Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as “any regulatory action 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 distribution of Federal benefits or obligations; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined not to be a significant regulatory action under Executive Order 12866. VA’s impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s Web site at http://www1.va.gov/orpm/, by following the link for “VA Regulations Published.”

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing a rule that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009 Veterans Medical Care Benefits and 64.011 Veterans Dental Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs, Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on September 16, 2013, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Dental health, Government contracts, Health care, Health professions, Health records, Veterans.

PART 17—MEDICAL

1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

2. In §17.169, add paragraph (g) to read as follows:

§ 17.169 VA Dental Insurance Program for veterans and survivors and dependents of veterans (VADIP).

(g) Limited preemption of State and local law. To achieve important Federal interests, including but not limited to the assurance of the uniform delivery of benefits under VADIP and to ensure the operation of VADIP plans at the lowest possible cost to VADIP enrollees, paragraphs (b), (c)(1), (c)(2), (d), and (e)(2) through (5) of this section preempt conflicting State and local laws, including laws relating to the business of insurance. Any State or local law, or regulation pursuant to such law, is without any force or effect on, and State or local governments have no legal authority to enforce them in relation to, the paragraphs referenced in this paragraph or decisions made by VA or a participating insurer under these paragraphs.

* * * * *

[FR Doc. 2013–24585 Filed 10–21–13; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721


RIN 2070–AJ95

Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances; Final Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Under the Toxic Substances Control Act (TSCA), EPA is amending a significant new use rule (SNUR) for perfluoroalkyl sulfonate (PFAS) chemical substances to add PFAS chemical substances that have completed the TSCA new chemical review process, but have not yet commenced production or import and is designating (for all listed PFAS chemical substances) processing as a significant new use. EPA is also finalizing a SNUR for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances that designates manufacturing (including importing) and processing for use as part of carpets or for treating carpet (e.g., for use in the carpet aftercare market) as a significant new use, except for use of two chemical substances as a surfactant in carpet cleaning products. For this SNUR, EPA is also making an exemption inapplicable to persons who import or process the LCPFAC chemical substances as part of an article. Persons subject to these SNURs will be required to notify EPA at least 90 days before commencing any significant new use. The required notifications will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This final rule is effective December 23, 2013.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2012–0268, is available at http://www.regulations.gov or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency...
I. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import) or process any of the chemical substances listed in Table 4 of the regulatory text in this document or that meet the LCPFAC chemical category definition as described in this rule.

Potentially affected entities may include, but are not limited to:

- Manufacturers (including importers) of one or more of subject chemical substances (North American Industrial Classification System (NAICS) codes 325 and 324110); e.g., chemical manufacturing and petroleum refineries.
- Carpet and rug mills (NAICS code 321410).
- Fiber, yarn, and thread mills (NAICS code 321311).
- Home furnishing merchant wholesalers (NAICS code 423220).
- Carpet and upholstery cleaning services (NAICS code 561740).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5, 40 CFR 721.9582, and 40 CFR 721.10536, which is in the regulatory text of this document. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

II. Background

A. What action is the agency taking?

In the Federal Register of August 15, 2012 (77 FR 48924) (FRL–9358–7), EPA proposed to amend a SNUR at 40 CFR 721.9582 for PFAS chemical substances to add PFAS chemical substances that have completed the TSCA new chemical review process, but have not yet commenced production or import, and to designate (for all listed PFAS chemical substances) processing as a significant new use. In addition, the Agency also proposed a new SNUR for LCPFAC chemical substances that designates manufacturing (including importing) and processing for use as part of carpets or for treating carpet (e.g., for use in the carpet aftercare market) as a significant new use. On December 30, 2009, EPA issued the “Long-Chain Perfluorinated Chemicals (PFCs) Action Plan” (Ref. 1). Today’s action is consistent with the purpose of that action plan.

