

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 9 and 721**

**[EPA-HQ-OPPT-2022-0867; FRL 9655-02-OCSP]**

**RIN 2070-AL10**

**Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA  
Inventory; Significant New Use Rule**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), EPA is finalizing a significant new use rule (SNUR) for 329 per- and poly-fluoroalkyl substances (PFAS) that are designated as inactive on the TSCA Chemical Substance Inventory. PFAS are a group of chemicals that have been used in industry and consumer products since the 1940s because of their useful properties, such as water and stain resistance. Many PFAS break down very slowly and can build up in people, animals, and the environment over time. Exposure at certain levels to specific PFAS can adversely impact human health and other living things. Persons subject to the final SNUR are required to notify EPA at least 90 days before commencing any manufacture (including import) or processing of the chemical substance for a significant new use. Once EPA receives a notification, EPA must review and make an affirmative determination on the notification, and take such action as is required by any such determination before the manufacture (including import) or processing for the significant new use can commence. Such a review will assess whether the new use may present unreasonable risk to health or the environment and ensure that EPA takes appropriate action as required to protect health or the environment.

**DATES:** This final rule is effective [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (EST) on [**INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0867, is available online at <https://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC) in Washington, DC. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Bethany Masten, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8803; email address: [TSCA\\_PFAS@epa.gov](mailto:TSCA_PFAS@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture (including import), process, or distribute in commerce chemical substances and mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- NAICS 221210—Natural Gas Distribution;
- NAICS 236220—Commercial and Institutional Building Construction;
- NAICS 324—Petroleum and Coal Product Manufacturing;
- NAICS 324—Petroleum and Coal Product Manufacturing;
- NAICS 32419—Petroleum Lubricating Oil and Grease Manufacturing;
- NAICS 325—Chemical Manufacturing;
- NAICS 325120—Industrial Gas Manufacturing;
- NAICS 325180—Other Basic Inorganic Chemical Manufacturing;
- NAICS 325199—All Other Basic Organic Chemical Manufacturing;
- NAICS 325211—Plastics Material and Resin Manufacturing;
- NAICS 325212—Synthetic Rubber Manufacturing;
- NAICS 325220—Artificial and Synthetic Fibers and Filaments Manufacturing;
- NAICS 325320—Pesticide and Other Agricultural Chemical Manufacturing;
- NAICS 325411—Medicinal and Botanical Manufacturing;
- NAICS 325412—Pharmaceutical Preparation Manufacturing;
- NAICS 325612—Polish and Other Sanitation Good Manufacturing;
- NAICS 325613—Surface Active Agent Manufacturing;
- NAICS 325998—All Other Miscellaneous Chemical Product and Preparation

Manufacturing;

- NAICS 326113—Unlaminated Plastics Film and Sheet (except Packaging)

Manufacturing;

- NAICS 327910—Abrasive Product Manufacturing;
- NAICS 333999—All Other Miscellaneous General Purpose Machinery Manufacturing;
- NAICS 334511—Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing;

- NAICS 336111—Automobile Manufacturing;
- NAICS 423120—Motor Vehicle Supplies and New Parts Merchant Wholesalers;
- NAICS 423420—Office Equipment Merchant Wholesalers;
- NAICS 423510—Metal Service Centers and Other Metal Merchant Wholesalers;
- NAICS 423740—Refrigeration Equipment and Supplies Merchant Wholesalers;
- NAICS 423990—Other Miscellaneous Durable Goods Merchant Wholesalers;
- NAICS 424690—Other Chemical and Allied Products Merchant Wholesalers;
- NAICS 424720—Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals);

- NAICS 424950—Paint, Varnish, and Supplies Merchant Wholesalers;
- NAICS 441110—New Car Dealers;
- NAICS 447190—Other Gasoline Stations;
- NAICS 551112—Offices of Other Holding Companies; and
- NAICS 562—Waste Management and Remediation Services.

