have worked to reduce exposure to various chemicals emitted from spray foam. For example, EPA and its federal partners have continued to work with industry to develop best practices for application of spray foam, and EPA’s Office of Research and Development has been developing methods to measure emissions of chemicals from spray foam as part of the ASTM Indoor Air Subcommittee D.22.05 on Spray Polyurethane Foam Insulation. The list of proposed and final standards represents the issues raised by the committee and the range of compounds of interest includes isocyanates, blowing agents, amine catalysts, flame retardants, and aldehydes.\(^{195}\) In addition to federal rules and guidance applying to the spray foam industry, insurance foam used in construction (e.g., high-pressure two-component spray foam) must meet insulation value requirements in state and local building codes, as discussed above in section VLC.1.d.

g. On which topics is EPA specifically requesting comment?

EPA requests comments on all aspects of this proposed decision to change the listings of certain foam blowing agents in the three for spray foam end-uses. In particular, EPA requests comments on the proposed decision to change the status of the identified substitutes to unacceptable (1) in high-pressure two-component spray foam and in one-component foam sealants on January 1, 2020, and (2) in low-pressure two-component spray foam on January 1, 2021. EPA is interested in comment on whether there are specific applications for one-component spray foam sealants, low-pressure two-component, and high-pressure two-component spray foam for which there are no alternatives available with lower overall risks to human health and the environment than the substitutes for which we are proposing a change of status: HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TI, for reasons of fire safety or technical feasibility. EPA requests comment on whether the proposed change of status dates for one-component spray foam sealants, low pressure two-component, and high pressure two-component spray foam are appropriate in light of technical challenges and the supply of other alternatives. Where commenters indicate more time is needed due to supply or technical challenges, EPA is interested in information concerning what is limiting supply of substitutes and on the specific technical steps and time needed for each step in order to transition to alternatives. Additionally, EPA requests comment on whether the change of status date for one component foam sealants and low-pressure two-component spray foam should be based upon the date the product may no longer be used or whether it should be based upon a date of manufacture of the product with no restriction on the use of products sold prior to the change of status date.

2. Proposed Revision To Change of Status Date of Certain HFCs and HFC Blends for Space- and Aeronautics-Related Foam Applications

EPA is proposing to change the date upon which certain HFCs and HFC blend foam blowing agents for space- and aeronautics-related applications change status from acceptable, subject to narrowed use limits, to unacceptable.

EPA is proposing to revise this change of status date to January 1, 2025. EPA is proposing to revise the change of status date only for space- and aeronautics-related applications and not for military uses.

Table 19 summarizes the end-uses and blowing agents that in the July 20, 2015, final rule were listed as unacceptable for military and space- and aeronautics-related applications as of January 1, 2022 and for which we are proposing to revise the change of status date to January 1, 2025.

### Table 19—Proposed Revisions to Change of Status Dates for Foam Blowing Agents

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitutes</th>
<th>Proposed decision *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid Polyurethane: Appliance .....................</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications and unacceptable for all other uses as of January 1, 2020. Unsuitable for military uses as of January 1, 2022 and unsuitable for space- and aeronautics-related applications as of January 1, 2025.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Commercial Refrigeration and Sandwich Panels.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications and unacceptable for all other uses as of January 1, 2020. Unsuitable for military uses as of January 1, 2022 and unsuitable for space- and aeronautics-related applications as of January 1, 2025.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Marine Flotation Foam.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications and unacceptable for all other uses as of January 1, 2020. Unsuitable for military uses as of January 1, 2022 and unsuitable for space- and aeronautics-related applications as of January 1, 2025.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Slabstock and Other</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications and unacceptable for all other uses as of January 1, 2020. Unsuitable for military uses as of January 1, 2022 and unsuitable for space- and aeronautics-related applications as of January 1, 2025.</td>
</tr>
<tr>
<td>Rigid Polyurethane and Polyisocyanurate Laminated Boardstock.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof.</td>
<td>Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications and unacceptable for all other uses as of January 1, 2020. Unsuitable for military uses as of January 1, 2022 and unsuitable for space- and aeronautics-related applications as of January 1, 2025.</td>
</tr>
</tbody>
</table>

We are proposing to revise the status change date for certain HFC and HFC blend foam blowing agents for space and aeronautics-related foam applications from acceptable, subject to narrowed use limits, to unacceptable.

c. When would the status change?

We are proposing to revise the status change date for certain HFC and HFC blend foam blowing agents for space and aeronautics-related foam applications from acceptable, subject to narrow use limits to unacceptable as of January 1, 2025—three years later than the current status change date of January 1, 2022. Based on recent discussions with other government agencies, EPA is aware that some space flight hardware used in the United States is being developed in the European Union. Under E.U. regulations, certain types of HFC foams may be blown and used after January 1, 2022, but by the mid-2020s those regulations will no longer allow the use of the HFC blowing agents restricted under EPA’s SNAP regulations. Further, the most recent U.S. space flight program is still being developed, and it now appears that it may not be possible to qualify all foams needed with alternative foam blowing agents by the current January 1, 2022, date in order to ensure the safety of space vehicles. Thus, we are proposing to extend the period during which the narrowed use limits apply for space and aeronautics related applications from January 1, 2022, to January 1, 2025.

d. What is the relationship between this proposed SNAP rule and other federal rules?

EPA is not aware of any other relevant federal rules that would be affected by this proposed revision to the change in status date for certain HFC and HFC blend foam blowing agents for space and aeronautics-related foam applications.

e. On which topics is EPA specifically requesting comment?

EPA requests comment on the revised date of January 1, 2025, for the change of status for certain HFC and HFC blend foam blowing agents space and aeronautics-related foam applications from acceptable, subject to narrowed use limits, to unacceptable.

3. Proposed Change of Status for Methylene Chloride in Flexible PU, Integral Skin PU, and Polyolefin Foams

As provided in the following table, EPA is proposing to change the status methylene chloride from acceptable to unacceptable for multiple foam blowing end-uses.

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitutes</th>
<th>Proposed decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexible PU</td>
<td>Methylene chloride</td>
<td>Unacceptable as of 30 days after publication of a final rule.</td>
</tr>
<tr>
<td>Integral Skin PU</td>
<td>Methylene chloride</td>
<td>Unacceptable as of January 1, 2017.</td>
</tr>
</tbody>
</table>

* Under the narrowed use limit, use is limited to military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.
a. What are the affected end-uses?

EPA is proposing to change the status of methylene chloride from acceptable to unacceptable when used as a blowing agent in the production of flexible PU foam, integral skin PU foam, and polyolefin foam. Flexible PU includes foam in furniture, bedding, chair cushions, and shoe soles. Integral skin PU includes car steering wheels, dashboards, and shoe soles. Polyolefin includes foam sheets and tubes.

Methylene chloride, also known as dichloromethane, has the chemical formula CH₂Cl₂ and the CAS Reg. No. 75–09–2. EPA initially listed this substitute as acceptable for flexible PU foam and integral skin PU foam acceptable in the initial SNAP rule (79 FR 13044; March 18, 1994), and then listed it as acceptable for polyolefin foam on August 26, 1994 (79 FR 44240).

b. How does methylene chloride compare to other blowing agents for these end-uses with respect to SNAP criteria?

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks (e.g., flammability, exposure, and toxicity) are discussed below. In addition, a technical support document 199 that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for these alternatives may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0063).

i. Flexible PU

(a) Environmental Impacts

Methylene chloride contains chlorine and thus could have an ODP. We are unaware of a calculated ODP for methylene chloride in the peer-reviewed literature, but it has historically been considered negligibly small.200 Recent research indicates that emissions of methylene chloride from multiple industrial sources have been increasing and could have a detectible impact on the ozone layer.201 despite the historical assumption of negligible ODP. For flexible polyurethane, available substitutes include acetone, Exxsol blowing agents, CO₂, ecomate™, HFO-152a, HFO-1336mzz(Z), methylal, saturated light HCs (C3-C6), trans-1-chloro-3,3,3-trifluoroprop-1-ene, and water. Of the other available alternatives for flexible PU, only trans-1-chloro-3,3,3-trifluoroprop-1-ene contains chlorine and thus might have an ODP. Trans-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP of 0.00024 to 0.00034 and estimates of its maximum potential impact on the ozone layer indicate a statistically insignificant impact, comparable to that of other substitutes in the same end-use that are considered to be non-ozone-depleting.202 203

Methylene chloride has a GWP of approximately nine. As shown in Table 21, other acceptable alternatives have GWPs that are comparable or lower than methylene chloride’s GWP of nine except for HFC-152a, which has a GWP of 124.

### Table 21—GWP, ODP, and VOC Status of Methylene Chloride Compared to Other Foam Blowing Agents in Flexible PU Foams, Integral Skin PU Foams, and Polyolefin Foams

<table>
<thead>
<tr>
<th>Blowing agents</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flexible PU Foams</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetone; CO₂; Ecomate; HFC-152a; Methylal; trans-1-chloro-3,3,3-trifluoroprop-1-ene; Water. AB Technology; Exxsol Blowing Agents; HFO-1336mzz(Z); Methylal; Saturated Light Hydrocarbons C3-C6</td>
<td>0–124</td>
<td>0–0.00034</td>
<td>No</td>
<td>Proposed unacceptable.</td>
</tr>
<tr>
<td>Acetone; CO₂; Ecomate; Formic Acid; HFO-1234ze; HFO-1336mzz(Z); AB Technology; Exxsol Blowing Agents; Formic Acid; HFO-1336mzz(Z); Methylal; Saturated Light Hydrocarbons C3-C6.</td>
<td>0–124</td>
<td>0–0.00034</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>CO₂; Ecomate; HFO-1234ze; HFC-152a; AB Technology; Exxsol Blowing Agents; Formic Acid; HFO-1334ze; HFC-152a; Saturated Light Hydrocarbon Blends; Saturated Light Hydrocarbons C3-C6.</td>
<td>0–124</td>
<td>0–0.00034</td>
<td>No</td>
<td>No change.</td>
</tr>
</tbody>
</table>

1The table does not include not-in-kind technologies listed as acceptable for the stated end-uses or additives combined with other acceptable blowing agents.


Methylene chloride is excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. With the exception of HCs, Exxsol blowing agents, HFO-1336mzz(Z), and methylal, the other alternatives contain compounds that are excluded from the definition of VOC. The manufacturer of HFO-1336mzz(Z) has petitioned EPA to exempt HFO-1336mzz(Z) from the definition of VOC under those regulations. As provided in our decisions listing these substitutes as acceptable, we determined that emissions of these alternatives in this end use would not pose a significantly greater risk than that posed by foam blowing agents that are not VOCs.

(b) Flammability

Methylene chloride exhibits no flash point under standard testing conditions and thus is considered nonflammable, although it does exhibit lower and upper flammability limits of 13 percent and 23 percent, respectively. Of the various alternatives, ecomat™, Exxsol blowing agents, HFC-152a, HCs, and methylal are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes.

(c) Toxicity

Health effects of concern with methylene chloride include cancer, liver, and kidney effects (longer-term exposure) and neurotoxic effects (acute exposure), in addition to irritation to the skin, eyes, and respiratory tract. Other alternatives for this end-use have potential health effects such as impacts on body weight, mononuclear infiltration of heart tissue, neurotoxic effects, and irritation to the skin, eyes, and respiratory tract; no other alternatives in this end-use have evidence of cancer as a health effect. Toxicity is not a significant concern in the workplace for methylene chloride or for the other available alternatives because they may be used for blowing flexible PU foam consistent with required or recommended workplace exposure limits. Workplace exposure limits for the other available alternatives range from 100 ppm to 5,000 ppm. Methylene chloride’s workplace exposure limits include a PEL of 25 ppm (8-hr TWA) and 125 ppm over a 15-minute period. Methylene chloride is regulated for its toxicity as a hazardous air pollutant under the CAA and potentially as a U-listed hazardous waste under RCRA (40 CFR 261.33).

None of the other alternative blowing agents are regulated as hazardous air pollutants or as U-listed hazardous wastes.

In the initial SNAP rulemaking, EPA listed methylene chloride as acceptable in this end-use, citing the presence of the OSHA regulations as sufficient to address workplace risk. Information regarding general population risk was not available for methylene chloride or for any of the other alternatives at the time EPA listed them as acceptable for this end use.

Since EPA’s initial listing decision for methylene chloride in flexible PU foam, the Agency has separately issued a health-based residual risk standard under section 112 of the CAA for flexible PU foam production. (National Emission Standards for Hazardous Air Pollutants Residual Risk and Technology Review for Flexible Polyurethane Foam Production, (79 FR 48073; August 15, 2014). In that regulation, EPA examined the risk to the general population and determined to prohibit the use of HAP-based blowing products, including methylene chloride, as auxiliary blowing agents in flexible PU slabstock foam production operations at major sources. Because EPA has separately determined in setting a risk-based standard that methylene chloride cannot be used as a blowing agent by major sources for production of flexible PU slabstock foam, we are proposing to change the status of methylene chloride in this end-use on the basis that it poses significantly more risk than other available alternatives.

ii. Integral Skin PU

(a) Environmental Impacts

Methylene chloride contains chlorine and thus could have an ODP. We are unaware of a calculated ODP for methylene chloride in the peer-reviewed literature, but it has historically been considered negligibly small. Recent research indicates that emissions of methylene chloride from multiple industrial sources have been increasing and could have a detectable impact on the ozone layer, despite the historical assumption of negligible ODP. For integral skin PU, available alternatives include acetone, CO₂, ecomat™, Exxsol blowing agents, formic acid, HFC-152a, HFO-1234ze(E), HFO-1336mzz(Z), methylal, methyl formate, saturated light HCs (C3-C6), trans-1-chloro-3,3,3-trifluoroprop-1-ene, and water. Of the other available alternatives for flexible PU, only trans-1-chloro-3,3,3-trifluoroprop-1-ene contains chlorine and thus might have an ODP. Trans-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP of 0.00024 to 0.00034 and estimates of its maximum potential impact on the ozone layer indicate a statistically insignificant impact, comparable to that of other substitutes in the same end-use that are considered to be non-ozone-depleting.

Methylene chloride has a GWP of approximately nine. As shown in Table 21, other acceptable alternatives have GWPs that are comparable or lower than methylene chloride’s GWP of nine except for HFC-152a, which has a GWP of 124.

Methylene chloride is excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. With the exception of HCs, Exxsol blowing agents, formic acid, HFO-1336mzz(Z), and methylal, the other alternatives contain compounds that are exempt from the definition of VOC. The manufacturer of HFO-1336mzz(Z) has petitioned EPA to exempt HFO-1336mzz(Z) from the definition of VOC under those regulations. As provided in our decisions listing these alternatives as acceptable, we determined that emissions of these alternatives in this end-use would not pose a significantly greater risk than that posed by foam blowing agents that are not VOCs.

(b) Flammability

Methylene chloride exhibits no flash point under standard testing conditions and thus is considered nonflammable, although it does exhibit lower and upper flammability limits of 13 percent and 23 percent, respectively. Of the other available alternatives, ecomat™, Exxsol blowing agents, HFC-152a, HCs, and methylal are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes.

In the initial SNAP rulemaking, EPA listed methylene chloride as acceptable in this end-use, citing the presence of the OSHA regulations as sufficient to address workplace risk. Information regarding general population risk was not available for methylene chloride or for any of the other alternatives at the time EPA listed them as acceptable for this end use.

Since EPA’s initial listing decision for methylene chloride in flexible PU foam, the Agency has separately issued a health-based residual risk standard under section 112 of the CAA for flexible PU foam production. (National Emission Standards for Hazardous Air Pollutants Residual Risk and Technology Review for Flexible Polyurethane Foam Production, (79 FR 48073; August 15, 2014). In that regulation, EPA examined the risk to the general population and determined to prohibit the use of HAP-based blowing products, including methylene chloride, as auxiliary blowing agents in flexible PU slabstock foam production operations at major sources. Because EPA has separately determined in setting a risk-based standard that methylene chloride cannot be used as a blowing agent by major sources for production of flexible PU slabstock foam, we are proposing to change the status of methylene chloride in this end-use on the basis that it poses significantly more risk than other available alternatives.


various alternatives, acetone, methyl formate, ecomate™, Exxsol blowing agents, HFC-152a, HCs, and methylal are flammable, and CO₂, formic acid, HFO-1234ze(E), HFO-1336mzz(Z), trans-1-chloro-3,3,3-trifluoroprop-1-ene, and water are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes.