This final rule requires persons who intend to manufacture (including import) or process one or more of the PFAS chemical substances listed in Table 4 of the regulatory text for the uses 40 CFR 721.9582(a)(2) to submit a Significant New Use Notice (SNUN) at least 90 days before commencing manufacture (including import) or processing. Given the structural similarity of these chemicals to the PFAS chemicals covered under 40 CFR 721.9582 and EPA’s health and environmental concerns associated with them, EPA has concluded that today’s action on these PFAS chemicals is warranted and any manufacturing (including importing) or processing for any use of these uncommenced PFAS chemicals would be a significant new use.

EPA is also finalizing a SNUR for LCPFAC chemical substances that requires persons to notify the Agency at least 90 days before commencing manufacture (including import) or processing for use as part of carpets or for treating carpet (e.g., for use in the carpet aftercare market) as a significant new use, except for use of two LCPFAC chemical substances as surfactants in carpet cleaning products. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

This final rule requires persons who import LCPFAC chemical substances as surfactant in aftermarket carpet cleaning products as an ongoing use. The use of these two chemical substances is not included as a significant new use in this final rule.

For this SNUR, EPA is also making the article exemption at 40 CFR 721.45(f) inapplicable to persons who import LCPFAC chemical substances as part of carpets. The article exemption at 40 CFR 721.45(f) is based on an assumption that people and the environment will generally not be exposed to chemical substances in articles (see 49 FR 35014; September 5, 1984). However, as stated in Unit IV. of the proposed rule (77 FR 48928; August 15, 2012), exposure to LCPFAC chemical substances may occur both during the carpet manufacture process and during the lifetime of the finished carpet. Therefore, exposure would increase if in the future LCPFAC chemical substances are incorporated in carpets and then imported. The article exemption at 40 CFR 721.45(f) remains in effect, however, for persons who import LCPFAC chemical substances as part of other types of articles. The article exemption at 40 CFR 721.45(f) also remains in effect for processing of LCPFAC chemical substances as part of an article (i.e., carpet) since EPA is aware that this is an ongoing use. This final action does not affect the exemption at 40 CFR 721.45(f) for PFAS chemical substances, which remains in effect for persons who import or process these chemical substances.

For all LCPFAC chemical substances, a general category of perfluorinated sulfonate chemical substances of any chain.
length. The PFAS chemical substances for which EPA is modifying an existing SNUR are currently listed in 40 CFR 721.9582 in paragraph (a)(1). The PFAS chemical substances that EPA is adding to an existing SNUR are being inserted into this list. All of these chemical substances are collectively referred to in this rule as perfluoralkyl sulfonates, or PFAS chemical substances.

The term LCPFAC refers to the long-chain category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons. Based on comments filed on the proposed SNUR and all information available to EPA, the category definition of LCPFAC chemical substances differs in this final rule from the definition described in the proposed SNUR. The upper limit of the perfluorinated carbon chain length is now 20 carbons. In the proposed SNUR, there was no upper limit. Also, the LCPFAC chemical subgroup described in 40 CFR 721.10536(b)(1)(vi) of the proposed rule is removed from the definition in this final SNUR.

LCPFAC chemical substances are synthetic chemicals that do not occur naturally in the environment. The LCPFAC chemical substances subject to this SNUR are identified as follows, where 5 < n < 21 or 6 < m < 21:

a. CF\(_n\)(CF\(_m\))\_n-COO\(^-\) M where M = H\(^+\) or any other group where a formal dissociation can be made;

b. CF\(_n\)(CF\(_m\))\_n-CH=CH\(_2\);

c. CF\(_n\)(CF\(_m\))\_n-(CH\(_2\))\_n-O-X where X is any chemical moiety;

d. CF\(_n\)(CF\(_m\))\_n-CH=CH\(_2\)-X where X is any chemical moiety, and

e. CF\(_n\)(CF\(_m\))\_n-Y-X where Y = non-S, non-N heteroatom and where X is any chemical moiety.