This action may also affect certain entities through pre-existing import, including import certification, and export notification rules under TSCA. Chemical importers are subject to the import provision of TSCA section 13 (15 U.S.C. 2612), which requires that the Secretary of the Treasury “refuse entry into the customs territory of the United States” of any substance, mixture, or article containing a chemical substance or mixture that fails to comply with any rule issued

under TSCA or that “is offered for entry in violation” of TSCA or certain rules or orders issued under TSCA, including rules issued under TSCA section 5. Persons who import any chemical substance in bulk form, as part of a mixture, or as part of an article (if required by rule) are also subject to TSCA section 13 import certification requirements and the corresponding regulations promulgated at 19 CFR 12.118 through 12.127 (see also 19 CFR 127.28). Chemical importers of the chemical substances in bulk form, as part of a mixture, or as part of an article (if required by rule) must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including regulations issued under TSCA sections 5, 6, 7 and Title IV. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

*B. What is the Agency's authority for taking this action?*

TSCA section 5(a)(2) (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) requires persons to submit a significant new use notice (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)(i)). TSCA further provides that such manufacturing (including import) or processing may not commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association

with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

TSCA section 26(c) (15 U.S.C. 2625(c)) authorizes EPA to take action under other sections of TSCA with respect to categories of chemical substances.

*C. What action is the Agency taking?*

This final SNUR will require persons to notify EPA at least 90 days before commencing any manufacture (including import) or processing of those 329 PFAS described in Unit II. that are designated as inactive on the TSCA Chemical Substance Inventory (TSCA Inventory) and that are not subject to an existing SNUR, including the existing SNURs cited at 40 CFR 721.9582 and 721.10536, for any use. EPA is providing a list of the 299 inactive PFAS that do not mask “fluor” or “fluorine” in the generic name in the public docket for this rule (Ref. 1). This category of PFAS chemical substances (“inactive PFAS”) is described further in Unit II.

EPA is exempting from the notice requirement PFAS present as impurities, any byproducts which are not used for commercial purposes, and the importing or processing of inactive PFAS-containing articles because notification for the commercial activity designation (as active or inactive) on the TSCA Inventory is not required for such substances (see 40 CFR 710.27(a)). Similarly, EPA is exempting from the notice requirement PFAS manufactured or processed: in small quantities solely for research and development, for test marketing purposes, as a non-isolated intermediate, or solely for export from the United States as described in 40 CFR 720.30(e) or 721.3, except where the Administrator has made a finding described in TSCA section 12(a)(2).

The SNUR was proposed in the *Federal Register* on January 26, 2023 (88 FR 4937 (FRL 9655-01-OCSP)). EPA received a total of 20 public comment submissions in response to the

notice. EPA received one ongoing use claim in Unit V. of the Response to Comments document (Ref. 2). EPA reviewed the ongoing use claim, requested additional information, and has determined that the use is not ongoing, as described in Unit XI.D.

*D. Why is the Agency taking this action?*

As noted in the January 26, 2023, proposed rule (88 FR 4937(FRL 9655-01-OCSPP)), this action is part of the comprehensive approach outlined in the Agency's "PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024" to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment (Ref. 3). This SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing (including import) or processing of inactive PFAS for new uses that may produce changes in human or environmental exposures.

The rationale and objectives for this SNUR are further explained in Unit III.

*E. What are the estimated incremental impacts of this action?*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of the chemical substances included in this rule. This analysis (Ref. 4), which is available in the docket, is discussed in Unit IX., and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be approximately \$26,894 per SNUN submission for large business submitters and \$11,204 for small business submitters. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country, which is estimated to be approximately \$43 per notification.

**II. Chemical Substances Subject to this Rule**

As discussed in Units II. and III. of the proposed rule (88 FR 4937, January 26, 2023 (FRL 9655-01-OCSP)), this SNUR applies to chemical substances designated as inactive on the TSCA Inventory that are also PFAS, except that inactive PFAS already subject to a significant new use rule, including but not limited to the significant new use rules cited at 40 CFR 721.9582 and 721.10536, are not subject to notice requirements under this action to avoid potential redundancies or conflicts between the SNURs.