(c) Toxicity

Health effects of concern with methylene chloride include cancer, liver, and kidney effects (longer-term exposure) and neurotoxic effects (acute exposure), in addition to irritation to the skin, eyes, and respiratory tract. Other alternatives for this end-use have potential health effects such as impacts on body weight, mononuclear infiltration of heart tissue, neurotoxic effects, and irritation to the skin, eyes, and respiratory tract; no other alternatives in this end-use have evidence of cancer as a health effect. Toxicity is not a significant concern in the workplace for methylene chloride or for the other available alternatives because they may be used for blowing integral skin PU consistent with required or recommended workplace exposure limits. Workplace exposure limits for the other available alternatives range from 100 ppm to 5000 ppm. Methylene chloride’s workplace exposure limits include a PEL of 25 ppm. (8-hr TWA) and 125 ppm over a 15-minute period. Methylene chloride is regulated for its toxicity as a hazardous air pollutant under the CAA and potentially as a U-listed hazardous waste under RCRA (40 CFR 261.33). None of the other alternative blowing agents are regulated as hazardous air pollutants or as U-listed hazardous wastes.

Methylene chloride is the only acceptable alternative in this end-use that is a carcinogen. On this basis, we are proposing that methylene chloride poses significantly greater toxicity risks than the other alternatives available for this end use. The risk posed by methylene chloride and the other alternatives based on the other SNAP review criteria are not significantly different. Because of the significantly greater toxicity risk posed by methylene chloride, we believe it poses significantly greater overall risk than other available substitutes and we are proposing to change the status to unacceptable.

iii. Polyolefin Foam

(a) Environmental Impacts

Methylene chloride contains chlorine and thus could have an ODP. We are unaware of a calculated ODP for methylene chloride in the peer-reviewed literature, but it has historically been considered negligibly small. Recent research indicates that emissions of methylene chloride from multiple industrial sources have been increasing and could have a detectable impact on the ozone layer, despite the historical assumption of negligible ODP. In polyolefin foam, available alternatives include CO₂, ecomate™, Exxsol blowing agents, methyl formate, HFO-152a, blends of HFC-152a and saturated light HCs, HFO-1234ze(E), saturated light HCs (C₃–C₆), trans-1-chloro-3,3,3-trifluoroprop-1-ene, and water. Of the other available alternatives for flexible PU, only trans-1-chloro-3,3,3-trifluoroprop-1-ene contains chlorine and thus could have an ODP. Trans-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP of 0.00024 to 0.00034 and estimates of its maximum potential impact on the ozone layer indicate a statistically insignificant impact, comparable to that of other substitutes in the same end-use that are considered to be non-ozone-depleting.

Methylene chloride has a GWP of approximately nine. As shown in Table 21, the other acceptable substitutes have GWPs that are comparable or lower than methylene chloride’s GWP of nine except for HFC-152a, which has a GWP of 124.

Methylene chloride is excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. With the exception of HCs, HC blends, and Exxsol blowing agents, the other alternatives contain compounds that are exempted from the definition of VOC. The manufacturer of HFO-1336mzz(Z) has petitioned EPA to exempt HFO-1336mzz(Z) from the definition of VOC under those regulations. As provided in our decisions listing these alternatives as acceptable, we determined that emissions of these alternatives in this end-use would not pose a significantly greater risk than that posed by foam blowing agents that are not VOCs.

(b) Flammability

Methylene chloride exhibits no flash point under standard testing conditions and thus is considered nonflammable, although it does exhibit lower and upper flammability limits of 13 percent and 23 percent, respectively. Of the various alternatives, blends of HFC-152a and HCs, ecomate™, Exxsol blowing agents, HFC-152a, HCs, and methyl formate are flammable, and CO₂, HFO-1234ze(E), trans-1-chloro-3,3,3-trifluoroprop-1-ene, and water are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes.

(c) Toxicity

Health effects of concern with methylene chloride include cancer, liver, and kidney effects (longer-term exposure) and neurotoxic effects (acute exposure), in addition to irritation to the skin, eyes, and respiratory tract. Other alternatives for this end-use have potential health effects such as impacts on body weight, mononuclear infiltration of heart tissue, neurotoxic effects, and irritation to the skin, eyes, and respiratory tract; no other alternatives in this end-use have evidence of cancer as a health effect. Toxicity is not a significant concern in the workplace for methylene chloride or for the other available alternatives because they may be used for blowing integral skin PU consistent with required or recommended workplace exposure limits. Workplace exposure limits for the other available alternatives range from 100 ppm to 5000 ppm. Methylene chloride’s workplace exposure limits include a PEL of 25 ppm. (8-hr TWA) and 125 ppm over a 15-minute period. Methylene chloride is regulated for its toxicity as a hazardous air pollutant under the CAA and potentially as a U-listed hazardous waste under RCRA (40 CFR 261.33). None of the other alternative blowing agents are regulated as hazardous air pollutants or as U-listed hazardous wastes.

Methylene chloride is the only acceptable alternative in this end-use that is a carcinogen. On this basis, we are proposing that methylene chloride poses significantly greater toxicity risks than the other alternatives available for this end use. The risk posed by methylene chloride and the other alternatives based on the other SNAP review criteria are not significantly different. Because of the significantly greater toxicity risk posed by methylene chloride, we believe it poses significantly greater overall risk than other available substitutes and we are proposing to change the status to unacceptable.

Methylene chloride's workplace exposure limits include a PEL of 25 ppm. (8-hr TWA) and 125 ppm over a 15-minute period. Methylene chloride is regulated for its toxicity as a hazardous air pollutant under the CAA and potentially as a U-listed hazardous waste under RCRA (40 CFR 261.33). None of the other alternative blowing agents are regulated as hazardous air pollutants or as U-listed hazardous wastes.

Methylene chloride is the only acceptable alternative in this end-use that is a carcinogen. On this basis, we are proposing that methylene chloride poses significantly greater toxicity risks than the other alternatives available for this end use. The risk posed by methylene chloride and the other alternatives based on the other SNAP review criteria are not significantly different. Because of the significantly greater toxicity risk posed by methylene chloride, we believe it poses significantly greater overall risk than other available substitutes and we are proposing to change the status to unacceptable.
that is a carcinogen. On this basis, we are proposing that methylene chloride poses significantly greater toxicity risks than the other alternatives available for this end use. The risk posed by methylene chloride and the other alternatives based on the other SNAP review criteria are not significantly different. Because of the significantly greater toxicity risk posed by methylene chloride, we believe it poses significantly greater overall risk than other available substitutes and we are proposing to change the status to unacceptable.

c. When would the status change?

EPA proposes to change the status of methylene chloride in flexible PU foam as of 30 days after a final rule is published in the Federal Register. Because this blowing agent has already been prohibited in flexible PU foam manufacturing operations for major sources by EPA’s National Emission Standards for Hazardous Air Pollutants (NESHAP) Polyurethane Foam Production, Technology Review for Flexible Polyurethane Foam Production (79 FR 48073; August 15, 2014), we expect that most businesses have already transitioned away from this substitute in that end-use. This proposed rule does not apply to area sources.

For integral skin PU foam and polyolefin, we propose the respective change of status dates to be January 1, 2017, and January 1, 2020. These dates are consistent with the change of status dates we previously established for certain HFCs in these end-uses (80 FR 42870; July 20, 2015). These dates were established considering factors such as the supply of alternatives, time required for testing of alternatives, and time required to prepare facilities for use of flammable foam blowing agents. By proposing to change the status of methylene chloride from acceptable to unacceptable, we expect that end-users will consider blowing agents other than methylene chloride as they plan their transition away from HFCs in these end-uses.

d. What is the relationship between this proposed SNAP rule and other federal rules?

In a recent rulemaking, National Emission Standards for Hazardous Air Pollutants Residual Risk and Technology Review for Flexible Polyurethane Foam Production, EPA prohibits the use of HAP, including methylene chloride, as auxiliary blowing agents in slabsstock flexible PU foam production operations at major sources as of November 13, 2014 (79 FR 48073; August 15, 2014). This action is consistent with that previously issued prohibition.

e. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on the proposed dates for a change of status for methylene chloride (30 days after publication of a final rule for flexible PU foam, January 1, 2017, for integral skin PU foam, and January 1, 2020, for polyolefin foam).

We request comments on, the extent to which methylene chloride is currently being used in these end-uses in integral skin PU, in polyolefin, or by area sources that manufacture flexible PU foam and the technical challenges that exist for transitioning from methylene chloride to other available alternatives.

4. Proposed Application of Listings to Foam Products

EPA is proposing to apply the unacceptability determinations in this action for foam blowing agents to closed cell foam products and products containing closed cell foam. In addition, EPA is proposing to apply all listings for foam blowing agents codified in the appendices to 40 CFR part 82 subpart G to such products. This would mean that closed cell foam products and products containing closed cell foams manufactured abroad and imported could not be used in the United States if the foam blowing agent was listed as unacceptable.

a. What are the affected end-uses?

The foam sector includes both closed cell and open cell foams. Closed cell foams are specifically designed to retain the foam blowing agent in the cells; in insulation foam products, the foam blowing agent continues to perform a function in providing thermal insulation, once the foam has already been blown. With open cell foams, the foam blowing agent completes its function once the foam is blown; almost all of the foam blowing agent escapes from the open cells prior to import, and any vestigial amounts remaining do not perform a function.

Foam blowing end-uses that contain closed-cell foams include rigid PU spray foam (all three applications described in section V.C.1); rigid PU commercial refrigeration and sandwich panels; rigid PU marine flotation foam; rigid PU appliance foam; rigid PU slabstock and other; rigid PU and polyisocyanurate laminated boardstock; polystyrene: Extruded boardstock and billet; extruded sheet, polystyren; and phenolic insulation board and bunstock. Foam blowing end-uses containing open cell foams include flexible PU and integral skin PU. Open cell phenolic, and some other open cell foams also exist within the SNAP foam blowing end-uses that include closed cell foams. Integral skin foam may include a rigid surface with an interior flexible core.

b. How would this proposal change the treatment of foam products under SNAP?

Currently, an unacceptable foam blowing agent may not be used to manufacture products in the United States, whether for domestic use or for export. However, products made abroad with unacceptable foam blowing agents may be imported and used in the United States. This is because EPA has historically interpreted the use prohibitions for this sector to apply to blowing foam with the foam blowing agent and not to the use of products made with foam. For example, commercial refrigerators containing appliance foam blown with an unacceptable blowing agent may be imported into and used in the United States, though commercial refrigerators manufactured in the United States may not be manufactured with foam blown with that same agent.

If this proposal were to be finalized as proposed, use of closed cell foam products (e.g., manufactured rigid PU insulation or XPS boardstock) or products that contain closed cell foam (e.g., household and commercial appliances, boats) manufactured with an unacceptable foam blowing agent on or after the specified date would be subject to the use prohibitions under SNAP. This would include, but would not be limited to, incorporating a closed cell foam blown with an unacceptable blowing agent into a subsequent product and installing a closed cell foam product or product containing closed cell foam. Products manufactured prior to the specified date would not be subject to the use prohibitions. In addition, under this proposal the use prohibitions would not apply to consumers once a product had been installed.

c. How do other stratospheric ozone protection requirements apply to foam products?

Several provisions of CAA Title VI and EPA’s implementing regulations are relevant to HFC foam products. Under regulations implementing CAA section 611, EPA requires labeling of products that contain an ODS and those that are manufactured with an ODS. EPA determined that open cell foams blown with an ODS must be labeled as a

Section 610 restricts sale and distribution and offers of sale and distribution of certain products containing or manufactured with CFCs and HCFCs. Section 610(d)(3)(A) explicitly provides an exception for foam insulation products containing HCFCs. EPA has implemented this restriction and the exception for HCFC foam insulation products through its Nonessential Products Ban regulations codified at 40 CFR part 82 subpart C. These regulations define foam insulation product as a product containing or consisting of the following types of foam:

- Closed cell rigid polyurethane foam;
- Closed cell rigid polystyrene boardstock foam;
- Closed cell rigid phenolic foam; and
- Closed cell rigid polyethylene foam where such foam is suitable in shape, thickness and design to be used as a product that provides thermal insulation or is used in manufacturing processes.

CAA section 605(a) prohibits the introduction into interstate commerce or use of any class II substance effective January 1, 2015, unless such substance: (1) Has been used, recovered, and recycled; (2) is used and entirely consumed (except for trace quantities) in the production of other chemicals; (3) is used as a refrigerant in appliances manufactured prior to January 1, 2020; or (4) is listed as acceptable for use as a fire suppression agent for nonresidential applications in accordance with section 612(c).

The section 605(a) implementing regulations codified at 40 CFR part 82, subpart A restrict the use of virgin HCFCs to air conditioning, refrigeration, and fire suppression applications, with minor exceptions. Thus, while the Nonessential Products Ban does not apply to HCFC insulating foams, section 605(a) and its implementing regulations prohibit the use of HCFCs for blowing foam in the United States. The combined effect of the Nonessential Products Ban and the section 605(a) implementing regulations is that HCFC foam insulation products may be imported, sold, and distributed in the United States but cannot be manufactured in the United States.

In the preamble to a July 11, 2000, SNAP proposed rule, EPA reviewed its authority under CAA section 610 and noted that HCFC Insulating foams were exempt from regulation under that section of the statute. EPA stated that “Title VI of the Act thus does not provide EPA with the authority to prevent imports of products containing those foams” (65 FR 42653, 42656). EPA did not, however, base this statement on a full examination of the various authorities under Title VI. In taking final action on that proposal, EPA noted that while under section 610 it could not ban the sale of HCFC foam insulation products, section 610 “does not address HCFC’s ability to regulate the transition from use of ODS to alternatives in the manufacturing of products such as foam.” EPA further noted: “Section 612 can restrict the use of a substitute in a product regardless of whether or not that product is considered nonessential under Section 610” (69 FR 58275, September 30, 2004). d. How is EPA reexamining treatment of foam products under SNAP?

In the August 6, 2014, NPRM (79 FR 46126; 46154), EPA proposed to consider use of a foam blowing agent to include use of closed cell foam products or products containing closed cell foam. In response to that proposal, some commenters supported applying the unacceptable determination to the use of closed cell foam products or products containing closed cell foam with unacceptable foam blowing agents, on the basis that it would maintain a “level playing field” for domestically manufactured products made with lower-GWP foam blowing agents that were going to compete with imported products. Some commenters also supported extending such a prohibition to open cell foams, stating that there was still some foam blowing agent left in the foam and citing the negative impacts of allowing cheaper imported products containing unacceptable foam blowing agents.

Other commenters opposed applying unacceptable determination to anything but the act of blowing foam in the United States. These commenters stated that this would be a significant departure from the Agency’s previous interpretation and suggested that EPA needed to explain the basis for such a change. For example, one commenter stated that “without any legal rationale, EPA has proposed to reverse its long-standing interpretation of the Clean Air Act with respect to the import of products containing HCFC-141b as a foam blowing agent.” In addition, some commenters pointed out that the proposal only allowed 60 days before this change in interpretation would apply to HCFC-141b, which they viewed as insufficient time to adjust. EPA did not take final action in the July 20, 2015, final rule (80 FR 42870) but instead elected to continue assessing the merits of the change.

In this action, EPA is again proposing to apply listings and prohibitions for foam blowing agents to use of closed cell foam products and products containing closed cell foam. To the extent EPA’s earlier statements regarding Title VI reflect an interpretation that the agency could not address imported closed cell foam products or products containing closed cell foam under any provision of Title VI, EPA is proposing to change that interpretation.

Section 612 requires EPA to promulgate regulations prohibiting the replacement of ODS with certain substitutes and to publish lists of the substitutes prohibited for specific uses as well as those found acceptable for those uses. EPA’s implementing regulations at 40 CFR 82.174 state, in part: “No person may use a substitute after the effective date of any rulemaking adding such substitute to the list of unacceptable substitutes” (40 CFR 82.174(d)). The SNAP regulations define “use” of a substitute as including, but not being limited to, “use in a manufacturing process or product, in consumption by the end-user, or in intermediate uses, such as formulation or packaging for other subsequent uses.” (§82.172)

EPA currently treats use of foam blowing agents in the manufacture of a foam product as covered by the use prohibition. In this action, EPA is proposing to apply the use prohibition more broadly in the case of closed cell foam products. With respect to other sectors, EPA has treated use of a product manufactured with or containing a substance as constituting use of the substance where the product holds some amount of the substance, the substance continues to perform its intended function, and the substance is likely to be emitted into the United States either during use of the product or at the time of its disposal. For example, an
aerosol can is manufactured to contain a substance as a propellant, and then that propellant leaks, is released by the end user during use of the aerosol can’s contents, or is emitted at the time of disposal if it has not already been used up. In the July 20, 2015 SNAP rule, in changing the status of certain substances with respect to aerosols, EPA prohibited use of aerosol products containing those substances, while stating that products manufactured prior to the change of status date could still be used after that date (80 FR 42883). By analogy, we are proposing that “use” of a foam blowing agent includes use of a closed cell foam product manufactured after the specified date. For such products, the foam blowing agent remains in the cells and continues to be used for the purpose of insulation during the lifetime of the product. Furthermore, emissions of the foam blowing agent occur at the time of disposal of the closed cell foam product. Thus, emissions from a closed cell product used in the United States can be expected to occur in the United States regardless of whether the product was manufactured domestically or abroad. This proposed action would ensure that products manufactured abroad and subsequently imported would be treated the same as products manufactured domestically.