The category of LCPFAC chemical substances, based on the chemical structures delineated in 40 CFR 721.10536 (b)(1)(i) through (b)(1)(v) of this final rule, also includes the salts and precursors of these perfluorinated carboxylates. LCPFAC precursors may be simple derivatives of perfluorooctanoic acid (PFOA)—when used as an aqueous dispersion agent in fluoropolymer production—is subject to this SNUR if the final fluoropolymer product is used as part of carpets or to treat carpets.

B. What is the agency’s authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a SNUN to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit II.C., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. However, EPA is making the exemption at 40 CFR 721.45(f) inapplicable to persons who import LCPFAC chemical substances as part of carpets under this SNUR. As a result, persons subject to the provisions of this rule would not be exempt from significant new use reporting if they import LCPFAC chemical substances as part of carpets. However, the articles exemption will remain in effect for persons who process chemical substances as part of an article because existing stocks of carpets may still contain LCPFAC substances.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (b)(2), (b)(3), and (b)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), (5)(f), 6 or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the Federal Register its reasons for not taking action.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements. Codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

III. Rationale and Objectives for This Final Rule

A. Rationale

As discussed in Units III. and IV. of the proposed rule (77 FR 48924; August 15, 2012), PFAS and LCPFAC chemical substances are found world-wide in the environment, wildlife, and humans. They are bioaccumulative in wildlife and humans, and are persistent in the environment. They affect toxicologic laboratory animals, producing reproductive, developmental, and systemic effects in laboratory tests. The exact sources and pathways by which these chemicals move into and through the environment and allow humans and wildlife to become exposed are not fully understood, but are likely to include releases from manufacturing of the chemicals, processing of these chemicals into products like carpets and textiles, and aging and wear of products containing them.

Since the manufacture (including import) and processing of PFAS and LCPFAC chemical substances for these uses have been discontinued in the United States, EPA expects their presence in humans and the environment to decline over time as has been observed in the past when production and use of other persistent chemicals has ceased. EPA is concerned that the manufacturing (including import) or processing of these chemical substances, as well as importing these chemicals as part of articles, for the new uses identified in this rule could be reinitiated in the future. If reinitiated, EPA believes that such use would increase the magnitude and duration of human and environmental exposure to
these chemical substances, constituting a significant new use.

EPA is adding processing of PFAS chemical substances (for any use in the United States, other than the uses listed under 40 CFR 721.9582 (a)(3), (a)(4), and (a)(5)) to the significant new uses of those chemical substances. EPA is concerned about the potential for PFAS chemical substances manufactured (including imported) for an ongoing use to be redirected to other uses without prior notice to the Agency. For example, a chemical substance could be initially manufactured for uses listed under 40 CFR 721.9582 (a)(3), (a)(4), or (a)(5), and then redirected for another use after its initial manufacture or import. For similar reasons, EPA is designating processing of LCPFAC chemical substances or use as part of carpets or to treat carpet as a significant new use, except for one specifically identified ongoing use of two LCPFAC chemical substances as a surfactant in aftermarket carpet cleaning products. As such, persons who process PFAS or LCPFAC chemical substances for a significant new use will be required to first notify EPA, even if they are not themselves manufacturers of the chemical substance. Note, the exemption at 40 CFR 721.45(f) is not applicable for persons who import these LCPFAC chemical substances as part of an article, but is applicable for persons who process these LCPFAC chemical substances as part of an article. Pursuant to 40 CFR 721.45(f), processing of PFAS and LCPFAC chemical substances as part of articles is exempt from notice requirements. Accordingly, EPA will have the opportunity to evaluate and control, where appropriate, activities associated with those uses, if such manufacturing (including importing) or processing were to start or resume. The required notification provided by a SNUN will provide EPA with the opportunity to evaluate activities associated with a significant new use and an opportunity to protect against unreasonable risks, if any, from exposure to PFAS and LCPFAC chemical substances.