For the purposes of this SNUR, the definition of “PFAS” includes chemicals that contain at least one of these three structures:

- R-(CF<sub>2</sub>)-CF(R')R'', where both the CF<sub>2</sub> and CF moieties are saturated carbons;
- R-CF<sub>2</sub>OCF<sub>2</sub>-R', where R and R' can either be F, O, or saturated carbons; or
- CF<sub>3</sub>C(CF<sub>3</sub>)R'R'', where R' and R'' can either be F or saturated carbons.

As described in Unit II. of the January 26, 2023, proposed rule (88 FR 4937 (FRL-9655-01-OCSP)), this definition was developed to focus on substances most likely to be persistent in the environment and EPA notes that this definition may not be identical to other definitions of PFAS used within EPA or by other domestic or international organizations.

The chemical substances for which EPA is finalizing a SNUR are the 329 PFAS that are both currently designated as inactive on the TSCA Inventory and that are not subject to an existing SNUR. The specific chemical identities for 30 of these substances that have been claimed as Confidential Business Information (CBI) have generic names (the nonconfidential substitute for the specific chemical name) that do not contain “fluor” or “fluorine.” EPA is providing a list of the 299 inactive PFAS that do not mask “fluor” or “fluorine” in the generic name in the public docket for this rule (Ref. 1). Because EPA is finalizing a structural definition of PFAS for this SNUR, EPA need not take additional steps to list the 30 inactive PFAS that are



not subject to an existing SNUR and whose generic names do not contain “fluor” or “fluorine”.

On October 14, 2022, prior to the publication of the proposed SNUR, EPA received a Notice of Activity for CASRN 306-92-3. This substance was erroneously included in the initial count and list of the 300 inactive PFAS that do not mask “fluor” or “fluorine” in the supplemental document, “List of Select Chemicals Subject to the Proposed Significant New Use Rule Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory” (Ref. 5). The designation of this substance was “active” at the time of the proposed rule and, as such, it is not subject to this final rule and the correct number of chemical substances for which EPA is finalizing a SNUR is 329.

EPA received one Notice of Activity for CASRN 35101-47-7 on March 2, 2023, after the publication of the proposed rule. As described in Unit IV of the proposed rule, uses arising after January 26, 2023, are significant new uses, and persons who began commercial manufacturing (including importing) or processing for a significant new use have to cease upon the effective date of the final rule. To resume their activities, these persons must first comply with all applicable SNUR notification requirements and wait until all TSCA prerequisites for the commencement of manufacturing (including importing) or processing have been satisfied.

### **III. Rationale and Objectives**

#### *A. What is the rationale for this action?*

As discussed in Units II. and III. of the proposed rule (88 FR 4937, January 26, 2023 (FRL-9655-01-OCSPP)), PFAS can adversely impact human health and the environment. This final action is part of a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment.

In the absence of this final SNUR, manufacturing (including importing) or processing for

the significant new uses in this rule could begin at any time after a manufacturer submits a Notice of Activity under section 8 of TSCA and the substance becomes “active” on the TSCA Inventory; EPA would not be provided prior notice under section 5 or an opportunity to review and address potential risks associated with the proposed new use. The manufacture (including import) or processing for any use of inactive PFAS would increase the magnitude and duration of exposure to humans and the environment to these chemicals. Given the concerns described in Units II. and III. of the proposed rule (88 FR 4937, January 26, 2023 (FRL-9655-01-OCSPP)), EPA has determined that notification and EPA’s required review are warranted for these chemicals prior to their potential reintroduction into commerce.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), as described in Unit IV. of the proposed rule (88 FR 4937, January 26, 2023 (FRL-9655-01-OCSPP)), EPA's decision to issue a SNUR for a particular chemical use follows an analysis of the relevant factors listed in section 5(a)(2) and need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. If a person decides to begin manufacturing (including importing) or processing any of these chemicals for the significant new use, the notice to EPA allows the Agency to evaluate the new use according to the specific parameters and circumstances surrounding the conditions of use at the time it receives such a notification.