EPA does not propose to treat use of an open cell foam product as constituting use of the foam blowing agent. The foam blowing agent in an open cell foam product does not continue to perform its intended function during the lifetime of the product. Except for insignificant amounts remaining in the cells, emissions of the foam blowing agent would occur at the time and place of manufacture. Therefore, we are proposing to differentiate between closed cell and open cell foam products for this purpose. This would be consistent with the different treatment of closed and open cell foam products under the section 611 labeling regulations.

e. When would use of closed cell foam products with unacceptable blowing agents be unacceptable?

For changes of status proposed in this rulemaking (section VI.C.1 and VI.C.2), we are proposing that the unacceptability determination would apply to use of closed cell foam products and products that contain closed cell foam where the products are manufactured on or after the change of status date. As noted in the July 15, 2015 SNAP rule with respect to MVAC and stand-alone refrigeration equipment (80 FR 42884), it is reasonable to allow use of products manufactured before the change of status date to avoid market disruption, creation of stranded inventory, and perverse incentives for releasing these substances to the environment.

For alternatives that have already been listed as unacceptable with a change of status date of January 1, 2017, or earlier—namely, HCFC blowing agents listed as unacceptable in appendices K, M, Q, and U to 40 CFR part 82 subpart G, and HFC blowing agents listed as unacceptable for rigid PU and PIR boardstock, extruded polystyrene sheet, and phenolic foams in appendix U to 40 CFR part 82 subpart G—we are proposing that the unacceptability determination would apply to use of closed cell foam products and products that contain closed cell foam manufactured on or after the date one year after the date of publication of a final rule. This timing is intended to allow importers and international manufacturers of such products time to adjust their manufacture and import plans. For substitutes that have already been listed as unacceptable with a change of status date after January 1, 2017—namely, HFC blowing agents listed as unacceptable in rigid PU slabs and other; rigid PU appliance foam; rigid PU commercial refrigeration and sandwich panels; rigid PU marine flotation foam; polyolefin; and polystyrene extruded boardstock and billet— we are proposing that the unacceptability determination would apply to use of closed cell foam products and products that contain closed cell foam manufactured on or after the change of status date for each end-use (January 1 of 2019, 2020, or 2021). For the substitutes already listed as unacceptable, we are proposing to add language regarding use of products to the relevant tables. We do not intend to re-open the listing of those substitutes as unacceptable or the change of status dates for those substitutes.

f. On which topics is EPA specifically requesting comment?

EPA requests comment on all aspects of this proposal. In particular, we request comment on our proposal to revise our previous interpretation and to consider use of the foam blowing agent to include use of closed cell foam products and products containing closed cell foam. We are also taking comment on whether use of an open cell foam product should constitute use of the foam blowing agent. Finally, we request comment on the amount of time provided after which closed cell foam products and products containing closed cell foams manufactured on or after the specified dates would be subject to the use prohibitions.

D. Fire Suppression and Explosion Protection

1. Proposed Listing of 2-bromo-3,3,3-trifluoropropene (2-BTP) as Acceptable, Subject to Use Conditions, for Total Flooding and Streaming

EPA is proposing to list 2-bromo-3,3,3-trifluoropropene (hereinafter referred to as 2-BTP) as acceptable, subject to use conditions, for use in engine nacelles and APUs on aircraft in total flooding fire suppression systems. In addition, EPA proposes to list 2-BTP as acceptable, subject to use conditions, for use in aircraft as a streaming agent. EPA is reviewing additional potential fire suppression applications for 2-BTP but is not taking action on those other uses in this proposed rule.

a. What are the affected end-uses?

The fire suppression and explosion protection end-uses addressed in this action are total flooding and streaming. Total flooding systems, which historically employed halon 1301 as a fire suppression agent, are used in both normally occupied and unoccupied areas. In the United States, approximately 90 percent of installed total flooding systems protect anticipated hazards from ordinary combustibles (i.e., Class A fires), while the remaining ten percent protect against applications involving flammable liquids and gases (i.e., Class B fires). It is also estimated that approximately 75 percent of total flooding systems protect electronics (e.g., computers, telecommunications, process control areas) while the remaining 25 percent protect other applications, primarily in civil aviation (e.g., engine nacelles/APUs, cargo compartments, lavatory trash receptacles), military weapons systems (e.g., combat vehicles, machinery spaces on ships, aircraft engines and tanks), oil/gas and manufacturing industries (e.g., gas/oil pumping, compressor stations), and maritime (e.g., machinery space, cargo pump rooms). Streaming applications, which have historically used halon 1211 as an extinguishing agent, include portable fire.
extinguishers designed to protect against specific hazards.

b. How does 2-BTP compare to other fire suppressants for these end-uses with respect to SNAP criteria?

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; and ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below. In addition, a technical support document that provides the Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives in the relevant end-uses may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

In addition to global impacts on the atmosphere, EPA evaluated potential impacts of emissions of 2-BTP on local air quality. 2-BTP is a VOC and is not excluded from that definition underCAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. EPA compared the annual VOC emissions from the use of 2-BTP as a total flooding agent to other anthropogenic sources of VOC emissions considering both worst case and more realistic scenarios. Under either scenario, emissions are a small fraction of a percentage (5.6 x 10-5 percent to 2.1 x 10-3 percent) of all anthropogenic VOC emissions in the United States in 2014.218219 Given this emission level, we determined it was not necessary to perform an assessment of the effect of these emissions on ambient ozone levels; any effect would be insignificant. This is particularly true since most releases of 2-BTP are expected to be at altitude, not in the lower troposphere. Other acceptable fire suppression agents currently in use in this end-use are also VOC (e.g., C6-perfluoroketone), and thus, use of 2-BTP would not pose more risk than use of other alternatives.

(b) Flammability

2-BTP is nonflammable, as are all other available total flooding agents.

(c) Toxicity

When identifying potential alternatives, toxicity is an important characteristic to consider for manufacturing personnel, service technicians, and end users. Typical concerns include residual oxygen concentration in the protected space.

### Table 22—GWP, ODP, and VOC Status of 2-BTP Compared to Other Total Flooding and Streaming Agents

<table>
<thead>
<tr>
<th>Fire suppressants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total flooding</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FK-5-1-12mmy2 (C6 Perfluoroketone)</td>
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<td>0</td>
<td>Yes</td>
<td>No change.</td>
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<tr>
<td>CF$_3$I</td>
<td>0.4</td>
<td>0.008</td>
<td>Yes</td>
<td>No change.</td>
</tr>
<tr>
<td>CO$_2$</td>
<td>1</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HCFC Blend A</td>
<td>1,546</td>
<td>0.048</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-227ea</td>
<td>3,220</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-125</td>
<td>3,500</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>Water, Inert gases, Powdered aerosols A–E</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td><strong>Streaming</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCFC Blend B</td>
<td>77</td>
<td>0.00098</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-227ea</td>
<td>3,220</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-236fa</td>
<td>9,810</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>CF$_3$I</td>
<td>&lt;1</td>
<td>0</td>
<td>Yes</td>
<td>No change.</td>
</tr>
<tr>
<td>CO$_2$</td>
<td>1</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>Water</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>H Galden HFPEs</td>
<td>2,790–6,230</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
</tbody>
</table>

1 GWP range represents GWPs for 30°N to 60°N and 60°S to 60°N emissions scenarios for a 100-year time horizon. A tropospherically well-mixed approximation of the GWP is equal to 0.59.217

2 HCFC Blend A is a blend consisting of HCFC-123 (4.75%), HCFC-22 (82%), HCFC-124 (9.5%), and D-limonene (3.75%).

3 HCFC Blend B is a proprietary blend consisting largely of HCFC-123.


218 ICF, 2016c. Analysis of annual VOC emissions from the use of 2-BTP.

219 Based on the 2014 annual total VOC emissions for the United States (i.e., approximately 17.13x10$^{6}$ MT) as reported in the National Emissions Inventory (EPA, 2015).
EPA has evaluated the risks associated with potential exposures to 2-BTP during production operations and the filling of fire extinguishers as well as in the case of an inadvertent discharge of the system during maintenance activities on the fire extinguishing system. EPA’s review of the human health impacts of 2-BTP, including the summary of available toxicity studies, and EPA’s review of the human health impacts of 2-BTP is in the dock for this rulemaking (EPA–HQ–OAR–2015–0663).

According to the MSDS, exposure to 2-BTP through ocular or dermal absorption, inhalation, or ingestion is unlikely to be harmful. However, the most likely pathway of exposure is through inhalation, which may cause central nervous system effects, such as dizziness, confusion, physical incoordination, drowsiness, anesthesia, or unconsciousness. EPA uses the NOAEL value as the basis to ensure protection to the worker population.

The cardiotoxic Lowest-Observed-Adverse-Effect-Level (LOAEL) for this agent is 1.0 percent (10,000 ppm), at which level exposure may cause increased sensitivity of the heart to adrenaline, which might cause irregular heartbeats and possibly ventricular fibrillation or death; the cardiotoxic NOAEL for this agent is 0.5 percent (5,000 ppm).

2-BTP vapors are heavier than air and may reduce oxygen available for breathing, causing asphyxiation in high concentrations. Such vapors pose a potential hazard if large volumes are trapped in enclosed or low places. In addition, as noted above, if person(s) are exposed to high concentrations, the person(s) may experience central nervous system effects, such as drowsiness and dizziness, which may result in the person(s) not realizing that he/she is suffocating. These health effects after exposure are similar for other common fire suppressants. Employees responsible for manufacturing the systems should wear the appropriate PPE, such as protective gloves, tightly sealed goggles, protective work clothing, and suitable respiratory protection in case of accidental release or insufficient ventilation. Use of respirators is recommended during activities in which exposure to the proposed substitute cannot be controlled through other means. When handling a leak in a storage container, protective clothing is recommended as well as vapor-in-air detection systems. Gloves (i.e., neoprene, polyvinyl chloride, or polyvinyl alcohol) should be worn when handling equipment containing the proposed substitute for prolonged periods.

For operations requiring regular handling of 2-BTP, engineering controls should include adequate ventilation systems and enclosed or confined operations to ensure exposure levels to the proposed substitute are below the occupational AEL. 2-BTP is not expected to pose a risk to workers when the engineering controls and PPE recommendations referenced in the MSDS for this proposed substitute are followed.

Exposure to 2-BTP is not likely during installation or servicing of 2-BTP total flooding systems for engines and APUs on aircraft. These are both considered to be unoccupied areas, meaning personnel cannot physically occupy these spaces, thus reducing the risk from exposure to an inadvertent discharge. The risk of accidental activation of the fire extinguishing system while personnel are present near the protected space is highly unlikely if proper procedures are followed. Proper instructions on system installation and servicing included in manuals for the 2-BTP systems should be adhered to. The locations of the 2-BTP bottles in the engine and APU compartments will vary by airplane model. The engine bottles could be installed inside or outside the pressurized volume, but they are connected through piping to the engines. APU bottles are typically installed forward of the APU firewall, outside of the pressurized volume of the plane. The bottles are hermetically sealed and the piping system is pressure tested, mitigating the potential for any leak of 2-BTP from the system.

According to the submitter, in the case of an inadvertent discharge of the system during maintenance activities on the fire extinguishing system or surrounding equipment, the cowl doors that would be open to allow access to the area will allow service personnel to immediately egress and avoid exposure. Furthermore, aircraft maintenance procedures provide specific instruction to prevent accidental discharge of 2-BTP systems. It is expected that procedures identified in the MSDS for 2-BTP and good manufacturing practices will be adhered to, and that the appropriate safety and PPE (e.g., protective gloves, tightly sealed goggles, protective work clothing, and suitable respiratory protection in case of accidental release or insufficient ventilation) consistent with OSHA guidelines will be used, as applicable, during manufacture and disposal of 2-BTP total flooding systems.

The toxicity risks can be minimized through the use conditions specified in section VI.D.c below. The risks after exposure are common to many total...
floodig agents, including those already listed as acceptable under SNAP for this same end-use such as C6-perfluoroketone. EPA is proposing to find 2-BTP acceptable, subject to use conditions, as a total flooding agent for use in engine nacelles and APUs on aircraft because the overall environmental and human health risk posed by the substitute is lower than or comparable to the overall risk posed by other alternatives listed as acceptable in the same end-use.

ii. Streaming Uses

(a) Environmental Impacts

In addition to halon 1211, the current market for streaming applications also includes HFCs, HFCs, and a variety of other agents (e.g., dry chemical, CO2, water). Specific alternatives used for streaming uses include HCFC Blend B (with an ODP of roughly 0.01 and a GWP of roughly 80), HFC-227ea (with an ODP of zero and a GWP of 3,220), and C7 Fluoroketone (with an ODP of zero and a GWP of approximately one). The ODP, GWP, and atmospheric lifetime of 2-BTP and other alternatives that are also used as total flooding agents are described above under total flooding applications. 2-BTP has a lower climate impact a shorter atmospheric lifetime compared to other alternatives in this end-use.

Regarding local air quality impacts, EPA compared the annual VOC emissions from the use of 2-BTP as a streaming agent to other anthropogenic sources of VOC emissions considering both worst case and more realistic scenarios. Under either scenario, emissions are a small fraction of a percentage (7.4 x 10^-3 percent to 2.1 x 10^-3 percent) of all anthropogenic VOC emissions in the United States in 2014. Given this emission level, we determined it was not necessary to perform an assessment of the effect of these emissions on ambient ozone levels; any effect would be insignificant. This is particularly true since most releases of 2-BTP are expected to be at altitude, not in the lower troposphere. Other acceptable fire suppression agents currently in use in this end-use are also VOC (e.g., C6-perfluoroketone, C7-fluoroketone), and thus, use of 2-BTP would not pose more risk than use of other alternatives.

(b) Flammability

2-BTP is nonflammable, as are all other available streaming agents.

(c) Toxicity

EPA evaluated occupational and general population exposure at manufacture and at end-use to ensure that the use of 2-BTP as a streaming agent will not pose unacceptable risks to workers or the general public. EPA has evaluated the risks associated with potential exposures to 2-BTP during production operations and the filling of fire extinguishers as well as in the case of an inadvertent discharge of the fire extinguisher during maintenance activities.

2-BTP is not expected to pose a risk to workers during manufacture when the engineering controls and PPE requirements as also referenced in the MSDS for this proposed substitute are followed as described below in section VI.D.1.c.i. The combination of appropriate engineering controls and the use of PPE will ensure exposure levels to the proposed substitute are below the occupational AEL. Exposure to 2-BTP is not likely during installation or servicing of 2-BTP fire extinguishers. As indicated by the submitter, the risk of accidental activation of the fire extinguisher while personnel are present in the protected space is highly unlikely if proper procedures are followed. Proper instructions on system installation and servicing included in manuals for the 2-BTP systems should be adhered to.

EPA also assessed potential end-use exposure scenario, 15-minute and 30-minute TWA exposures for 2-BTP following potential release of agent from the handheld extinguisher on-board aircraft. These exposures were then compared to the cardiotoxic LOAEL for 2-BTP. The modeled 15-minute and 30-minute exposures for varying ventilation rates were significantly lower than the LOAEL of 10,000 ppm for 2-BTP, as well as below the NOAEL of 5,000 ppm. 2-BTP handheld extinguishers must follow required minimum room volumes established by UL 2129, Halocarbon Clean Agent Fire Extinguishers, when discharged into a confined space. This standard prohibits the exceedance of the cardiotoxic LOAEL for any fire suppressant (i.e., 10,000 ppm or 1.0% for 2-BTP). Therefore, per UL 2129, labels for 2-BTP extinguishers will contain the statement, “Do not use in confined spaces less than 896 cubic feet per extinguisher.” Based on the above results, 2-BTP is not expected to pose significant risk to end users when used as a streaming fire extinguishing agent in aircraft.

There are various precautions described above, but the actual use conditions are described below. The general population risks during release or disposal of the agent are described in section VI.D.1.b above. The risks after exposure are common to many stream agents, including those already listed as acceptable under SNAP for this same end-use, such as C6-perfluoroketone. EPA is proposing to find 2-BTP acceptable, subject to use conditions, as a streaming agent on aircraft because the overall environmental and human health risk posed by the substitute is lower than or comparable to the overall risk posed by other alternatives listed as acceptable in the same end-use.

c. What are the proposed use conditions?

i. Engine Nacelles and APU Fire Suppression Systems on Aircraft Only

EPA is proposing to add 2-BTP to the list of acceptable total flooding substitutes, subject to use conditions. For the total flooding end-use, the proposed use conditions would require that 2-BTP be used only for engine nacelles and APU on aircraft.

ii. Handheld Extinguishers in Aircraft Only

For the streaming end-use, the use condition would require that 2-BTP be used only for handheld extinguishers in aircraft.

d. What further information is EPA providing in the acceptable subject to use conditions listing for 2-BTP?