Consistent with EPA’s past practice for issuing SNURs under TSCA section 5(a)(2), EPA’s decision to promulgate a SNUN for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency’s action is based on EPA’s determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before EPA authorizes manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows the Agency to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

With this action, the Agency is designating as significant new uses of LCPFAC chemical substances use as part of carpet or to treat carpet. The Agency believes the 2010/2015 PFOA Stewardship Program, in which companies committed to work toward eliminating facility emissions and product content of PFOA—a LCPFAC chemical substance—by 2015, will eliminate many other ongoing uses of LCPFAC chemical substances. As those uses are phased out in the United States, EPA anticipates taking additional regulatory actions to prevent resumption of the uses without prior notice to EPA.

B. Objectives

Based on the considerations in Unit III.A. of this rule, EPA will achieve the following objectives with regard to the significant new use(s) that are designated in this rule:

1. EPA will receive notice of any person’s intent to manufacture (including import) or process PFAS or LCPFAC chemical substances for the described significant new use before that activity begins.
2. EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing (including importing) or processing PFAS or LCPFAC chemical substances for the described significant new use.
3. EPA will be able to regulate prospective manufacturers (including importers) or processors of PFAS or LCPFAC chemical substances before the described significant new use of the chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA’s determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

• The projected volume of manufacturing and processing of a chemical substance.
• The extent to which a use changes the type and form of exposure to a chemical substance.
• The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
• The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.
• The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of the PFAS and LCPFAC chemical substances subject to this rule, as discussed herein, EPA considered relevant information about the toxicity of these substances, likely human exposures and environmental releases associated with possible uses, and the four factors listed in TSCA section 5(a)(2).

Except for the ongoing uses specified in 40 CFR 721.9582 (a)(3) through (a)(5), the Agency believes the manufacture (including import) and processing of any of the PFAS chemical substances subject to this rule has been discontinued. Any new use of these chemicals, including processing, could change the type and form of exposure and/or the magnitude and duration of exposure to humans and the environment relative to what currently exists. Based on these considerations of the statutory factors discussed in this unit, EPA has determined that the manufacture (including import) or processing of any of the PFAS chemical substances subject to this rule, for any use except ongoing uses specified in 40 CFR 721.9582 (a)(3) through (a)(5), is a significant new use.

Exposure to LCPFAC chemical substances may occur both during the carpet manufacture process and during the lifetime of the finished carpet via inhalation and ingestion of dust generated from the abrasion of carpets. This is of particular concern for children since they engage in a variety of activities on carpets for longer periods of time and have a greater degree of hand-to-mouth activity in their earliest years. This will change both the magnitude of exposure and the duration of exposure. Except for one ongoing use specified in 40 CFR 721.10536(b)(3), the Agency believes the manufacture (including import) and processing of LCPFAC chemical substances as part of carpet or to treat carpet has been discontinued. EPA also believes LCPFAC chemicals substances are no longer imported as part of carpet. If reinitiated, EPA believes these uses of LCPFAC chemical substances would significantly increase the magnitude and duration of exposure to humans and the
environment relative to what currently exists. Based on these considerations of the statutory factors discussed in this unit, EPA has determined that the manufacture (including import) or processing of any of the LCPFAC chemical substances subject to this rule for use as part of carpet or to treat carpets, except ongoing uses specified in 40 CFR 721.10536(b)(3), is a significant new use. EPA has further determined that importing any of the LCPFAC chemical substances subject to this rule as part of carpet constitutes a significant new use and warrants making inapplicable the article exemption at 40 CFR 721.45(f).

V. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the Federal Register of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who may have begun commercial manufacture (including import) or processing of the chemical substance(s) subject to this rule for a significant new use after the proposal was published on August 15, 2012 (77 FR 48924), must cease such activity before the effective date of this final rule. To resume their activities, these persons will have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses. To the extent that additional ongoing uses were found in the course of rulemaking, EPA has excluded these uses from the final SNUR. EPA promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

VI. Test Data and Other Information

EPA recognizes that TSCA section 5 does not usually require developing any particular test data before submission of a SNUN. There are two exceptions: (1) Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)); and (2) development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)). In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25 and 40 CFR 720.50). However, in general, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture (including import), processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:
1. Human exposure and environmental releases that may result from the significant new uses of the chemical substance.
2. Potential benefits of the chemical substance.
3. Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VII. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(e), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