*B. What are the objectives of this action?*

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

- EPA will receive notice of any person’s intent to manufacture (including import) or process the chemical substances for the described significant new use before that activity begins.

- EPA will have an opportunity to review and evaluate information submitted in a SNUN before the notice submitter begins manufacturing (including importing) or processing the chemical substances for the described significant new use.

- EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacture or processing for the significant new use could commence.

#### **IV. Significant New Use Determination**

TSCA section 5(a)(2) 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 or form of exposure of human beings or the environment 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 (including importing), 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 constitutes a significant new use of an inactive PFAS, EPA considered relevant information about the toxicity or expected 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). Since the manufacture (including import) and processing of

inactive PFAS has been discontinued in the United States, exposure will decrease over time. As such, EPA expects their presence in humans and the environment to decline over time. If any new uses of inactive PFAS were to resume after having been phased out, EPA believes that such uses could both change the type and form and increase the magnitude and duration of human and environmental exposure to the substances, constituting a significant new use.

EPA acknowledges that the reporting of commercial activity under the TSCA Inventory Notification (Active-Inactive) Requirements Rule (“Active-Inactive rule”) was not required for several activities, including, but not limited to, importing or processing of inactive PFAS-containing articles, and manufacturing (including importing) or processing of inactive PFAS as impurities, byproducts not used for commercial purposes, small quantities solely for research and development, for test marketing purposes, as a non-isolated intermediate, or solely for export from the United States (Ref. 6). Thus, EPA has determined that the designation of these PFAS as inactive does not provide a sufficient basis to conclude that there are not ongoing uses of inactive PFAS for these activities, and because this SNUR is based on information obtained from the Active-Inactive rule, EPA is not at this time designating uses for these activities as significant new uses. Based on consideration of the statutory factors discussed herein, EPA has determined as significant new uses: manufacture (including import) or processing of inactive PFAS for any use except:

- 1) Importing or processing of inactive PFAS-containing articles; and/or
- 2) Manufacture (including import) or processing of inactive PFAS:
  - As impurities,
  - As byproducts not used for commercial purposes,
  - In small quantities solely for research and development,

- For test marketing purposes,
- For use as a non-isolated intermediate, or
- Solely for export from the United States.

## **V. 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.

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 Pre-manufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacturing (including importing) or processing for the significant new use could commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the *Federal Register*, a statement of EPA's finding.

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 TSCA section 13, which requires that the Secretary of the Treasury “refuse entry into the customs territory of the United States” of any substance, mixture, or article containing a chemical substance or mixture that fails to comply with any rule issued under TSCA or that “is offered for entry in violation” of TSCA or certain rules or orders issued under TSCA, including SNURs issued under TSCA section 5.

Persons who import any chemical substance in bulk form, as part of a mixture, or as part of an article (if required by rule) are also subject to TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those 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.

## **VI. 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 (FRL-3658-5)), 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. This rule was proposed on January 26, 2023 (88 FR 4937 (FRL-9655-01-OCSPP)). Uses arising after the publication of the proposed rule are distinguished from uses that existed at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule. EPA solicited public comment to identify any ongoing manufacturing or processing of inactive PFAS subject to the proposed SNUR. EPA received one ongoing use claim captured in the Response to Comments in Unit V. (Ref. 2). EPA reviewed the ongoing use claim, requested additional

information, and has determined that the use is not ongoing, as described in Unit XI.D.

Persons who began commercial manufacturing (including importing) or processing of the chemical substances for a significant new use identified as of January 26, 2023, must cease any such activity upon the effective date of this final rule. To resume their activities, these persons first have to comply with all applicable SNUR notification requirements and wait until all TSCA prerequisites for the commencement of manufacturing (including importing) or processing have been satisfied. Consult the *Federal Register* document of April 24, 1990 (55 FR 17376 (FRL-3658-5)) for a more detailed discussion of the cutoff date for ongoing uses.