In the “Further Information” column of the regulatory listing, EPA is providing the following additional information for establishments manufacturing, installing and maintaining total flooding systems using this agent:

- This agent should be used in accordance with the safety guidelines in the latest edition of the National Fire Protection Association (NFPA) 2001 Standard for Clean Agent Fire Extinguishing Systems.
- In the case that 2-BTP is inhaled, person(s) should be immediately removed and exposed to fresh air; if breathing is difficult, person(s) should seek medical attention.
- In case of eye exposure, person(s) should immediately flush the eyes, including under the eyelids, with

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222 ICF, 2016. Analysis of annual VOC emissions from the use of 2-BTP.
fresh water and move to a non-contaminated area, and medical attention should be sought if irritation develops or persists;

• Eye wash and quick drench facilities should be available. In case of ocular exposure, person(s) should immediately flush the eyes, including under the eyelids, with fresh water and move to a non-contaminated area; Exposed persons should remove all contaminated clothing and footwear to avoid irritation; and medical attention should be sought if irritation develops or persists;

• Although unlikely, in case of ingestion of 2-BTP, the person(s) should consult a physician immediately;

• Manufacturing space should be equipped with specialized engineering controls and well ventilated with a local exhaust system and low-lying source ventilation to effectively mitigate potential occupational exposure; regular testing and monitoring of the workplace atmosphere should be conducted;

• Employees responsible for chemical processing should wear the appropriate PPE, such as protective gloves, tightly sealed goggles, protective work clothing, and suitable respiratory protection in case of accidental release or insufficient ventilation;

• All spills should be cleaned up immediately in accordance with good industrial hygiene practices; and

• Training for safe handling procedures should be provided to all employees that would be likely to handle containers of the agent or extinguishing units filled with the agent.

• Safety features that are typical of total flooding systems such as pre-discharge alarms, time delays, and system abort switches should be provided, as directed by applicable OSHA regulations and NFPA standards. Use of this agent should also conform to relevant OSHA requirements, including 29 CFR 1910, subpart L, sections 1910.160 and 1910.162.

In the “Further Information” column of the regulatory listing, EPA is providing the following additional information for establishments manufacturing, installing and maintaining streaming agents:

• This agent should also be used in accordance with the latest edition of NFPA Standard 10 for Portable Fire Extinguishers;

• In the case that 2-BTP is inhaled, person(s) should be immediately removed and exposed to fresh air; if breathing is difficult, person(s) should seek medical attention;

• Eye wash and quick drench facilities should be available. In case of ocular exposure, person(s) should immediately flush the eyes, including under the eyelids, with fresh water and move to a non-contaminated area; Exposed persons should remove all contaminated clothing and footwear to avoid irritation; and medical attention should be sought if irritation develops or persists;

• Although unlikely, in case of ingestion of 2-BTP, the person(s) should consult a physician immediately;

• Manufacturing space should be equipped with specialized engineering controls and well ventilated with a local exhaust system and low-lying source ventilation to effectively mitigate potential occupational exposure; regular testing and monitoring of the workplace atmosphere should be conducted;

• Employees responsible for chemical processing should wear the appropriate PPE, such as protective gloves, tightly sealed goggles, protective work clothing, and suitable respiratory protection in case of accidental release or insufficient ventilation;

• All spills should be cleaned up immediately in accordance with good industrial hygiene practices;

• Training for safe handling procedures should be provided to all employees that would be likely to handle containers of the agent or extinguishing units filled with the agent;

• 2-BTP use as a streaming fire extinguishing agent in handheld extinguishers on aircraft should be in accordance with UL 711, Rating and Testing of Fire Extinguishers and the Federal Aviation Administration (FAA) Minimum Performance Standard for Hand-Held Extinguishers (DOT/FAA/AR–01/37), with regard to the size and number of extinguishers depending on the size of aircraft. 2-BTP handheld extinguishers should also follow required minimum room volumes established by UL 2129, Halocarbon Clean Agent Fire Extinguishers, when discharged into a confined space.

This standard prohibits the exceedance of the cardiotoxic LOAEL for any fire suppressant (i.e., 10,000 ppm or 1.0 percent for 2-BTP).

e. When would the listing apply?

EPA proposes that this listing would apply 30 days after the date of publication of a final rule. This date, the same as the proposed effective date of this regulation, allows for the safe use of this substitute at the earliest opportunity.

f. What is the relationship between this proposed SNAP rule and other federal rules?

As required for a new chemical, the manufacturer of this agent submitted a Toxic Substance Control Act (TSCA) Premanufacture Notice (PMN) for review by EPA. The PMN, designated as P–14–260, has completed EPA review and the manufacturer is presently subject to requirements contained in a TSCA section 5(e) Consent Order. Other future manufacturers and processors will be subject to a TSCA section 5(a)(2) Significant New Use Rule (SNUR) that is expected to be promulgated in 2016. The requirements of the consent order and SNUR would apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of 2-BTP, unless exempted. Consistent with today’s proposed listing, the consent order and SNUR will require use of 2-BTP for aircraft either (1) as a total flooding agent in engine nacelles and APUs on aircraft or (2) as a streaming agent in handheld extinguishers in aircraft. As noted above in section V.L.D.1.d, FAA has issued guidance on the use of hand-held fire extinguishers on aircraft that is relevant to the streaming uses proposed in this rule.

g. On which topics is EPA specifically requesting comment?

EPA is requesting comment on all aspects of the proposed listing decision, including the proposed use conditions.

2. Proposed Change of Status for Certain Perfluorocarbons

As described in Table 23, EPA is proposing to change the listings from acceptable to unacceptable for C₃F₈ (PFC-218) and C₃F₁₀ (PFC-410) in total flooding systems. We note that these changes of status apply to the manufacture of new equipment using these agents. Existing equipment that contains these agents may continue to be used for the remaining lifetime of the equipment.
a. What is the affected end-use?

The fire suppression and explosion protection end-uses addressed in this action is total flooding. The fire suppression industry has historically used halons, a class of halogenated chemicals containing bromine, as clean extinguishing agents (i.e., those that do not leave residue following system discharge) in many different applications. Halon 1301 has been used in fixed total flooding systems.

Halons have a unique combination of characteristics including being electrically non-conductive, dissipating rapidly without residue (i.e., clean), efficiently extinguishing most types of fires, and low toxicity. These agents are extremely effective on ordinary fires, and low toxicity. These agents are extremely effective on ordinary combustibles, flammable liquids and gases, and electrical fires (i.e., Class A, Class B, and Class C fires, respectively). These characteristics allowed halon systems to be widely used to effectively protect valuable and sensitive assets in locations such as computer and control rooms, electronic data processing facilities, museums, military equipment, shipboard machinery, space, aircraft, and oil and gas industry facilities.

Halons have very high ODPs because they contain bromine, which has a higher reactivity with ozone than chlorine. Specifically, the ODP of halon 1301 is 15.9. EPA banned the production and import of newly produced halons beginning January 1, 1994 (58 FR 65018; December 10, 1993) consistent with the requirements of the CAA and the Montreal Protocol. In addition, EPA issued regulations codified at 40 CFR part 82 subpart H to reduce emissions of halon through technician training and proper disposal. The U.S. fire suppression industry supported the phase out of halon production by working to find effective substitutes and to reduce unnecessary emissions of halon. Recycled halon is relied on for continuing uses of halons.

In response to the early 1994 phaseout of halon production, industry took early actions to find alternatives including less ozone-depleting HCFCs, non-ozone-depleting HFCs, as well as a variety of lower-GWP or no-GWP alternatives (e.g., inert gases, CO₂, powdered aerosols, foams, water). Industry also took actions to minimize emissions and halon recycling emerged as an important initiative to both reduce unnecessary emissions, and to ensure supplies of halons during the transition. Other efforts included changes to national and international fire codes and standards to discourage the use of halons for testing and training while supporting the adoption of the alternatives listed as acceptable in fire suppression and explosion protection by EPA’s SNAP program.

b. Which fire suppressants is EPA proposing to list as unacceptable?

EPA is proposing to list C₃F₈ (PFC-410) and C₃F₈ (PFC-218) as unacceptable in certain uses for which they are currently listed as acceptable subject to narrowed use limits.

c. How do the proposed unacceptable fire suppressants compare to other fire suppressants for this end-use with respect to SNAP criteria?

The SNAP program considers a number of environmental criteria when evaluating substitutes: ODP; climate effects, primarily based on GWP; local air quality impacts, particularly potential impacts on smog formation from emissions of VOC; and ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below. In addition, a technical support document 229 that provides the Federal Register citations containing data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for acceptable alternatives in the relevant end-uses may be found in the docket for this rulemaking (EPA–HQ–OAR–2015–0663).

(a) Environmental Impacts

PFCs are fully fluorinated compounds, unlike CFCs, HCFCs, or HFCs. These chemicals have an ODP of zero, are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS, and have high GWPs (5,000–10,000 times greater than CO₂). Although the actual contributions to global warming depend upon the quantities emitted, because of their long atmospheric lifetimes, the warming effects of PFCs are essentially irreversible. As discussed in Section III above and in EPA’s Endangerment Finding (74 FR 66496; December 7, 2009), EPA determined that PFCs are one of the six key well-mixed greenhouse gases in the atmosphere—in addition to CO₂, CH₄, N₂O, HFCs, and SF₆—whose current and projected concentrations were found to threaten the public health and welfare of current and future generations.

TABLE 23—PROPOSED CHANGE OF STATUS DECISIONS FOR TOTAL FLOODING

<table>
<thead>
<tr>
<th>Total flooding</th>
<th>Substitutes</th>
<th>Proposed decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFCs (C₃F₈ and C₃F₁₀)</td>
<td>Unacceptable as of one year after publication of a final rule.</td>
<td></td>
</tr>
</tbody>
</table>

TABLE 24—GWP, ODP, AND VOC STATUS OF C₃F₈, AND C₃F₁₀ COMPARED TO OTHER TOTAL FLOODING AGENTS

<table>
<thead>
<tr>
<th>Fire suppressants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>C₃F₈, C₃F₁₀</td>
<td>8,830–8,860</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>C₅F₁₂</td>
<td>0.4</td>
<td>0.006</td>
<td>Yes</td>
<td>No change.</td>
</tr>
<tr>
<td>FK-5-1-12mmwy²</td>
<td>&lt;1</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HCFC-124, HCFC Blend A</td>
<td>610–1,550</td>
<td>0.048–0.22</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>Halotron II, HFC-125, HFC-227ea</td>
<td>1,600–3,500</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-236fa</td>
<td>9,810</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-23</td>
<td>14,800</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
</tbody>
</table>


### Table 24—GWP, ODP, and VOC Status of C₃F₈ and C₆F₁₀ Compared to Other Total Flooding Agents—Continued

<table>
<thead>
<tr>
<th>Fire suppressants</th>
<th>GWP</th>
<th>ODP</th>
<th>VOC</th>
<th>Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water, Inert gases, Powdered aerosols A–E</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td><strong>Streaming</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C₃F₈</td>
<td>9,300</td>
<td>0</td>
<td>No</td>
<td>Unacceptable.</td>
</tr>
<tr>
<td>CO₂</td>
<td>77–1,546</td>
<td>0.00098–0.048</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>C₇ fluoroketone, FK-5-1-12mny2</td>
<td>3,220–9,810</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HCFC Blend B, HCFC-123, HCFC-124</td>
<td>3,220–9,810</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>HFC-227ea, HFC-236fa</td>
<td>2,790–6,230</td>
<td>0</td>
<td>No</td>
<td>No change.</td>
</tr>
<tr>
<td>H Galden HFP</td>
<td>Water</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As shown in Table 24, C₃F₈ has a GWP of 8,830. EPA found the substitute acceptable only in those limited instances where no other alternative is technically feasible due to performance or safety requirements (60 FR 31092; July 13, 1995). C₆F₁₀ has a GWP of 8,860. Because of similar concerns including the GWPs, EPA listed these as substitutes that would be used as a last resort. Other commonly-used alternatives for total flooding applications have lower GWPs including HFC-227ea (with GWP of 3,220), HCFC-125 (with a GWP of 3,500), and C₇ Fluoroketone (with a GWP of approximately one).

(b) Flammability

C₃F₈ and C₆F₁₀ are non-flammable, like all other fire suppression agents listed as acceptable under SNAP.

(c) Toxicity

In evaluating the toxicity concerns with fire suppression agents, we evaluate consumer and worker exposures to discharges of substitutes during fire emergencies and accidental discharges. In these acute, episodic exposures to the substitutes, cardiac sensitization is of particular interest. The term cardiac sensitization refers to an increased susceptibility of the heart to adrenaline (or other catecholamines) which may result in potentially fatal heart arrhythmias. Human heart arrhythmias and sudden deaths resulting from overexposure to CFCs, halons, and other halogenated hydrocarbons have been documented in workplace settings.

The determination of the toxicity risk to either workers or the general population from an accidental discharge of either a flooding or streaming agent substitute is also dependent on a number of other related factors. For total flood systems, the magnitude of exposure will depend on the design concentration of the flooding agent (as determined by the substitute’s extinguishing concentration plus a safety factor, as specified by NFPA guidelines) and the length of time it takes a person to evacuate the area in which the total agent is released. Because total flood systems are designed to achieve a uniform concentration of agent within a space, the magnitude of exposure is independent of the size of space, size of fire, or proximity of person to the fire. In assessing exposure the design concentration of a total flood substitute is compared to its cardiotoxic NOAEL and LOAEL levels. Generally, for occupied areas, if the design concentration is higher than the agent’s NOAEL level, conditions are placed on the use of the agent to ensure human safety (e.g., lower time allowed for safe egress).

Compared to other substitutes in the same total flooding end-use, these PFCs have lower toxicity profiles. The cardiotoxic NOAEL for C₃F₈ is 40 percent which is well above its demonstrated extinguishing concentration of 5.5 percent in total flood applications, indicating its safe use in occupied areas. The cardiotoxic NOAEL for C₆F₁₀ is 30 percent which is also well above its demonstrated extinguishing concentration of 7.3 percent with cup burner tests in heptane (with a resulting design concentration of 8.8 percent), also indicating its safe use in occupied areas. In comparison, HFC-227ea has a cardiotoxic NOAEL of nine percent and an extinguishing concentration of 5.2 percent (minimum extinguishing concentration for Class A fires) and C₆-perfluoroketone has a cardiotoxic NOAEL of ten percent and an extinguishing concentration of 3.5 percent (minimum extinguishing concentration for Class A fires). HFC-227ea and C₆-perfluoroketone, the concentrations needed to extinguish typical Class A fires are below the NOAEL. In addition, NFPA 2001 Standard for Clean Agent Extinguishing Systems contains the times for safe human exposure at specific concentrations for both HFC-227ea and C₆-perfluoroketone in order to allow safe egress of personnel from the protected space in the event of a system discharge. Current industry practices include additional safeguards for these systems such as pre-discharge alarms and time-delays. While C₆F₁₀ and C₃F₈ have lower toxicity profiles, the greater toxicity risks of the other alternatives for the same end-uses are mitigated by requirements as established in NFPA 2001, which requires that the alternative have first been reviewed in a process equivalent to that used by SNAP and then provides the minimum requirements for the safe design, installation, maintenance, and operation of total flooding systems using clean agent alternatives such as HFC-227ea and C₆-perfluoroketone.

In comparing the environmental and health risks of C₃F₈ and C₆F₁₀ with other alternatives in the same total flooding end-use, C₃F₈ and C₆F₁₀ both have higher GWPs. While C₃F₈ and C₆F₁₀ have lower toxicity profiles, the greater toxicity of other alternatives in the same end-use are mitigated by the fact that requirements for safe use of these alternatives are contained in fire protection industry standards (e.g., NFPA 2001). Other criteria are comparable to many agents already listed as acceptable under SNAP for this end-use. Because the GWPs for C₃F₈ and C₆F₁₀ are significantly higher and thus pose significantly greater risk than other alternatives in the same end-use, we are proposing to list C₃F₈ and C₆F₁₀ as unacceptable for total flooding applications.