VIII. Discussion of the Final Significant New Use Rule and Response to Comments

This action finalizes the SNUR proposed in the Federal Register on August 15, 2012 (77 FR 48924). This final rule requires persons who intend to manufacture (including import) or process one or more of the chemical substances listed in Table 4 of the regulatory text for the uses identified in 40 CFR 721.9582(a)(2) to submit a SNUN at least 90 days before commencing manufacture (including import) or processing. This rule also requires persons who intend to manufacture (including import) or process one or more LCPFAC chemical substances, as defined in 40 CFR 721.10536(b)(1), for use as part of carpets or for treating carpets (except for one specifically identified ongoing use of two LCPFAC chemical substances as a surfactant in aftermarket carpet cleaning products) to submit a SNUN at least 90 days before commencing manufacture (including import) or processing.

It should be noted that the LCPFAC chemical substances category definition now delineates a perfluorinated carbon chain length upper limit of 20 carbons. The definition in the proposed rule contained no upper limit. Also, the LCPFAC chemical subgroup that was described in 40 CFR 721.10536(b)(1)(vi) of the proposal is removed from the definition in this final SNUR. The rationale for these changes is explained in greater detail in the response to comments below.

The Agency reviewed and considered all comments received related to the proposed rule. Copies of all non-CBI comments are available at http://www.regulations.gov in the public docket for this action, EPA–OPPT–2012–0268. A discussion of the comments germane to the rulemaking and the Agency’s responses follow.

1. Comment summary. In defining the chemicals subject to this SNUR in the proposed rule, no upper limit was given for carbon chain length. Submitters suggested an upper limit of 20 carbons, which would exclude from the LCPFAC...
category definition polymers weighing greater than 1,000 daltons.

Response. EPA agrees with commenters that there should be an upper limit to the chain length in the definition. PFAC chemicals with greater than 20 perfluorinated carbons can be considered polymers within the polymer exemption under 40 CFR 723.250 (e.g., exceed a molecular weight of 1,000 daltons and contain at least three monomer units). As it is not the Agency’s intent to regulate fluoropolymers in this rule, the LCPFAC category definition in this final rule includes a perfluorinated carbon chain length upper limit of 20.

2. Comment summary. Commenters requested clarification as to whether or not fluoropolymers are included in the LCPFAC definition. Commenters also requested a definition of fluoropolymers that clearly distinguished them from fluorotelomer-based chemicals.

Response. It is not the Agency’s intent to regulate fluoropolymers. The category definition is changed in this final rule to include a perfluorinated carbon chain length upper limit of 20. With this change, fluoropolymers no longer meet the LCPFAC chemical substances definition.

Since fluoropolymers are not subject to this SNUR, EPA will not include a definition of fluoropolymers. However, the Agency notes that it has distinguished fluoropolymer and fluorotelomer-based chemicals in two corresponding enforceable consent agreement test rules published on July 8, 2005 (70 FR 39630 and 70 FR 39623).

3. Comment summary. Several commenters argued that the proposed 40 CFR 721.10536(b)(1)(vi) (“structurally similar degradation products of any of the compounds in (i) through (v) of this paragraph”) is prohibitively broad and unnecessary and therefore unenforceable. They argued that it should be either removed or replaced with a definition that explicitly delineates LCPFAC precursors.

Response. The Agency agrees that the chemical subgroup definition described in 40 CFR 721.10536(b)(1)(vi) is unnecessary and it is removed from the LCPFAC category definition in this final rule. The Agency believes that 40 CFR 721.10536(b)(1)(i)–(b)(1)(v) do not exclude any LCPFAC chemical substances defined in 40 CFR 721.10536(b)(1)(vi), and thus sufficiently define the LCPFAC category of chemicals.

4. Comment summary. A commenter claimed that the LCPFAC chemical category definition is not adequate to verify which chemicals are in use by suppliers. Instead, a thorough list of CAS numbers is needed.