## **VII. Development and Submission of Information**

EPA recognizes that TSCA section 5 does not usually require developing new information (*e.g.*, generating test data) before submission of a SNUN. There is an exception: development of information is required where the chemical substance subject to the SNUR is also subject to a rule, order, or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule or order covering the chemical substance, persons are required to submit only information in their possession or control and to describe any other information known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include information that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture (including import), processing, distribution in commerce, use, or disposal. Potentially useful information includes physical-chemical property data and any information related to persistence, bioaccumulation, toxicity, and other characteristics that may help predict the impact of a chemical substance on health or the

environment.

Submitting a SNUN that does not include information sufficient to permit a reasoned evaluation may increase the likelihood that EPA will either respond with a determination that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use or, alternatively, that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs and define the terms of any potentially necessary controls if the submitter provides detailed information on human exposure and environmental releases that may result from the significant new use of the chemical substances.

### **VIII. SNUN Submissions**

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what information may be useful in evaluating a significant new use notice. 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(c), 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 <https://www.epa.gov/chemicals-under-tsca>.

### **IX. Economic Analysis**



*A. What is the analysis for SNUNs?*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of the chemical substances included in this rule (Ref. 4). In the event that a SNUN is submitted, costs are estimated at approximately \$26,894 per SNUN submission for large business submitters and \$11,204 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 \$19,020 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business as defined at 13 CFR 121.201, a reduced user fee of \$3,330 (40 CFR 700.45(b)(1)). Additionally, these estimates reflect the costs and fees as they are known at the time this rule is promulgated. EPA's complete economic analysis is available in the public docket for this rule (Ref. 4).

*B. What is the analysis for export notifications?*

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 TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA 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). While EPA is unable to make any estimate of the likely number of export notifications for the chemicals covered in this SNUR, as stated in the accompanying economic analysis of this SNUR, the estimated cost of the export notification requirement on a per unit basis is approximately \$43.

**X. Scientific Standards, Evidence, and Available Information**

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science, as applicable. These information sources supply information relevant to whether a particular use would be a significant new use, based on relevant factors including those listed under TSCA section 5(a)(2). As noted in Unit III., EPA's decision to promulgate a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use.

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this SNUR, in Unit II. of the January 26, 2023, proposed rule (88 FR 4937 (FRL-9655-01-OCSP)), and in the references cited throughout the preamble of the proposed rule. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, it is appropriate to secure a future notice and review process for these uses, at such time as they are known more definitely. The extent to which the various information, procedures, measures, methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for a significant new use rule.

## **XI. Response to Public Comment**

The Agency reviewed and considered all comments received related to the January 26, 2023, proposed rule (88 FR 4937(FRL-9655-01-OCSP)). Copies of all comments are available in the docket for this action (EPA-HQ-OPPT-2022-0867), and EPA responses are in the Response to Comments document (Ref. 2), which is also available in the docket. Several primary

comment topics included: the Agency's statutory authority; the definition of PFAS; significant new uses; ongoing manufacturing and processing; chemical identity claimed as CBI; byproducts, impurities, and non-isolated intermediates; and costs and fees of SNUN submissions which are summarized in this unit, along with EPA responses.

1. *Comment:* Several commenters stated that EPA is acting within its authority under TSCA with the proposed SNUR. Other commenters commented that EPA is acting outside of its statutory authority and one commenter claimed that the inactive status of a chemical or chemicals on the TSCA Inventory should not be used as the sole basis for a SNUR and that the proposal appears to undercut the simple notification procedure for changing the status of a chemical substance from inactive to active that Congress included when TSCA was amended. One commenter stated that Congress did not include in the 2016 amendments a provision that requires any form of substantive review of substances prior to change of status from inactive to active. The same commenter stated that EPA appears not to have undertaken a chemical-by-chemical review for the three hundred substances subject to this SNUR, and findings on a chemical-specific basis have not been provided.