(d) Summary

EPA has listed as acceptable several substitutes that pose lower overall risk to human health and the environment than the two fire suppression alternatives, C₃F₈ and C₆F₁₀, whose status we are proposing to change to...
 unacceptable. The risks other than GWP are not significantly different for the other available alternatives in the same total flooding end-use than for the fire suppression agents we are proposing to list as unacceptable. Neither the substitutes we are proposing to list as unacceptable nor the other available alternatives pose a significantly greater risk based on toxicity because all may be used consistent with NFPA 2001. However, the GWP s for the fire suppression agents, C\textsubscript{3}F\textsubscript{8} and C\textsubscript{4}F\textsubscript{10}, which we are proposing to list as unacceptable, are significantly higher and thus pose significantly greater risk. Because the GWP s for C\textsubscript{3}F\textsubscript{8} and C\textsubscript{4}F\textsubscript{10} are significantly higher than other available alternatives in this end-use and there is no significant difference in risk based on the other evaluation criteria, we are proposing to list C\textsubscript{3}F\textsubscript{8} and C\textsubscript{4}F\textsubscript{10} as unacceptable for total flooding applications.

d. When would the status change?

Today, the demand in the fire suppression total flooding end-use is being met through the availability of clean agents and not-in-kind (NIK) substitutes (i.e., non-gaseous agents, including powdered aerosols, foam, and water mist).\textsuperscript{230} The current market for the total flooding end-use consists of commercially available and proven alternatives including HCFCs, HFCs, inert gases, and a variety of NIK extinguishing agents (e.g., powdered aerosols, foams water) and technologies. National and international standards currently cover the requirements, specifications, and recommendations for design, installation, testing, maintenance, and safety factors for many of these alternatives in the total flooding end-use.

Considering the above, and the current suite of other available substitutes in the fire suppression total flooding end uses EPA is proposing to change the listings from acceptable to unacceptable for C\textsubscript{3}F\textsubscript{8} and C\textsubscript{4}F\textsubscript{10} in total flooding systems as of one year after publication of a final rule. Based on the information available to EPA today on the total flooding agent markets as discussed above, including through various discussions with industry representatives, users have other available alternatives with lower overall risks to human health and the environment. Given the broad commercial availability of the alternative systems already and coverage by national and international standards of many of the alternatives, one year provides a reasonable timeframe for the change in status for C\textsubscript{3}F\textsubscript{8} and C\textsubscript{4}F\textsubscript{10} in total flooding systems.

e. What is the relationship between this proposed SNAP rule and other federal rules?

EPA is not aware of other federal rules applying to these two fire suppression agents in the total flooding end-use.

f. On which topics is EPA specifically requesting comment?

EPA requests comments on all aspects of these proposed changes. EPA specifically requests comment on the proposed decision to change the status of C\textsubscript{3}F\textsubscript{8} and C\textsubscript{4}F\textsubscript{10} to unacceptable one year after the date of publication of a final rule, and requests updated information with regard to the use of these PFCs in total flooding applications as well as the availability of other substitutes for this end-use. EPA is also interested in advance comments on whether to take similar action with respect to certain additional fire suppression agents. Specifically, EPA requests advance comments and updated information on total flooding uses of SF\textsubscript{6}, HFC-23, and HFC-125, and on both total flooding and streaming uses of HFC-227ea. SF\textsubscript{6} is listed as acceptable subject to narrowed use limits for use as a discharge test agent in military uses and civil aircraft uses only (60 FR 31092; July 13, 1995). SF\textsubscript{6} is a nonflammable, nontoxic gas which is colorless and odorless. SF\textsubscript{6} is relatively inert, and has an atmospheric lifetime of 3,200 years, with a GWP of 22,800. SF\textsubscript{6} is the most potent GHG the IPCC has evaluated. The U.S. Navy has used SF\textsubscript{6} as a test gas simulac in place of halon in new halon total flooding systems on ships which have been under construction prior to identification and qualification of substitute agents. Halon systems are no longer included in designs for new ships. Similarly, the airline industry had an interest in using SF\textsubscript{6} as a discharge test agent simulating halon 1301 in aircraft system certification testing to ensure aircraft in-flight fire safety. The amount of SF\textsubscript{6} released in developing and certifying these critical systems for commercial aircraft was estimated to be approximately 1,000 pounds per year or less for this development period, however airlines continue to build new aircraft with halon systems. EPA is not aware of SF\textsubscript{6} use in other commercial sector testing regimes, and EPA imposed a narrowed use limit on SF\textsubscript{6} as a discharge test agent to ensure that emissions of this agent remain minimal. The NFPA 12a and NFPA 2001 standards recommend that halon or other total flooding gases not be used in discharge testing, but that alternative methods of ensuring enclosure and piping integrity and system functioning be used. Alternative methods can often be used, such as the “door fan” test for enclosure integrity, UL 1058 testing to ensure system functioning, pneumatic test of installed piping, and a “puff” test to ensure against internal blockages in the piping network. These stringent design and testing requirements have largely obviated the need to perform a discharge test for total flood systems containing either halon 1301 or a substitute agent outside of military and civil aircraft uses.

EPA requests comment and updated information on whether there is current or continuing use of SF\textsubscript{6} in this end-use and the availability of substitutes or alternative technologies or processes that would obviate its continued use.

HFC-23 is listed as acceptable as a total flooding substitute. In the SNAP final rule of March 18, 1994 (59 FR 13044), EPA decided not to adopt the proposed narrowed use limits on HFC-23 in response to comments that its cardiotoxicity profile was favorable compared to its design or inerting concentration and in some cases it was the only acceptable alternative in particular applications such as: (1) Where temperatures are likely to go below zero degrees, (2) where pre-inerting is required for occupied areas, and (3) where occupied areas can suffer considerable variation in fire volume. HFC-23 is used as a total flooding agent in occupied areas because of its favorable cardiotoxicity profile with values of 30 percent for the NOAEL and 50 percent for the LOAEL, compared to a design concentration of 14.4 percent, based on cup burner tests in heptane. Compared to an inerting concentration in methane of 20.5 percent and an inerting design concentration of 22.6 percent in methane, the agent made for an excellent candidate for use in explosion inertion. Nevertheless, it is also a potent greenhouse gas with a GWP of 14,800.

In its 2014 Assessment, the UNEP TEAP HTOC reported on the status of the use of halons and alternatives in the various sector of use including in pipelines and the oil and gas industry.\textsuperscript{231} Halon 1301 is used for


maintaining legacy systems used to prevent explosions and to suppress fires in inhospitable locations such as the Alaskan North Slope in the United States. This situation remains the same today since "existing facilities were designed and constructed with halon 1301 fixed systems as an integral part of the safety system design as well as the physical layout of the facility." New facilities adopt inherently safe design approaches that eliminate the potential flammable or explosive hazards. New technologies such as advanced detection systems also reduce reliance on need to close and inert the space. However, where an inerting agent is still required in occupied spaces, halon 1301 has been replaced by HFC-23 or C6-perfluoroketone, if temperatures permit. Currently, HFC-23 is the only alternative determined to meet both the requirement to mitigate inerting high-GWP gas release, such as methane, and perform its function in fully enclosed spaces in very cold climatic conditions. EPA requests comment and updated information on the continuing use of HFC-23 in this and potentially other applications in this end-use and the availability of substitutes or alternative technologies or processes that would obviate its continued use.

With significant progress made by the U.S. total flooding systems industry in adopting a variety of suppression agent alternatives, EPA understands that, as a result, a mix of agents are in use today with high-GWP HFCs occupying a substantial portion of the products on the market. Currently, HFCs account for approximately 23 percent of the alternatives used to replace halon 1301, while HFC-227ea constitutes a majority of that total, with some use of other HFCs such as HFC-23 and HFC-125.323 EPA, therefore, also requests comment and updated information on the continuing use of HFC-125 and HFC-227ea in fire protection and explosion protection. HFC-227ea is an acceptable alternative for both total flooding (59 FR 12044; March 18, 1994) and streaming (64 FR 22987; April 28, 1999) applications; HFC-125 is an acceptable alternative for total flooding uses (59 FR 12044; March 18, 1994). The extinguishing concentration for HFC-227ea for typical Class A fires in heptane is below its NOAEL making it appropriate for use as a total flooding agent in normally occupied spaces, while the extinguishing concentration for HFC-125 is above its cardiotoxic NOAEL making it appropriate for use in spaces that are not normally occupied. EPA is requesting comment and updated information on the continuing use of these alternatives and the availability of substitutes or alternative technologies or processes that would obviate their continued use.

3. Proposed Removal of Powdered Aerosol D in Total Flooding From the List of Substitutes Acceptable for Use Subject to Use Conditions

Powdered Aerosol D is a pyrotechnic particulate aerosol and explosion suppressant that also is marketed under the trade names of Aero-K® and Stat-X®. This fire suppressant is supplied to users as a solid housed in a double-walled hermetically-sealed steel container. When the unit is triggered by heat (300 °C), the product is pyrotechnically activated to produce gases and aerosol particles from a mixture of chemicals. EPA listed Powdered Aerosol D as acceptable subject to use conditions as a total flooding agent (71 FR 56359; September 7, 2006). The use conditions required that Powdered Aerosol D be used only in areas that are not normally occupied, because the Agency did not have sufficient information at that time supporting its safe use in areas that are normally occupied. Based on a review of additional information from the submitter to support the safe use of Powdered Aerosol D in normally occupied spaces, EPA subsequently determined that Powdered Aerosol D is also acceptable for use in total flooding systems for normally occupied spaces (79 FR 62863; October 21, 2014). The listing provides that Powdered Aerosol D is acceptable for total flooding uses, which includes both unoccupied and occupied spaces. In the October 2014 listing action, EPA noted that in a subsequent rulemaking, the Agency would remove the previous listing of acceptable subject to use conditions. Today, EPA is proposing to remove this listing for Powdered Aerosol D.

VII. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at http://www2.epa.gov/laws-regulations/laws-and-executive-orders.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. It raises novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. These are available in docket EPA–HQ–OAR–2015–0663 under the titles, “Climate Benefits of the Proposed SNAP Program Status Change Rule” and “Preliminary Cost Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives used in Refrigeration and Air Conditioning, Foams, and Fire Suppression.”

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection requirements contained in the existing regulations and has assigned OMB control number 2060–0226. This proposed rule contains no new requirements for reporting or recordkeeping.

C. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small businesses. For purposes of assessing the impacts of this proposed rule on small entities, EPA evaluated small businesses as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201. The Agency has determined that about 90 small businesses could be subject to the rulemaking, and roughly 76 percent of the small businesses subject to this proposed rulemaking would be expected to experience compliance costs of less than one percent of annual sales revenue. Details of this analysis are presented in the document entitled, “Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives used in Refrigeration and Air Conditioning, Motor Vehicle Air Conditioners, Foams, and Fire Suppression.” EPA evaluated the potential costs to small businesses associated with the proposed rule. EPA estimates that the total annualized compliance costs for all small businesses would be approximately $11.8 to $14.4 million at a seven percent discount rate, or $11.5 to $14.0 million at a three percent discount rate.233


233 ICF, 2016a. Preliminary Cost Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives used in Refrigeration and Air
Today’s action allows equipment manufacturers the additional options of using propane, HFO-1234yf, and 2-BTP in the specified end-uses but does not mandate such use. Because these substitutes are not yet being used in the United States for the end-uses (with the exception of limited test-marketing), no change in business practice would be required to meet the use conditions, resulting in no adverse impact compared to the absence of this rule. Provisions that allow venting of hydrocarbon refrigerants in the uses of propane addressed by this proposed rule would reduce regulatory burden. We have therefore concluded that this action would relieve regulatory burden for all small entities that choose to use propane as a refrigerant in the end-uses in this proposed listing. The use conditions of this proposed rule apply to manufacturers of commercial ice machines, water coolers, and very low temperature refrigeration equipment that choose to use propane.

The requirements of this proposed rule with respect to HFCs, if finalized as proposed, would impact small businesses that manufacture food processing and dispensing equipment, household refrigerators and freezers, cold storage refrigeration systems, and polyurethane foams; operators of cold storage refrigeration systems, including refrigerated warehouses, wholesalers, and food manufacturers; and manufacture and use cold storage warehouses, and small businesses that import products containing closed cell phenolic, polyisocyanurate, polyolefin, PU, and polystyrene foams manufactured with HFC or HCFC foam blowing agents. The proposal to prohibit use of methylene chloride as a foam blowing agent is not anticipated to impact small businesses because this substance is not expected to be used currently as a blowing agent. This rule’s provisions do not create enforceable requirements for refrigeration and AC technicians, but they would indirectly affect technicians servicing motor vehicle AC systems, certain types of retail food refrigeration equipment, cold storage warehouses, and commercial AC equipment where the technician, rather than the refrigeration or AC equipment owner, purchases servicing equipment for different refrigerants. EPA expects these indirect impacts on technicians are minimal, because the transitions to different refrigerants required by this proposed rule are already occurring due to corporate social responsibility initiatives (e.g., Consumer Goods Forum pledge concerning HFC refrigerants), and because many of the still-acceptable alternatives are already used for these refrigeration or AC equipment types. Further, most acceptable HFC refrigerant blends can be recovered and serviced using equipment that service technicians already own. In some uses, there is no significant impact of the proposed rule because the substitutes proposed to be prohibited are not widely used (e.g., use of perfluorocarbons for fire suppression, use of methylene chloride as a foam blowing agent in various types of foam). A significant portion of the businesses regulated under this proposed rule are not small businesses (e.g., commercial AC manufacturers). We have therefore concluded that this action will not have a significant impact on a significant number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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. EPA is aware that the California Air Resources Board is considering regulation of a number of the substitutes and end-uses in this proposed rule. EPA specifically solicits comment on whether any state agencies have existing environmental requirements affecting the substitutes and the end-uses in this proposed rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action. EPA specifically solicits additional comment on this proposed action from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This proposed rule restricts the use of certain substitutes that have greater overall risks for human health and the environment, primarily due to their high global warming potential. The reduction in GHG emissions would provide climate benefits for all people, including benefits for children and future generations. The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure to the alternatives addressed in the comparisons of toxicity for the various substitutes, as well as risk screens for the substitutes that are proposed to be listed as acceptable, subject to use conditions, or are newly listed as unacceptable.234 235 236 237 238 The risk screens are in the docket for this rulemaking.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. For the end-uses that are related to energy effects such as refrigeration and AC, a number of alternatives are available to replace those refrigerants that are proposed as unacceptable in this action; many of the alternatives are as energy efficient or more energy efficient than the substitutes being used.
proposed unacceptable. Thus, we have concluded that this proposed rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act (NNTAA) and 1 CFR Part 51

This action involves technical standards. EPA proposes to use standards from UL in the use conditions for propane. These use conditions would ensure that these new substitutes for very low temperature refrigeration equipment, commercial ice machines, and water coolers, do not present significantly greater risk to human health or the environment than other alternatives.


Specifically, these standards are:
1. Supplement SB to UL Standard 399: Requirements for Drinking Water Coolers Employing A Flammable Refrigerant in the Refrigerating System (7th Edition, August 22, 2008). This document establishes requirements for self-contained drinking water coolers, including those supplying cold and/or hot water and those employing flammable refrigerants. The standard is available at http://ulstandards.ul.com/standard/?id=399, and may be purchased by mail at: COMM 2000, 151 Eastern Avenue, Bensenville, IL 60106; Email: orders@comm-2000.com; Telephone: 1–888–853–3503 in the U.S. or Canada (other countries dial +1–415–352–2168); Internet address: http://ulstandards.ul.com/ or www.comm-2000.com. The cost of UL 399 is $798 for an electronic copy and $998 for hardcopy. UL also offers a subscription service to the SCCL that allows unlimited access to their standards and related documents. The cost of obtaining this standard is not a financial burden for equipment manufacturers and purchase is not required for those selling, installing and servicing the equipment. Therefore, EPA concludes that the UL standard being incorporated by reference is reasonably available.
2. Supplement SA to UL Standard 471: Requirements for Refrigerators and Freezers Employing A Flammable Refrigerant in the Refrigerating System (10th Edition, November 24, 2010). This document establishes requirements for commercial refrigerators and freezers that employ a refrigerant that has been identified as having flammable characteristics. The standard is available at http://ulstandards.ul.com/standard/?id=471&edition=10&doctype=ulstd, and may be purchased by mail at: COMM 2000, 151 Eastern Avenue, Bensenville, IL 60106; Email: orders@comm-2000.com; Telephone: 1–888–853–3503 in the U.S. or Canada (other countries dial +1–415–352–2168); Internet address: http://ulstandards.ul.com/ or www.comm-2000.com. The cost of UL 471 is $716 for an electronic copy and $897 for hardcopy. UL also offers a subscription service to the SCCL that allows unlimited access to their standards and related documents. The cost of obtaining this standard is not a significant financial burden for equipment manufacturers and purchase is not required for those selling, installing and servicing the equipment. Therefore, EPA concludes that the UL standard being incorporated by reference is reasonably available.
3. Supplement SA to UL Standard 563: Requirements for Ice Makers Employing a Flammable Refrigerant in the Refrigeration System (8th Edition, July 31, 2009). This document establishes requirements for automatic ice makers, including unitary and remote ice makers. The standard is available at http://ulstandards.ul.com/standard/?id=563&edition=8&doctype=ulstd, and may be purchased by mail at: COMM 2000, 151 Eastern Avenue, Bensenville, IL 60106; Email: orders@comm-2000.com; Telephone: 1–888–853–3503 in the U.S. or Canada (other countries dial +1–415–352–2168); Internet address: http://ulstandards.ul.com/ or www.comm-2000.com. The cost of UL 563 is $716 for an electronic copy and $897 for hardcopy. UL also offers a subscription service to the SCCL that allows unlimited access to their standards and related documents. The cost of obtaining this standard is not a financial burden for equipment manufacturers and purchase is not required for those selling, installing and servicing the equipment. Therefore, EPA concludes that the UL standard being incorporated by reference is reasonably available.