Response. EPA believes the most precise way to identify the chemicals subject to this SNUR is through the chemical structure definition. Downstream customers should have sufficient information from suppliers (i.e., CAS number and unique chemical identity) to generate the specific structure for any potentially reportable substance, which they can compare to the LCPFAC category definition.

5. Comment summary. A commenter suggested that 40 CFR 721.10536(b)(1)(iii) of the regulatory text should state “CF2(CF2)nCH2CH2”, where m > 6” rather than “CF2(CF3)nCH2CH2”, where m > 5” to be consistent with PFAS precursors identified in the PFOA Stewardship Program.

Response. EPA disagrees with this comment. The specific structural formula was chosen to accommodate the possibility of oxidation cleavage of the olefin to produce PFOA directly. Applied to the representative structure suggested by the commenter, this mechanism would produce perfluorononanoic acid (PFNA), which is one carbon longer than PFOA, the smallest of the LCPFAC chemical substances.

6. Comments summary. A commenter expressed concern that the article exemption was not made inapplicable to PFAS as part of carpets.

Response. The Agency recognizes this concern and is addressing it in the upcoming proposed SNUR for long-chain perfluoroalkyl carboxylate chemical substances. Doing so in the upcoming proposed SNUR will allow EPA to solicit and respond to any public comments.

7. Comment summary. Submitters requested clarification on the applicability of the articles exemption to export notifications.

Response. This SNUR does not require notice of export for articles as part of the section 5 action. In accordance with 40 CFR 707.60(b), persons who export LCPFAC chemical substances contained in articles remain exempt from notices of export under TSCA 12(b).

8. Comment summary. One commenter asserted that the following statement in the proposed rule’s preamble is incorrect: “These precursors include certain fluoropolymers and all fluorotelomers.” In support of this assertion, the submitter notes that many new short-chain fluorotelomer products cannot break down to PFOA.

Response. The LCPFAC category definition does not include short-chain fluorotelomers. The quote refers only to precursors of the long-chain perfluorinated chemicals defined in 40 CFR 721.10536(b)(1), which excludes short-chain fluorotelomers. Fluoropolymers are also no longer included in the LCPFAC definition.

9. Comment summary. A commenter noted that even fluoropolymers not made with PFOA can have detectable levels of PFOA in them due to environmental cross-contamination, which creates an enforcement and compliance problem. The uncertainty this issue creates suggests that fluoropolymers should be excluded from the LCPFAC definition. The commenter also requested clarification of the term ‘contamination’ used in the preamble.

Response. Fluoropolymers are not subject to this SNUR. In the preamble of the proposed rule, the Agency referred to a ‘contaminated’ chemical as one that does not meet the LCPFAC definition itself, but that contains a LCPFAC chemical substance due to its intentional use during chemical formulation. In such a case, this LCPFAC chemical substance would be subject to this SNUR for the significant new uses described in 40 CFR 721.10536(b)(2). For example, APFO used as an emulsifier in the production of fluoropolymers would be subject to this SNUR for the significant new uses described in 40 CFR 721.10536(b)(2).

IX. Economic Analysis

A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of the chemical substance included in this rule (Ref. 2). In the event that a SNUN is submitted, costs are estimated at $8,589 per SNUN submission for large business submitters and $6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a $2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than $40 million when combined with those of the parent company (if any), a reduced user fee of $100 (40 CFR 700.45(b)(1)). The costs of
submission of SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in this SNUR. EPA’s complete economic analysis is available in the public docket for this rule (Ref. 2).

The final SNUR will require importers of LCPFAC chemical substances as part of carpets to notify EPA at least 90 days before importing any such articles containing chemicals subject to the final rule. The final rule may also affect firms that do not currently import carpet containing the chemicals, but who may be interested in importing these articles in the future. Typically, firms have an understanding of the contents of the articles they import. However, EPA acknowledges that importers of articles may have varying levels of knowledge about the chemical content of the articles that they import.