*Response:* EPA disagrees that this SNUR, issued pursuant to TSCA section 5(a) undercuts the notification procedure established under TSCA section 8(b). TSCA section 8(b)(5)(B)(i) requires that “[a]ny person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.” This Notice of Activity reporting requirement applies to all chemical substances designated as inactive, including those subject to this SNUR. EPA separately has authority under TSCA section 5(a) to determine that uses of a chemical substance (or category of chemical substances)

are “significant new uses” for which notification to EPA is required before manufacture (including import) or processing for the significant new use can commence. EPA has authority under TSCA section 5(a) to promulgate SNURs for “any chemical substance,” without regard to whether the chemical substance is designated as active or inactive. There is also no requirement that EPA need undertake a chemical-by-chemical review as the commenter suggests. One common characteristic of concern of PFAS is that many break down very slowly and can build up in people, animals, and the environment over time (Ref. 7). As described in Unit IV. of the January 26, 2023, proposed rule (88 FR 4639 (FRL-9655-01-OCSPP)), the baseline projected volume for these 329 inactive PFAS is presumed to be minimal based on their inactive TSCA Inventory designation. As such, any new manufacturing or processing of any of these chemical substances would significantly change the production volume and produce changes in human or environmental exposures to these chemical substances. Thus, EPA has determined it is necessary to review and make an affirmative determination on potential risks of the chemical substances under section 5 before the manufacture (including import) or processing of the chemical substances for the described significant new use could begin.

2. *Comment:* Many commenters discussed the proposed definition of PFAS for this rule. Several commenters suggested that EPA identify covered PFAS by specific identification rather than through a structural definition. One commenter stated that structural definitions are difficult to use as they require an extensive understanding of the often-complex chemistry of PFAS, and structural definitions may also be ambiguous and over-inclusive. Other commenters stated that should EPA move ahead with a broad definition and stated that the definition should be consistent with the definition of PFAS the Agency uses in other regulations, or that EPA should work with Federal partners to ensure a consistent Federal definition of PFAS. Two commenters

stated that EPA should adopt a definition of PFAS that more closely aligns with the Organization for Economic Co-operation and Development's (OECD) broad definition (Ref. 8).

*Response:* EPA believes it has been chemically precise in the proposed structural definition and appreciates that there are differences between the definition of PFAS used for this rule, for other actions in the Agency, and by other Federal agencies. The Agency considered adopting various definitions, including some of those suggested by commenters, but ultimately determined those definitions were not appropriate for this rule because they were not developed to focus on substances most likely to be persistent in the environment while excluding those substances that are "lightly" fluorinated. In reaching this decision, EPA considered that OECD also stipulates that there may be different definitions of "PFAS" for different entities or for different purposes, and that it may be appropriate for there to be different definitions or interpretations depending on the specific scenario. The proposed definition focused on substances with greater potential for exposures to people and/or the environment and by extension more potential to present risks. Adopting the OECD definition of PFAS for this rule would have included many substances whose only fluorine molecule is in a terminal -CF<sub>3</sub> and that do not share a structure that is likely to result in the substance's persistence in the environment, or which would degrade to a substance that shares toxicological or physiochemical properties with PFOA, PFOS, or GenX (Ref. 9).

EPA disagrees that the scope of substances subject to notification requirements should be a discrete list and not a structural definition. EPA points out that other regulations promulgated pursuant to TSCA have relied on a structural definition when appropriate (e.g., the LCPFAC SNUR defines covered substances using a structural definition (40 CFR 721.10536), and the polymer exemption rule for new chemical PMNs defines covered PFAS polymers using

structural definitions (40 CFR 723.250)).