EPA concludes that the ASHRAE standard being incorporated by reference is reasonably available.

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J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action’s health and risk assessments are contained in the comparisons of toxicity for the various substitutes, as well as risk screens for the substitutes that are proposed to be listed as acceptable, subject to use conditions, or are newly listed as unacceptable.

VIII. References


Doniger and Yurek, 2016. Doniger, David (NRDC) and Stephen Yurek (AHRI). February 1, 2016. AHRI/NRDC Letter Regarding Chiller Actions Under SNAP.


ICF, 2009a. Revised Final Draft Assessment of the Potential Impacts of HFO-1234yf and the Associated Production of TFA on Aquatic Communities and Local Air Quality.


ICF, 2010c. Revised Assessment of the Potential Impacts of HFO-1234yf and the Associated Production of TFA on Aquatic Communities, Soil and Plants, and Local Air Quality.

ICF, 2010d. Sensitivity Analysis CMAQ results on projected maximum TFA rainwater concentrations and maximum 8-hr ozone concentrations.


ICF, 2014b. Risk Screen on Substitutes for HCFC-22 in Residential and Light Commercial Air Conditioning and Heat Pumps; Substitute: Propane (R-220).


List of Subjects in 40 CFR Part 82
Environmental protection, Air pollution control, Incorporation by reference, Recycling, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: March 29, 2016.

Gina McCarthy, Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 82 as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart F—Recycling and Emissions Reduction

2. Amend § 82.154 by adding paragraph (a)(1)(iv) to read as follows:

§ 82.154 Prohibitions.

(a) * * *

(1) * * *

(iv) Effective [DATE 30 DAYS AFTER PUBLICATION OF THE FINAL RULE], propane (R-290) in self-contained commercial ice machines, very low temperature refrigeration equipment, and water coolers.

* * * * *

Subpart G—Significant New Alternatives Policy Program

3. Appendix B to subpart G of part 82 is amended by adding three entries at the end of the table titled “Refrigerants—Acceptable Subject to Use Conditions” to read as follows:

Appendix B to Subpart G of Part 82—Substitutes Subject to Use Restrictions and Unacceptable Substitutes

Refrigerants—Acceptable Subject to Use Conditions

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Decision</th>
<th>Conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motor vehicle air conditioning (newly manufactured medium-duty passenger vehicles).</td>
<td>HFO-1234yf</td>
<td>Acceptable subject to use conditions.</td>
<td>As of [date 30 days after publication of final rule]: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639 (adopted 2011), including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844 (revised October 2011). (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739 (adopted 2009). Manufacturers must keep the FMEA on file for at least three years from the date of creation.</td>
<td>Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS. Reg. No. 754–12–1).</td>
</tr>
</tbody>
</table>
### Refrigerants—Acceptable Subject to Use Conditions—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Decision</th>
<th>Conditions</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Motor vehicle air conditioning (newly manufactured heavy-duty pickup trucks) | HFO-1234yf .......... | Acceptable subject to use conditions. | As of [date 30 days after publication of final rule]:  
(1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639 (adopted 2011), including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844 (revised October 2011).  
(2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739 (adopted 2009). Manufacturers must keep the FMEA on file for at least three years from the date of creation. | Additional training for service technicians recommended.  
HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No 754–12–1). |
| Motor vehicle air conditioning (newly manufactured complete heavy-duty vans only). | HFO-1234yf .......... | Acceptable subject to use conditions. | As of [date 30 days after publication of final rule]:  
(1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639 (adopted 2011), including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844 (revised October 2011).  
(2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739 (adopted 2009). Manufacturers must keep the FMEA on file for at least three years from the date of creation. | Additional training for service technicians recommended.  
HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No 754–12–1).  
HFO-1234yf is acceptable for complete heavy-duty vans. Complete heavy-duty vans are not altered by a secondary or tertiary manufacturer. |

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**Fire Suppression and Explosion Protection—Acceptable Subject to Narrowed Use Limits: Total Flooding Agents**

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Conditions</th>
<th>Further information</th>
</tr>
</thead>
</table>
| Total flooding                    | HFC-236fa ..        | Acceptable subject to narrowed use limits. | Acceptable when manufactured using any process that does not convert perfluorobutyl (PFB) directly to HFC-236fa in a single step:  
For use in explosion suppression and explosion inertion applications, and for use in fire suppression applications where other non-PFC agents or alternatives are not technically feasible due to performance or safety requirements:  
(a) Because of their physical or chemical properties, or  
(b) where human exposure to the extinguishing agents may result in failure to meet safety guidelines in the latest edition of the NFPA 2001 Standard for Clean Agent Fire Extinguishing Systems. | Use of this agent should be in accordance with the safety guidelines in the latest edition of the NFPA 2001 Standard for Clean Agent Fire Systems.  
Users should observe the limitations on HFC-236fa acceptability by taking the following measures:  
(i) Conduct an evaluation of foreseeable conditions of end-use;  
(ii) determine that the physical or chemical properties, or other technical constraints of the other available agents preclude their use; and  
(iii) determine that human exposure to the other alternative extinguishing agents may result in failure to meet safety guidelines in the latest edition of the NFPA 2001 Standard for Clean Agent Fire Extinguishing Systems.  
Documentation of such measures should be available for review upon request.  
The principal environmental characteristic of concern for HFC-236fa is its high GWP of 9400 and long atmospheric lifetime of 226 years. Actual contributions to global warming depend upon the quantities emitted.  
See additional comments 1, 2, 3, 4, 5. |

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Additional comments:
1—Should conform with relevant OSHA requirements, including 29 CFR 1910, Subpart L, Sections 1910.160 and 1910.162.
2—Per OSHA requirements, protective gear (SCBA) should be available in the event personnel should reenter the area.
3—Discharge testing should be strictly limited to that which is essential to meet safety or performance requirements.
4—The agent should be recovered from the fire protection system in conjunction with testing or servicing, and recycled for later use or destroyed.
5—EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protective equipment (e.g., respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to halon substitutes.

* * * * *

5. Appendix K to subpart G of part 82 is revised to read as follows:

FOAM BLOWING—UNACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOAM BLOWING—UNACCEPTABLE SUBSTITUTES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Replacements for HCFC-141b in the following rigid polyurethane/polyisocyanurate applications:</td>
<td>HCFC-22, HCFC-142b and blends thereof.</td>
<td>Unacceptable</td>
<td>Alternatives exist with lower or zero-ODP.</td>
</tr>
<tr>
<td>—Boardstock</td>
<td></td>
<td>Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td></td>
</tr>
<tr>
<td>—Appliance</td>
<td></td>
<td>Unacceptable</td>
<td></td>
</tr>
<tr>
<td>—Spray</td>
<td>HCFC-124</td>
<td>Closed cell foam products and products containing closed cell foams manufactured with this substitute on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td>Alternatives exist with lower or zero-ODP.</td>
</tr>
<tr>
<td>All foam end-uses</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Appendix M to subpart G of part 82 is revised to read as follows:

FOAM BLOWING—UNACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOAM BLOWING—UNACCEPTABLE SUBSTITUTES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All foam end-uses:</td>
<td>HCFC-141b</td>
<td>Unacceptable</td>
<td>Alternatives exist with lower or zero-ODP.</td>
</tr>
<tr>
<td>—rigid polyurethane and polysisocyanurate laminated boardstock</td>
<td></td>
<td>Closed cell foam products and products containing closed cell foams manufactured with this substitute on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td></td>
</tr>
<tr>
<td>—rigid polyurethane appliance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>—rigid polyurethane spray and commercial refrigeration, and sandwich panels</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>—rigid polyurethane slabstock and other foams</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>—polystyrene extruded insulation boardstock and billet</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>—phenolic insulation board and bunstock</td>
<td></td>
<td></td>
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<tr>
<td>—flexible polyurethane</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>—polystyrene extruded sheet</td>
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<td></td>
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<tr>
<td>Except for: ¹</td>
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<td></td>
<td></td>
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<tr>
<td>—space vehicle</td>
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<tr>
<td>—nuclear</td>
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<td></td>
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<tr>
<td>—defense</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>—research and development for foreign customers</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

¹ Exemptions for specific applications are identified in the list of acceptable substitutes.

7. Appendix O to subpart G of part 82 is revised to read as follows:

Appendix O to Subpart G of Part 82—Substitutes Listed in the September 27, 2006 Final Rule, Effective November 27, 2006
### FIRE SUPPRESSION AND EXPLOSION PROTECTION SECTOR—TOTAL FLOODING SUBSTITUTES—ACCEPTABLE SUBJECT TO USE CONDITIONS

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Conditions</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total flooding</td>
<td>Gelled Halocarbon/Dry Chemical Suspension (Envirogel) with sodium bicarbonate additive.</td>
<td>Acceptable subject to use conditions.</td>
<td>Use of whichever hydrofluorocarbon gas (HFC-125, HFC-227ea, or HFC-236fa) is employed in the formulation must be in accordance with all requirements for acceptability (i.e., narrowed use limits) of that HFC under EPA’s SNAP program.</td>
<td>Use of this agent should be in accordance with the safety guidelines in the latest edition of the NFPA 2001 Standard for Clean Agent Fire Extinguishing Systems, for whichever hydrofluorocarbon gas is employed, and the latest edition of the NFPA 2010 standard for Aerosol Extinguishing Systems. Sodium bicarbonate release in all settings should be targeted so that increased blood pH level would not adversely affect exposed individuals. Users should provide special training, including the potential hazards associated with the use of the HFC agent and sodium bicarbonate, to individuals required to be in environments protected by Envirogel with sodium bicarbonate additive extinguishing systems. Each extinguisher should be clearly labeled with the potential hazards from use and safe handling procedures. See additional comments 1, 2, 3, 4, 5.</td>
</tr>
<tr>
<td>Total flooding</td>
<td>Powdered Aerosol E (FirePro®).</td>
<td>Acceptable subject to use conditions.</td>
<td>For use only in normally unoccupied areas.</td>
<td>Use of this agent should be in accordance with the safety guidelines in the latest edition of the NFPA 2010 standard for Aerosol Extinguishing Systems. For establishments manufacturing the agent or filling, installing, or servicing containers or systems to be used in total flooding applications, EPA recommends the following: Adequate ventilation should be in place to reduce airborne exposure to constituents of agent; an eye wash fountain and quick drench facility should be close to the production area; training for safe handling procedures should be provided to all employees that would be likely to handle containers of the agent or extinguishing units filled with the agent; workers responsible for clean up should allow for maximum settling of all particulates before reentering area and wear appropriate protective equipment; and all spills should be cleaned up immediately in accordance with good industrial hygiene practices. See additional comments 1, 2, 3, 4, 5.</td>
</tr>
<tr>
<td>Total flooding</td>
<td>Phosphorous Tribromide (PBr₃).</td>
<td>Acceptable subject to use conditions.</td>
<td>For use only in aircraft engine nacelles.</td>
<td>For establishments manufacturing the agent or filling, installing, or servicing containers or systems, EPA recommends the following: Adequate ventilation should be in place and/or positive pressure, self-contained breathing apparatus (SCBA) should be worn; training for safe handling procedures should be provided to all employees that would be likely to handle containers of the agent or extinguishing units filled with the agent; and all spills should be cleaned up immediately in accordance with good industrial hygiene practices. See additional comments 1, 2, 3, 4, 5.</td>
</tr>
</tbody>
</table>

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**Additional comments:**
1—Should conform to relevant OSHA requirements, including 29 CFR 1910, Subpart L, Sections 1910.160 and 1910.162.
2—Per OSHA requirements, protective gear (SCBA) should be available in the event personnel should reenter the area.
3—Discharge testing should be strictly limited to that which is essential to meet safety or performance requirements.
4—The agent should be recovered from the fire protection system in conjunction with testing or servicing, and recycled for later use or destroyed.
5—EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protective equipment (e.g., respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to halon substitutes.

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**8. Appendix Q to subpart G of part 82** is revised to read as follows:

**Appendix Q to Subpart G of Part 82—Unacceptable Substitutes Listed in the March 28, 2007 Final Rule, Effective May 29, 2007**
### FOAM BLOWING UNACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>End use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid polyurethane commercial refrigeration</td>
<td>HCFC-22, HCFC-142b as substitutes for HCFC-141b.</td>
<td>Unacceptable 1</td>
<td>Alternatives exist with lower or zero-ODP.</td>
</tr>
<tr>
<td>Rigid polyurethane sandwich panels</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid polyurethane slabstock and other foams</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid polyurethane and polysiocyanurate laminated boardstock</td>
<td>HCFC-22, HCFC-142b as substitutes for CFCs.</td>
<td>Unacceptable 2</td>
<td>Alternatives exist with lower or zero-ODP.</td>
</tr>
<tr>
<td>Rigid polyurethane appliance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid polyurethane spray and commercial refrigeration, and sandwich panels</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigid polyurethane slabstock and other foams</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Polystyrene extruded insulation boardstock and billet</td>
<td></td>
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<tr>
<td>Phenolic insulation board and bunstock</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexible polyurethane</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polystyrene extruded sheet</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 For existing users of HCFC-22 and HCFC-142b as of November 4, 2005 other than in marine applications, the unacceptability determination is effective on March 1, 2008. For existing users of HCFC-22 and HCFC-142b as of November 4, 2005 in marine applications, including marine flotation foam, the unacceptability determination is effective on September 1, 2009. For an existing user of HCFC-22 or HCFC-142b that currently operates in only one facility that it does not own, and is scheduled to transition to a non-ODS, flammable alternative to coincide with a move to a new facility and installation of new process equipment that cannot be completed by March 1, 2008, the unacceptability determination is effective on January 1, 2010.

2 For existing users of HCFC-22 and HCFC-142b in polystyrene extruded insulation boardstock and billet and the other foam end uses, as of November 4, 2005, the unacceptability determination is effective on January 1, 2010.

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### 9. Appendix U to subpart G of part 82

Appendix U to Subpart G of Part 82—Unacceptable Substitutes and Substitutes Subject to Use Restrictions Listed in the July 20, 2015 Final Rule, Effective September 18, 2015

* * * *

### FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Narrowed use limits</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid Polyurethane: Appliance</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel Tl and Formacel Z-6.</td>
<td>Acceptable Subject to Narrowed Use Limits.</td>
<td></td>
<td>Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: Process or product in which the substitute is needed; Substitutes examined and rejected; Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or Anticipated date other substitutes will be available and projected time for switching.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Commercial Refrigeration and Sandwich Panels</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel Tl and Formacel Z-6.</td>
<td>Acceptable Subject to Narrowed Use Limits.</td>
<td></td>
<td>Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: Process or product in which the substitute is needed; Substitutes examined and rejected; Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or Anticipated date other substitutes will be available and projected time for switching.</td>
</tr>
</tbody>
</table>
### FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Narrowed use limits</th>
<th>Further information</th>
</tr>
</thead>
</table>
| Flexible Polyurethane Sheet.    | HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof. | Acceptable Subject to Narrowed Use Limits.    | Acceptable from January 1, 2017, until January 1, 2022 in military applications and until January 1, 2025 in space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
- Process or product in which the substitute is needed;  
- Substitutes examined and rejected;  
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
- Anticipated date other substitutes will be available and projected time for switching. |
| Rigid Polyurethane Slabstock and Other. | HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6. | Acceptable Subject to Narrowed Use Limits.    | Acceptable from January 1, 2019, until January 1, 2022, in military applications and until January 1, 2025, in space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
- Process or product in which the substitute is needed;  
- Substitutes examined and rejected;  
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
- Anticipated date other substitutes will be available and projected time for switching. |
| Rigid Polyurethane and Polysocyanurate Laminated Boardstock. | HFC-134a, HFC-245fa, HFC-365mfc and blends thereof. | Acceptable Subject to Narrowed Use Limits.    | Acceptable from January 1, 2017, until January 1, 2022, in military applications and until January 1, 2025, in space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
- Process or product in which the substitute is needed;  
- Substitutes examined and rejected;  
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
- Anticipated date other substitutes will be available and projected time for switching. |
| Rigid Polyurethane:           | Marine Flotation Foam. | HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6. | Acceptable Subject to Narrowed Use Limits.    | Acceptable from January 1, 2020, until January 1, 2022, in military applications and until January 1, 2025, in space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
- Process or product in which the substitute is needed;  
- Substitutes examined and rejected;  
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
- Anticipated date other substitutes will be available and projected time for switching. |
| Polystyrene: Extruded Sheet.  | HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6. | Acceptable Subject to Narrowed Use Limits.    | Acceptable from January 1, 2017, until January 1, 2022, in military applications and until January 1, 2025, in space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
- Process or product in which the substitute is needed;  
- Substitutes examined and rejected;  
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
- Anticipated date other substitutes will be available and projected time for switching. |

Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

Information should include descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

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- Anticipated date other substitutes will be available and projected time for switching.