While not required by the SNUR, these parties may incur costs to take additional steps to determine whether the articles they plan to import are covered by this SNUR. This determination may involve gathering information from suppliers along the supply chain, and/or testing samples of the article itself. EPA believes that the LCPFAC chemical substances included in this final rule are no longer being manufactured (including imported) for use as part of carpet or for treating carpet (e.g., for use in the carpet aftercare market) in the United States, except for use of two chemical substances in carpet cleaning solution, and that LCPFAC chemical substances are not being imported as part of carpets. Therefore, EPA believes that these costs would be minimal.

B. Export Notification

Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under section 5. For persons exporting a substance the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (i.e., the number of countries to which the chemical is exported). EPA is unable to make any estimate of the likely number of export notifications for the chemical covered in this SNUR.

X. References

As indicated under ADDRESSES, a docket has been established for this rule under docket ID number EPA–HQ– OPPT–2012–0268. The following is a listing of the documents cited in this document. The docket includes information considered by EPA in developing this rule, including the documents listed in this unit, which are physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, please consult the technical person listed under FOR FURTHER INFORMATION CONTACT. The docket is available for review as specified under ADDRESSES.


XI. Statutory and Executive Order Reviews

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

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this SNUR is not a “significant regulatory action,” because it does not meet the criteria in section 3(f) of the executive order. Accordingly, this action was not reviewed by OMB under Executive Orders 12866 and 13563 (76 FR 3821; January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA, 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 that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations in Title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9, which was published in the related collection instrument, or form, if applicable. The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070–0038 (EPA ICR No. 1188). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average 92 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 et seq., the Agency hereby certifies that promulgation of this SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a “significant new use.” By definition of the word “new” and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activity. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. For example, the number of SNUNs was four in Federal fiscal year (FY) 2005, eight in FY 2006, six in FY 2007, eight in FY 2008, and seven in FY 2009. During this 5-year period, three small entities submitted a SNUN. Therefore, EPA believes that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL–5735–4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.
D. Unfunded Mandates Reform Act (UMRA)

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this regulatory action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531–1538.

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule does not significantly or uniquely affect the communities of Indian Tribal governments, nor involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000) do not apply to this rule.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer Advancement Act (NTTAA)

Since this action does not involve any technical standards; section 12(d) of the NTTAA, 15 U.S.C. 272 note, does not apply to this action.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

XII. Congressional Review Act (CRA)

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.


Wendy C. Hamnett,
Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9—[AMENDED]

§ 9.1 OMB approvals under the Paperwork Reduction Act.

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| --- | --- | --- | --- | ---

40 CFR citation | OMB control No.
--- | ---

721.10536 | 2070–0038

* * * * *

PART 721—[AMENDED]

3. The authority citation for part 721 continues to read as follows:


4. In § 721.9582:

a. Revise paragraph (a)(1) introductory text.

b. Add Table 4 to paragraph (a)(1).

c. Revise paragraphs (a)(2) through (5).

The revisions and addition read as follows:

§ 721.9582 Certain perfluoroalkyl sulfonates.

(a) Chemical substances and significant new uses subject to reporting. (1) The chemical substances listed in Table 1, Table 2, Table 3, and Table 4 of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

* * * * *

TABLE 4—FOURTH SET OF PFAS CHEMICALS SUBJECT TO REPORTING

<table>
<thead>
<tr>
<th>Premanufacture Notice Case No.</th>
<th>Generic chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–01–0035</td>
<td>Modified fluoroalkyl adduct</td>
</tr>
<tr>
<td>P–09–0100</td>
<td>Fluorooalkyl derivative</td>
</tr>
<tr>
<td>P–99–0091</td>
<td>Perfluorooctane sulfonate</td>
</tr>
<tr>
<td>P–83–0036</td>
<td>Modified fluoroalkyl adduct</td>
</tr>
<tr>
<td>P–98–0036</td>
<td>Fluorinated polylsiloxane</td>
</tr>
<tr>
<td>P–83–0126</td>
<td>Fluorinated polysiloxane</td>
</tr>
<tr>
<td>P–83–0126</td>
<td>Fluorooalkyl derivative</td>
</tr>
<tr>
<td>P–98–0036</td>
<td>Perfluorooctane sulfonate</td>
</tr>
</tbody>
</table>

(2) The significant new uses are:

(i) Manufacturing (including importing) or processing of any chemical substance listed in Table 1 of paragraph (a)(1) of this section for any use.