Additionally, there are PFAS on the TSCA Inventory whose generic names do not clearly state the substance is fluorinated (i.e., no “fluor” included in the generic name). The inclusion of those chemicals on a discrete list for reporting under this rule would disclose structural information for these substances that has been claimed as CBI. EPA is finalizing the rule as proposed and is providing the list of the 299 inactive PFAS that do not mask “fluor” or “fluorine” in the generic name in the public docket for this rule. EPA believes that providing a list of the 299 PFAS should eliminate most ambiguity, and notes that an entity with a valid commercial need for EPA to verify if a substance is on the inventory can submit a Bona Fide Intent to Manufacture or Import Notice (“bona fide notice”). EPA will consider the information submitted in a bona fide notice and, if the Agency believes that the submitter has demonstrated a genuine intent to manufacture or import, search the full TSCA Inventory master file and provide a written determination to the submitter on the TSCA Inventory status (including SNUR status) for the requested chemical substance.

3. *Comment:* Several commenters stated that SNURs are intended to address truly new uses. The commenters state that the dormant status of a substance on the TSCA Inventory does not mean that a previous use should be considered new when reintroduced into commerce. Two commenters stated that under TSCA, EPA is required to evaluate a substance prior to promulgating a SNUR. One commenter suggested that EPA specifically exclude from the notification requirements any uses that were identified to EPA in previously submitted PMNs. Another commenter said that addressing the discontinued use of an existing chemical with a SNUR is only administratively efficient where other requirements of TSCA section 5 have been met and where (1) stakeholder groups are broadly aware of the proposal and (2) agree with EPA

that the use is permanently discontinued or being phased out; the commenter stated that these elements have not been met.

*Response:* EPA disagrees that the previous use of a chemical substance listed as inactive on the TSCA Inventory should not be considered new when such use is restarted. TSCA section 5 gives EPA the authority to designate uses of a chemical as Significant New Uses, including but not limited to uses that were ongoing in the past but are not longer in process. Part of EPA's rationale for promulgating this SNUR is that the chemical substances subject to this SNUR are considered to be PFAS. Certain PFAS are associated with risk to human health and the environment, and one common characteristic of concern of PFAS is that many break down very slowly and can build up in people, animals, and the environment over time. Therefore, EPA has determined that any use of these PFAS would produce changes in human or environmental exposures and should trigger a SNUN and accompanying EPA review and action as necessary. EPA also disagrees in part with the commenter who suggested that EPA specifically exclude from the SNUN requirements any uses that were identified to EPA in previously submitted PMNs. However, uses of chemical substances for which a PMN has been submitted (and for which EPA has reasonably available information that such uses are ongoing) are considered ongoing uses for which the SNUR does not apply. If production of a chemical has ceased, the use of the chemical substance is not considered to be ongoing and such use is covered by this SNUR.

EPA required reporting (with certain exemptions from reporting at 40 CFR 710.27(a)) under the Active-Inactive reporting rule of each chemical substance manufactured (including imported) or processed in the U.S. over a 10-year period ending on June 21, 2016, and there was no manufacturing (including import), or processing reported for these inactive PFAS (Ref. 6).

EPA believes the comment period for the proposed SNUR allowed for stakeholder groups to be broadly aware of the proposal notice and provided an additional opportunity for industry to provide specific documentation of the status of each chemical. EPA received one ongoing use claim and has determined that the use is not ongoing, as described in Unit XI.D.

4. *Comment:* An anonymous submitter notified EPA that it intends to manufacture a PFAS covered by the proposed SNUR. The commenter stated that since EPA is not authorized under TSCA to adopt a SNUR for an ongoing use, it should exclude this substance from the final SNUR.

*Response:* EPA investigated the confidentially submitted information and determined that the manufacture of this substance is not ongoing. EPA is therefore not excluding the manufacture of this substance from the final SNUR.