Information should include descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

Information should include descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.
## FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Narrowed use limits</th>
<th>Further information</th>
</tr>
</thead>
</table>
| Polystyrene: Extruded Boardstock and Billet. | HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, Formacel B, and Formacel Z-6. | Acceptable Subject to Narrowed Use Limits. | Acceptable from January 1, 2021, until January 1, 2025, in space- and aerosaftics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
• Process or product in which the substitute is needed;  
• Substitutes examined and rejected;  
• Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
• Anticipated date other substitutes will be available and projected time for switching. |
| Integral Skin Polyurethane.                 | HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6. | Acceptable Subject to Narrowed Use Limits. | Acceptable from January 1, 2017, until January 1, 2022, in military applications and until January 1, 2025, in space- and aerosaftics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
• Process or product in which the substitute is needed;  
• Substitutes examined and rejected;  
• Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
• Anticipated date other substitutes will be available and projected time for switching. |
| Polyolefin                                   | HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6. | Acceptable Subject to Narrowed Use Limits. | Acceptable from January 1, 2020, until January 1, 2022, in military applications and until January 1, 2025, in space- and aerosaftics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
• Process or product in which the substitute is needed;  
• Substitutes examined and rejected;  
• Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
• Anticipated date other substitutes will be available and projected time for switching. |
| Phenolic Insulation Board and Bunstock.      | HFC-143a, HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof. | Acceptable Subject to Narrowed Use Limits. | Acceptable from January 1, 2017, until January 1, 2022, in military applications and until January 1, 2025, in space- and aerosaftics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
• Process or product in which the substitute is needed;  
• Substitutes examined and rejected;  
• Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
• Anticipated date other substitutes will be available and projected time for switching. |

## UNACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Foam Blowing End-uses.</td>
<td>HCFC-141b and blends thereof.</td>
<td>Unacceptable effective September 18, 2015. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td>HCFC-141b has an ozone depletion potential of 0.11 under the Montreal Protocol. EPA previously found HCFC-141b unacceptable in all foam blowing end-uses (appendix M to subpart G of 40 CFR part 82). HCFC-141b has an ozone depletion potential (ODP) of 0.11. Use or introduction into interstate commerce of virgin HCFC-22 and HCFC-142b for foam blowing is prohibited after January 1, 2010 under EPA’s regulations at 40 CFR part 82 subpart A unless used, recovered, and recycled. These compounds have ODPs of 0.055 and 0.065, respectively.</td>
</tr>
<tr>
<td>All Foam Blowing End-uses.</td>
<td>HCFC-22, HCFC-142b, and blends thereof.</td>
<td>Unacceptable effective September 18, 2015. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td>HCFC-141b has an ozone depletion potential of 0.11 under the Montreal Protocol. EPA previously found HCFC-141b unacceptable in all foam blowing end-uses (appendix M to subpart G of 40 CFR part 82). HCFC-141b has an ozone depletion potential (ODP) of 0.11. Use or introduction into interstate commerce of virgin HCFC-22 and HCFC-142b for foam blowing is prohibited after January 1, 2010 under EPA’s regulations at 40 CFR part 82 subpart A unless used, recovered, and recycled. These compounds have ODPs of 0.055 and 0.065, respectively.</td>
</tr>
</tbody>
</table>
### UNACCEPTABLE SUBSTITUTES—Continued

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexible Polyurethane.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof.</td>
<td>Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.</td>
<td>These foam blowing agents have global warming potentials (GWPs) ranging from 725 to 1,430. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Polystyrene: Extruded Sheet.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2017, except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Phenolic Insulation Board and Bunstock.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof.</td>
<td>Unacceptable as of January 1, 2017, except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from 725 to 4,470. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Integral Skin Polyurethane.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2017, except where allowed under a narrowed use limit.</td>
<td>These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Slabstock and Other.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2019, except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before January 1, 2019, may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Rigid Polyurethane and Polyisocyanurate Laminated Boardstock.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof.</td>
<td>Unacceptable as of January 1, 2017, except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE] may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from 725 to 1,430. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Marine Flotation Foam.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2020 except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before January 1, 2020, may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Commercial Refrigeration and Sandwich Panels.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2020 except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before January 1, 2020, may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Rigid Polyurethane: Appliance.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2020 except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before January 1, 2020, may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Polystyrene: Extruded Boardstock and Billet.</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2017, except where allowed under a narrowed use limit. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before January 1, 2017, may be used after that date.</td>
<td>These foam blowing agents have GWPs ranging from 725 to 1,430. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Polyolefin ..........</td>
<td>HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.</td>
<td>Unacceptable as of January 1, 2020, except where allowed under a narrowed use limit.</td>
<td>These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
</tbody>
</table>
10. Add appendix V to subpart G of part 82, to read as follows:

### Appendix V to Subpart G of Part 82—Substitutes Subject to Use Restrictions and Unacceptable Substitutes Listed in the [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] Final Rule

**REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS**

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Use Conditions</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial ice machines (self-contained) (new only).</td>
<td>Propane (R-290) ..........</td>
<td>Acceptable, subject to use conditions.</td>
<td>As of [date 30 days after publication of final rule]; this refrigerant may be used only in new equipment designed specifically and clearly identified for the refrigerant—i.e., this refrigerant may not be used as a conversion or “retrofit” refrigerant for existing equipment.</td>
<td>Applicable OSHA requirements at 29 CFR part 1910 must be followed, including those at 29 CFR 1910.106 (flammable and combustible liquids), 1910.110 (storage and handling of liquefied petroleum gases), 1910.157 (portable fire extinguishers), and 1910.1000 (toxic and hazardous substances). Proper ventilation should be maintained at all times during the manufacture and storage of equipment containing hydrocarbon refrigerants through adherence to good manufacturing practices as per 29 CFR 1910.106. If refrigerant levels in the air surrounding the equipment rises above one-fourth of the lower flammability limit, the space should be evacuated and re-entry should occur only after the space has been properly ventilated. Technicians and equipment manufacturers should wear appropriate personal protective equipment, including chemical goggles and protective gloves, when handling these refrigerants. Special care should be taken to avoid contact with the skin since these refrigerants, like many refrigerants, can cause freeze burns on the skin. A Class B dry powder type fire extinguisher should be kept nearby. Technicians should only use spark-proof tools when working on refrigerators and freezers with these refrigerants. Any recovery equipment used should be designed for flammable refrigerants. Any refrigerant releases should be in a well-ventilated area, such as outside of a building. Only technicians specifically trained in handling flammable refrigerants should service refrigerators and freezers containing these refrigerants. Technicians should gain an understanding of minimizing the risk of fire and the steps to use flammable refrigerants safely. Room occupants should evacuate the space immediately following the accidental release of this refrigerant. If a service port is added then retail food refrigerators and freezers using these refrigerants should have service aperture fittings that differ from fittings used in equipment or containers using non-flammable refrigerant. “Differ” means that either the diameter differs by at least ( \frac{1}{8} ) inch or the thread direction is reversed (i.e., right-handed vs. left-handed). These different fittings should be permanently affixed to the unit at the point of service and maintained until the end-of-life of the unit, and should not be accessed with an adaptor.</td>
</tr>
</tbody>
</table>

### Further information:

- (a) “DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. Do Not Use Mechanical Devices To Defrost Refrigerator. Do Not Puncture Refrigerant Tubing.” This marking must be provided on or near any evaporators that can be contacted by the consumer.
- (b) “DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. To Be Repaired Only By Trained Service Personnel. Do Not Puncture Refrigerant Tubing.” This marking must be located near the machine compartment.
- (c) “CAUTION—Risk of Fire or Explosion. Flammable Refrigerant Used. Consult Repair Manual/Owner's Guide Before Attempting To Service This Product. All Safety Precautions Must Be Followed.” This marking must be located near the machine compartment.
- (d) “CAUTION—Risk of Fire or Explosion. Dispose of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used.” This marking must be provided on the exterior of the refrigeration equipment.
- (e) “CAUTION—Risk of Fire or Explosion Due To Puncture Of Refrigerant Tubing; Follow Handling Instructions Carefully. Flammable Refrigerant Used.” This marking must be provided near all exposed refrigerant tubing. All of these markings must be in letters no less than 6.4 mm (\( \frac{1}{4} \) inch) high.
### REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

<table>
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<th>Decision</th>
<th>Use Conditions</th>
<th>Further information</th>
</tr>
</thead>
</table>
| Very low temperature refrigeration equipment (new only). | Propane (R-290) | Acceptable, subject to use conditions. | The equipment must have red Pantone Matching System (PMS) #185 marked pipes, hoses, or other devices through which the refrigerant passes, to indicate the use of a flammable refrigerant. This color must be applied at all service ports and other parts of the system where service puncturing or other actions creating an opening from the refrigerant circuit to the atmosphere might be expected and must extend a minimum of one (1) inch in both directions from such locations. As of [date 30 days after publication of final rule]: This refrigerant may be used only in new equipment designed specifically and clearly identified for the refrigerant—i.e., this refrigerant may not be used as a conversion or "retrofit" refrigerant for existing equipment. This refrigerant may only be used in equipment that meets all requirements in Supplement SB to UL 471. In cases where the final rule includes requirements more stringent than those of UL 471, the appliance must meet the requirements of the final rule in place of the requirements in the UL Standard. The charge size for the equipment must not exceed 150 grams (5.29 ounces) in each refrigerant circuit of the very low temperature refrigeration equipment. As provided in clauses SB6.1.2 to SB6.1.5 of UL 471, the following markings must be attached at the locations provided and must be permanent:  
(a) "DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. Do Not Use Mechanical Devices To Defrost Refrigerator. Do Not Puncture Refrigerant Tubing." This marking must be provided on or near any evaporators that can be contacted by the consumer.  
(b) "DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. To Be Repaired Only By: Trained Service Personnel. Do Not Puncture Refrigerant Tubing." This marking must be located near the machine compartment.  
(c) "CAUTION—Risk of Fire or Explosion. Flammable Refrigerant Used. Consult Repair Manual/Owner’s Guide Before Attempting To Service This Product. All Safety Precautions Must Be Followed." This marking must be located near the machine compartment.  
(d) "CAUTION—Risk of Fire or Explosion. Dispose of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used." This marking must be provided on the exterior of the refrigeration equipment.  
(e) "CAUTION—Risk of Fire or Explosion Due To Puncture Of Refrigerant Tubing; Follow Handling Instructions Carefully. Flammable Refrigerant Used." This marking must be provided near all exposed refrigerant tubing. All of these markings must be in letters no less than 6.4 mm (¼ inch) high. Applicable OSHA requirements at 29 CFR 1910.106. If refrigerant levels in the air exceed one-fourth of the lower flammability limit, the space should be evacuated and re-entry should occur only after the space has been properly ventilated. Technicians and equipment manufacturers should wear appropriate personal protective equipment, including chemical goggles and protective gloves, when handling ethane. Special care should be taken to avoid contact with the skin since ethane, like many refrigerants, can cause freeze burns on the skin. A Class B dry powder type fire extinguisher should be kept nearby. Technicians should only use spark-proof tools when working on equipment with flammable refrigerants. Any recovery equipment used should be designed for flammable refrigerants. Any refrigerant releases should be in a well-ventilated area, such as outside of a building. Only technicians specifically trained in handling flammable refrigerants should service equipment containing ethane. Technicians should gain an understanding of minimizing the risk of fire and the steps to use flammable refrigerants safely. Room occupants shall evacuate the space immediately following the accidental release of this refrigerant. If a service port is added then retail food refrigerators and freezers using these refrigerants should have service aperture fittings that differ from fittings used in equipment or containers using non-flammable refrigerant. "Differ" means that either the diameter differs by at least ¼ inch or the thread direction is reversed (i.e., right-handed vs. left-handed). These different fittings should be permanently affixed to the unit at the point of service and maintained until the end-of-life of the unit, and should not be accessed with an adaptor. |
## REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Use Conditions</th>
<th>Further information</th>
</tr>
</thead>
</table>
| Water coolers (new only)   | Propane (R-290) | Acceptable, subject to use conditions. | The equipment must have red PMS #185 marked pipes, hoses, or other devices through which the refrigerant passes, to indicate the use of a flammable refrigerant. This color must be applied at all service ports and other parts of the system where service puncturing or other actions creating an opening from the refrigerant circuit to the atmosphere might be expected and must extend a minimum of one (1) inch in both directions from such locations. As of [date 30 days after publication of final rule]: This refrigerant may be used only in new equipment designed specifically and clearly identified for the refrigerant—i.e., this refrigerant may not be used as a conversion or “retrofit” refrigerant for existing equipment. This refrigerant may be used only in water coolers that meet all requirements listed in Supplement SB to UL 399 (1998-2016) in cases where the rule includes requirements more stringent than those of the UL 399, the appliance must meet the requirements of the final rule in place of the requirements in the UL Standard. The charge size must not exceed 150 grams (5.29 ounces) per refrigerant circuit in the water cooler. The equipment must have red PMS #185 marked pipes, hoses, or other devices through which the refrigerant passes, to indicate the use of a flammable refrigerant. This color must be applied at all service ports and other parts of the system where service puncturing or other actions creating an opening from the refrigerant circuit to the atmosphere might be expected and must extend a minimum of one (1) inch in both directions from such locations. As provided in clauses SB6.1.2 to SB6.1.5 of UL 399, the following markings must be attached at the locations provided and must be permanent:

(a) “DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. Do Not Use Mechanical Devices To Defrost Refrigerator. Do Not Puncture Refrigerant Tubing.” This marking must be provided on or near any evaporators that can be contacted by the consumer.

(b) “DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. To Be Repaired Only By Trained Service Personnel. Do Not Puncture Refrigerant Tubing.” This marking must be located near the machine compartment.

(c) “CAUTION—Risk of Fire or Explosion. Flammable Refrigerant Used. Consult Repair Manual/Owner’s Guide Before Attempting To Service This Product. All Safety Precautions Must Be Followed.” This marking must be located near the machine compartment. | Very low temperature equipment using propane may also use another acceptable refrigerant substitute in a separate refrigerant circuit or stage (e.g., one temperature stage with propane and a second stage with ethane). Applicable OSHA requirements at 29 CFR part 1910 must be followed, including those at 29 CFR 1910.94 (ventilation) and 1910.106 (flammable and combustible liquids), 1910.110 (storage and handling of liquefied petroleum gases), 1910.157 (portable fire extinguishers), and 1910.1000 (toxic and hazardous substances). Proper ventilation should be maintained at all times during the manufacture and storage of equipment containing hydrocarbon refrigerants through adherence to good manufacturing practices as per 29 CFR 1910.106. If refrigerant levels in the air surrounding the equipment rise above one-fourth of the lower flammability limit, the space should be evacuated and re-entry should occur only after the space has been properly ventilated. Technicians and equipment manufacturers should wear appropriate personal protective equipment, including chemical goggles and protective gloves, when handling ethane. Special care should be taken to avoid contact with the skin since ethane, like many refrigerants, can cause freeze burns on the skin. A Class B dry powder type fire extinguisher should be kept nearby. |
REFRIGERANTS—ACCEPtable SUBJECT TO USE CONDITIONS—Continued

<table>
<thead>
<tr>
<th>End-use</th>
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<th>Use Conditions</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centrifugal chillers</td>
<td>HFC-134a ...............</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>If a service port is added then retail food refrigerators and freezers using these refrigerants should have service aperture fittings that differ from fittings used in equipment or containers using non-flammable refrigerant. “Differ” means that either the diameter differs by at least 1/6 inch or the thread direction is reversed (i.e., right-handed vs. left-handed). These different fittings should be permanently affixed to the unit at the point of service and maintained until the end-of-life of the unit, and should not be accessed with an adaptor.</td>
<td></td>
</tr>
<tr>
<td>(new only).</td>
<td></td>
<td></td>
<td>(d) “CAUTION—Risk of Fire or Explosion. Dispose of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used.” This marking must be provided on the exterior of the refrigeration equipment.</td>
<td></td>
</tr>
<tr>
<td>Centrifugal chillers</td>
<td>HFC-134a and R-404A.</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>Acceptable after January 1, 2024, only in military marine vessels where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.</td>
<td></td>
</tr>
<tr>
<td>(new only).</td>
<td></td>
<td></td>
<td>(e) “CAUTION—Risk of Fire or Explosion Due To Puncture Of Refrigerant Tubing; Follow Handling Instructions Carefully, Flammable Refrigerant Used.” This marking must be provided near all exposed refrigerant tubing.</td>
<td></td>
</tr>
<tr>
<td>Positive displacement</td>
<td>HFC-134a ...............</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>If a service port is added then retail food refrigerators and freezers using these refrigerants should have service aperture fittings that differ from fittings used in equipment or containers using non-flammable refrigerant. “Differ” means that either the diameter differs by at least 1/6 inch or the thread direction is reversed (i.e., right-handed vs. left-handed). These different fittings should be permanently affixed to the unit at the point of service and maintained until the end-of-life of the unit, and should not be accessed with an adaptor.</td>
<td></td>
</tr>
<tr>
<td>chillers (new only).</td>
<td></td>
<td></td>
<td>(d) “CAUTION—Risk of Fire or Explosion. Dispose of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used.” This marking must be provided on the exterior of the refrigeration equipment.</td>
<td></td>
</tr>
</tbody>
</table>

1 The Director of the Federal Register approves the materials in these footnotes for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at U.S. EPA’s Air and Radiation Docket; EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington DC or at the National Archives and Records Administration (NARA). For questions regarding access to these standards, the telephone number of EPA’s Air and Radiation Docket is 202–566–1742. For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.  

REFRIGERANTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS

<table>
<thead>
<tr>
<th>End-use</th>
<th>Substitutes</th>
<th>Decision</th>
<th>Narrowed use limits</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centrifugal chillers</td>
<td>HFC-134a ...............</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>Acceptable after January 1, 2024, only in military marine vessels where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.</td>
<td></td>
</tr>
<tr>
<td>(new only).</td>
<td></td>
<td></td>
<td>(d) “CAUTION—Risk of Fire or Explosion. Dispose of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used.” This marking must be provided on the exterior of the refrigeration equipment.</td>
<td></td>
</tr>
<tr>
<td>Centrifugal chillers</td>
<td>HFC-134a and R-404A.</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>Acceptable after January 1, 2024, only inhuman-rated spacecraft and related support equipment where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.</td>
<td></td>
</tr>
<tr>
<td>(new only).</td>
<td></td>
<td></td>
<td>(e) “CAUTION—Risk of Fire or Explosion Due To Puncture Of Refrigerant Tubing; Follow Handling Instructions Carefully, Flammable Refrigerant Used.” This marking must be provided near all exposed refrigerant tubing.</td>
<td></td>
</tr>
<tr>
<td>Positive displacement</td>
<td>HFC-134a ...............</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>Acceptable after January 1, 2024, only in military marine vessels where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.</td>
<td></td>
</tr>
<tr>
<td>chillers (new only).</td>
<td></td>
<td></td>
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### REFRIGERANTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

<table>
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<tr>
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<tr>
<td>Positive displacement chillers (new only).</td>
<td>HFC-134a and R-404A.</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>Acceptable after January 1, 2024, only inhuman-rated spacecraft and related support equipment where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.</td>
<td>Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Application in which the substitute is needed;</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Substitutes examined and rejected;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Anticipated date other substitutes will be available and qualified and projected time for switching.</td>
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<tr>
<td>Positive displacement chillers (new only).</td>
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### REFRIGERANTS—UNACCEPTABLE SUBSTITUTES

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<tbody>
<tr>
<td>Centrifugal chillers (new only).</td>
<td>FOR12A, FOR12B, HFC-134a, HFC-227ea, HFC-236fa, HFC-245fa, R-125/134a/600a (28.1/70/1.9), R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-423A, R-424A, R-434A, R-438A, R-507A, RS-44 (2003 composition), and THR-03.</td>
<td>Unacceptable as of January 1, 2024 except where allowed under a narrowed use limit.</td>
<td>These refrigerants have GWPs ranging from approximately 900 to 9,810. Other alternatives will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Centrifugal chillers (new only).</td>
<td>Propylene (R-1270) and R-443A .......................</td>
<td>Unacceptable as of [date 30 days after publication of final rule].</td>
<td>These refrigerants are highly photochemically reactive in the lower atmosphere and may deteriorate local air quality (that is, may increase ground level ozone). Other alternatives are available for this end-use with lower overall risk to human health and the environment.</td>
</tr>
<tr>
<td>Cold storage warehouses (new only).</td>
<td>Propylene (R-1270) and R-443A .......................</td>
<td>Unacceptable as of [date 30 days after publication of final rule].</td>
<td>These refrigerants are highly photochemically reactive in the lower atmosphere and may deteriorate local air quality (that is, may increase ground level ozone). Other alternatives are available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Household refrigerators and freezers (new only).</td>
<td>FOR12A, FOR12B, HFC-134a, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-423A, R-429A, R-434A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, and THR-03.</td>
<td>Unacceptable as of January 1, 2021.</td>
<td>These refrigerants have GWPs ranging from approximately 900 to 3,985. Other alternatives will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
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REFRIGERANTS—UNACCEPTABLE SUBSTITUTES—Continued

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<tr>
<td>Positive displacement chillers (new only).</td>
<td>FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/134a/600a (28.1/70/1.9), R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-424A, R-434A, R-437A, R-438A, R-507A, RS-44 (2003 composition), SP34E, and THR-03.</td>
<td>Unacceptable as of January 1, 2024 except where allowed under a narrowed use limit.</td>
<td>These refrigerants have GWP ratios ranging from approximately 900 to 3,985. Other alternatives will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Positive displacement chillers (new only).</td>
<td>Propylene (R-1270) and R-443A</td>
<td>Unacceptable as of [date 30 days after publication of final rule].</td>
<td>These refrigerants are highly photochemically reactive in the lower atmosphere and may deteriorate local air quality (that is, may increase ground level ozone). Other alternatives are available for this end-use with lower overall risk to human health and the environment.</td>
</tr>
<tr>
<td>Residential and light commercial air conditioning and heat pumps (new only).</td>
<td>Propylene (R-1270) and R-443A</td>
<td>Unacceptable as of [date 30 days after publication of a final rule].</td>
<td>These refrigerants are highly photochemically reactive in the lower atmosphere and may deteriorate local air quality (that is, may increase ground level ozone). Other alternatives are available for this end-use with lower overall risk to human health and the environment.</td>
</tr>
<tr>
<td>Residential and light commercial air conditioning—unitary split AC systems and heat pumps (retrofit only).</td>
<td>All refrigerants identified as flammability Class 3 in ANSI/ASHRAE Standard 34-2013. All refrigerants meeting the criteria for flammability Class 3 in ANSI/ASHRAE Standard 34-2013. This includes, but is not limited to, refrigerant products sold under the names R-22a, 22a, Blue Sky 22a refrigerant, Coolant Express 22a, DURACOOL-22a, EC-22, Ecofreeze EF-22a, EF-22a, Envirosafe 22a, ES-22a, Frost 22a, HC-22a, Maxi-Fridge, MX-22a, Oz-Chill 22a, Priority Cool, and RED TEK 22a.</td>
<td>Unacceptable as of [date 30 days after publication of a final rule].</td>
<td>These refrigerants are highly flammable and present a flammability risk when used in equipment designed for nonflammable refrigerants. Other alternatives are available for this end-use with lower overall risk to human health and the environment.</td>
</tr>
</tbody>
</table>

1 The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at U.S. EPA’s Air and Radiation Docket; EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington DC or at the National Archives and Records Administration (NARA). For questions regarding access to this standard, the telephone number of EPA’s Air and Radiation Docket is 202–586–1742. For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

2 American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) 6300 Interfirst Drive, Ann Arbor, MI 48108; 1–800–558–9637 (new only).


FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS

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<th>Narrowed use limits</th>
<th>Further information</th>
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<tbody>
<tr>
<td>Rigid PU: Spray foam—high-pressure two-compoment.</td>
<td>HFC-134a, HFC-249a, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc and Formacel T1.</td>
<td>Acceptable subject to narrowed use limits.</td>
<td>Acceptable from January 1, 2020, until January 1, 2025, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before January 1, 2025, may be used after that date.</td>
<td>Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.</td>
</tr>
</tbody>
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### FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

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<th>Narrowed use limits</th>
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| Rigid PU: Spray foam—low-pressure two-component. | HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TI. | Acceptable subject to narrowed use limits. | Acceptable from January 1, 2021, until January 1, 2025, only in military or space-and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. Closed cell foam products and products containing closed cell foams manufactured with these substitutes on or before January 1, 2025, may be used after that date. | Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  
- Process or product in which the substitute is needed;  
- Substitutes examined and rejected;  
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  
- Anticipated date other substitutes will be available and projected time for switching. |

### FOAM BLOWING AGENTS—UNACCEPTABLE SUBSTITUTES

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<tr>
<td>Flexible PU</td>
<td>Methylene chloride</td>
<td>Unacceptable as of [date 30 days after publication of final rule].</td>
<td>Methylene chloride is a carcinogen and may present a toxicity risk. Other alternatives are available for this end-use with lower overall risk to human health and the environment. Methylene chloride is a carcinogen and may present a toxicity risk. Other alternatives are available for this end-use with lower overall risk to human health and the environment.</td>
</tr>
<tr>
<td>Integral Skin PU</td>
<td>Methylene chloride</td>
<td>Unacceptable as of January 1, 2017 ...</td>
<td></td>
</tr>
<tr>
<td>Polyolefin</td>
<td>Methylene chloride</td>
<td>Unacceptable as of January 1, 2020 ...</td>
<td>Methylene chloride is a carcinogen and may present a toxicity risk. Other alternatives are available for this end-use with lower overall risk to human health and the environment.</td>
</tr>
<tr>
<td>Rigid PU: Spray foam—one component foam sealants.</td>
<td>HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TI.</td>
<td>Unacceptable as of January 1, 2020. ...</td>
<td>These foam blowing agents have GWPs ranging from higher than 730 to approximately 1,500. Other alternatives will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Rigid PU: Spray foam—high-pressure two-component.</td>
<td>HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TI.</td>
<td>Unacceptable as of January 1, 2020, except where allowed under a narrowed use limit.</td>
<td>These foam blowing agents have GWPs ranging from higher than 730 to approximately 1,500. Other alternatives will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
</tr>
<tr>
<td>Rigid PU: Spray foam—low-pressure two-component.</td>
<td>HFC-134a, HFC-245fa, and blends thereof; blends of HFC-365mfc with at least four percent HFC-245fa, and commercial blends of HFC-365mfc with seven to 13 percent HFC-227ea and the remainder HFC-365mfc; and Formacel TI.</td>
<td>Unacceptable as of January 1, 2021, except where allowed under a narrowed use limit.</td>
<td>These foam blowing agents have GWPs ranging from higher than 730 to approximately 1,500. Other alternatives will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
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### FIRE SUPPRESSION AND EXPLOSION PROTECTION AGENTS—ACCEPTABLE SUBJECT TO USE CONDITIONS

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<th>Further information</th>
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<td>Streaming</td>
<td>2-BTP</td>
<td>Acceptable, subject to use conditions.</td>
<td>As of [date 30 days after publication of final rule], acceptable only for use in handheld extinguishers in aircraft.</td>
<td>This fire suppressant has a relatively low GWP of 0.23–0.26 and a short atmospheric lifetime of approximately seven days. This agent is subject to requirements contained in a Toxic Substance Control Act (TSCA) section 5(e) Consent Order and any subsequent TSCA section 5(a)(2) Significant New Use Rule (SNUR).</td>
</tr>
</tbody>
</table>
FIRE SUPPRESSION AND EXPLOSION PROTECTION AGENTS—ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

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<tr>
<th>End-use</th>
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| Total flooding| 2-BTP      | Acceptable, subject to use conditions. | For establishments manufacturing, installing and maintaining handheld extinguishers using this agent:  
1. Use of this agent should be used in accordance with the latest edition of NFPA Standard 10 for Portable Fire Extinguishers;  
2. In the case that 2-BTP is inhaled, person(s) should be immediately removed and exposed to fresh air; if breathing is difficult, person(s) should seek medical attention;  
3. Eye wash and quick drench facilities should be available. In case of ocular exposure, person(s) should immediately flush the eyes, including under the eyelids, with fresh water and move to a non-contaminated area. Exposed person(s) should remove all contaminated clothing and footwear to avoid irritation, and medical attention should be sought if irritation develops or persists;  
4. Although unlikely, in case of ingestion of 2-BTP, the person(s) should consult a physician immediately;  
5. Manufacturing space should be equipped with specialized engineering controls and well ventilated with a local exhaust system and low-lying source ventilation to effectively mitigate potential occupational exposure; regular testing and monitoring of the workplace atmosphere should be conducted;  
6. Employees responsible for chemical processing should wear the appropriate PPE, such as protective gloves, tightly sealed goggles, protective work clothing, and suitable respiratory protection in case of accidental release or insufficient ventilation;  
7. All spills should be cleaned up immediately in accordance with good industrial hygiene practices; and  
8. Training for safe handling procedures should be provided to all employees that would be likely to handle containers of the agent or extinguishing units filled with the agent.  
9. 2-BTP use as a streaming fire extinguishing agent in handheld extinguishers in aircraft should be in accordance with UL 711, Rating and Testing of Fire Extinguishers and the Federal Aviation Administration (FAA) Minimum Performance Standard for Hand-Held Extinguishers (DOT/FAA/AR–01/37), with regard to the size and number of extinguishers depending on the size of aircraft.  
10. 2-BTP handheld extinguishers should follow required minimum room volumes established by UL 2129, Halocarbon Clean Agent Fire Extinguishers, when discharged into a confined space. This fire suppressant has a relatively low GWP of 0.23–0.26 and a short atmospheric lifetime of approximately seven days. This agent is subject to requirements contained in a TSCA section 5(e) Consent Order and any subsequent TSCA section 5(a)(2) SNUR. 

For establishments manufacturing, installing, and servicing engine nacelles and auxiliary power units on aircraft:

1. This agent should be used in accordance with the safety guidelines in the latest edition of the National Fire Protection Association (NFPA) 2001 Standard for Clean Agent Fire Extinguishing Systems;  
2. In the case that 2-BTP is inhaled, person(s) should be immediately removed and exposed to fresh air; if breathing is difficult, person(s) should seek medical attention;  
3. Eye wash and quick drench facilities should be available. In case of ocular exposure, person(s) should immediately flush the eyes, including under the eyelids, with fresh water and move to a non-contaminated area.  

As of [date 30 days after publication of final rule], acceptable only for use in engine nacelles and auxiliary power units on aircraft.
### FIRE SUPPRESSION AND EXPLOSION PROTECTION AGENTS—ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

<table>
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<tr>
<th>End-use</th>
<th>Substitute</th>
<th>Decision</th>
<th>Use conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exposed person(s) should remove all contaminated clothing and footwear to avoid irritation, and medical attention should be sought if irritation develops or persists;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(4) Although unlikely, in case of ingestion of 2-BTP, the person(s) should consult a physician immediately;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(5) Manufacturing space should be equipped with specialized engineering controls and well ventilated with a local exhaust system and low-lying source ventilation to effectively mitigate potential occupational exposure; regular testing and monitoring of the workplace atmosphere should be conducted;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(6) Employees responsible for chemical processing should wear the appropriate PPE, such as protective gloves, tightly sealed goggles, protective work clothing, and suitable respiratory protection in case of accidental release or insufficient ventilation;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(7) All spills should be cleaned up immediately in accordance with good industrial hygiene practices;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(8) Training for safe handling procedures should be provided to all employees that would be likely to handle containers of the agent or extinguishing units filled with the agent;</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>(9) Safety features that are typical of total flooding systems such as pre-discharge alarms, time delays, and system abort switches should be provided, as directed by applicable OSHA regulations and NFPA standards; use of this agent should also conform to relevant OSHA requirements, including 29 CFR 1910, subpart L, sections 1910.160 and 1910.162.</td>
</tr>
</tbody>
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### FIRE SUPPRESSION AND EXPLOSION PROTECTION AGENTS—UNACCEPTABLE SUBSTITUTES

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<tbody>
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<td>Total flooding</td>
<td>PFCs (C₃F₈ and C₄F₁₀).</td>
<td>Unacceptable as of [date one year after publication of final rule].</td>
<td>These fire suppressants have GWPs ranging from 8,830 to 8,860. Other alternatives will be available for this end-use with lower overall risk to human health and the environment by the status change date.</td>
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[FR Doc. 2016–08163 Filed 4–15–16; 8:45 am]  
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<td>49 CFR</td>
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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

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