(ii) Manufacturing (including importing) or processing of any chemical substance listed in Table 2 of paragraph (a)(1) of this section for any
use, except as noted in paragraph (a)(3) of this section.

(iii) Manufacturing (including importing) or processing of any chemical substance listed in Table 3 of paragraph (a)(1) of this section for any use, except as noted in paragraphs (a)(3) through (5) of this section.

(iv) Manufacturing (including importing) or processing of any chemical substance listed in Table 4 of paragraph (a)(1) of this section for any use.

(3) Manufacturing (including importing) or processing of any chemical substance listed in Table 2 and Table 3 of paragraph (a)(1) of this section for the following specific uses shall not be considered as a significant new use subject to reporting under this section:

(i) Use as an anti-erosion additive in fire-resistant phosphate ester aviation hydraulic fluids.

(ii) Use as a component of a photoresist substance, including a photo acid generator or surfactant, or as a component of an anti-reflective coating, used in a photolithography process to produce semiconductors or similar components of electronic or other miniaturized devices.

(iii) Use in coating for surface tension, static discharge, and adhesion control for analog and digital imaging films, papers, and printing plates, or as a surfactant in mixtures used to process imaging films.

(iv) Use as an intermediate only to produce other chemical substances to be used solely for the uses listed in paragraph (a)(3)(i), (ii), or (iii) of this section.

(4) Manufacturing (including importing) or processing of tetraethylammonium perfluorooctanesulfonate (CAS No. 56773–42–3) for use as a fume/mist suppressant in metal finishing and plating baths shall not be considered as a significant new use subject to reporting under this section. Examples of such metal finishing and plating baths include: Hard chrome plating; nickel, cadmium, or decorative chromium plating; chromic acid anodizing; and alkaline zinc plating.

Specific requirements.

The provisions of subpart A of this part apply to this section except as modified by this paragraph (c).

(1) Revocation of certain notification exemptions. With respect to imports of carpets, the provisions of §721.45(f) do not apply to this section. A person who imports a chemical substance identified in this section as part of a carpet is not exempt from submitting a significant new use notice. The other provision of §721.45(f), respecting processing a chemical substance as part of an article, remains applicable.

(2) [Reserved]

5. Add §721.10536 to subpart E to read as follows:

§721.10536 Long-chain perfluoroalkyl carboxylate chemical substances.

(a) Definitions. The definitions in §721.3 apply to this section. In addition, the following definition applies: Carpet means a finished fabric or similar product intended to be used as a floor covering. This definition excludes resilient floor coverings such as linoleum and vinyl tile.

(b) Chemical substances and significant new uses subject to reporting.

(1) The chemical substances identified below, where 5 < n < 21 or 6 < m < 21, are subject to reporting under this section for the significant new uses described in paragraph (b)(2) of this section.

(ii) Phosphinic acid, bis(perfluoro-C6-C12-alkyl) derivs. (CAS No. 68412–69–1).

(c) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph (c).

5-Add §721.10536 to subpart E to read as follows:

§721.10536 Long-chain perfluoroalkyl carboxylate chemical substances.

(a) Definitions. The definitions in §721.3 apply to this section. In addition, the following definition applies: Carpet means a finished fabric or similar product intended to be used as a floor covering. This definition excludes resilient floor coverings such as linoleum and vinyl tile.

(b) Chemical substances and significant new uses subject to reporting.

(1) The chemical substances identified below, where 5 < n < 21 or 6 < m < 21, are subject to reporting under this section for the significant new uses described in paragraph (b)(2) of this section.

(ii) Phosphinic acid, bis(perfluoro-C6-C12-alkyl) derivs. (CAS No. 68412–69–1).