5. *Comment:* Several commenters provided feedback on the options described in the proposed rule for potential further agency action to list out in the regulation either the specific chemical identity or generic name of all of the chemicals that fall within the scope of the proposed SNUR. Some commenters stated that EPA must identify all substances for which the chemical identity has been claimed as CBI, regardless as to whether “fluor” or “fluorine” appears in the name. Another commenter stated that TSCA section 14(d)(3) allows information claimed as CBI to be disclosed if the Agency determines that disclosure is “necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.” Thus, the commenter stated that EPA should override CBI claims in the context of this proposed SNUR and identify those PFAS whose generic names do not include “fluor” or “fluorine”. The commenter concluded that since these PFAS are inactive, any business interest in their confidentiality is minimal and overridden by the need of states and the public for the



information. Another commenter stated that although EPA must maintain substantiated CBI claims for these substances, EPA can include the generic names and PMN and accession numbers, which are not CBI, which will minimize the potential for confusion about whether certain substances are subject to this proposal. Another commenter stated that EPA should use its authority under TSCA section 14(f) to require re-substantiation of and review the chemical identity CBI claims for these PFAS. Additionally, the commenter stated that EPA should initiate review of the remaining specific chemical identity CBI claims to ensure they comply with TSCA section 14. Another commenter relinquished its CBI claims for the specific chemical identities for twelve substances listed in the confidential portion of the TSCA Inventory that EPA has identified as being subject to the proposed SNUR and requested that EPA move them to the public portion of the TSCA Inventory.

*Response:* EPA disagrees that all substances for which the chemical identity has been claimed as CBI must be identified. Under section 14(c) of TSCA, submitters may claim information submitted to EPA under TSCA as CBI. The listing of a chemical substance as “inactive” on the TSCA inventory does not itself impact CBI claims relating to such chemical substance, including CBI claims relating to the structure or chemical identity of a chemical substance. Further, as explained previously, EPA is finalizing a structural definition of the chemical substances subject to this SNUR, and EPA believes that persons will be able to identify PFAS subject to this SNUR based on that structural definition, regardless of whether there is a universally known unique identifier. For additional convenience, EPA is providing a list of the inactive PFAS that do not mask “fluor” or “fluorine” in the generic name in the public docket for this rule.

EPA disagrees that its conclusions pursuant to section 5 of TSCA supporting the

proposed SNUR for these substances meet the very different conclusions that would prompt mandatory CBI review in accordance with section 14(f). The fact that the substances are currently designated as inactive following reporting under section 8(b) of TSCA does not mean that the substance identities are no longer treated as confidential by the original CBI claimant or by subsequent or prospective manufacturers, and therefore EPA has not determined that the status of a substance as inactive on the TSCA inventory is a “reasonable basis to believe” that chemical identity information about such substance “does not qualify” for CBI protection, as is required by TSCA section 14(f)(2)(B). Further, CBI claims asserted prior to the enactment of the Lautenberg amendments to TSCA in 2016 do not automatically expire as do most post-Lautenberg CBI claims. However, if a SNUN on any of these substances is submitted, EPA would review any renewed CBI claim for chemical identity at that time, in accordance with the requirements of TSCA section 14(g). Submitters of such SNUNs that assert a CBI claim for chemical identity should expect that if the generic name submitted with such a claim does not identify the substance as a PFAS, EPA expects to require revision of the generic name to meet the generic name requirements in TSCA section 14(c). Finally, the request that EPA initiate review of the remaining specific chemical identity CBI claims to ensure they comply with TSCA section 14 is outside the scope of this rulemaking.

EPA acknowledges the commenter who relinquished its CBI claims for the specific chemical identities and plans to move the twelve substances into the public portion of the TSCA Inventory.

6. *Comment:* Many commenters stated that requiring reporting on the manufacture of any substances that were exempt under the Active-Inactive Rule would not be appropriate, including substances manufactured and processed solely for export or test marketing, non-isolated

intermediates, and all other exemptions from PMN requirements listed at 40 CFR 720.30(h) (Ref. 6). Other commenters expressed opposition to the proposed exemptions. One commenter stated that exposure to minuscule amounts of PFAS is a threat to human health and safety, and the reintroduction of inactive PFAS, in even the smallest quantities, should therefore be subject to the same intense health and safety review as other quantities of PFAS. One commenter urged EPA to finalize the rule without regulatory exemptions and extend the proposed SNUR to byproducts because they are significant sources of PFAS exposure and environmental releases.

*Response:* EPA acknowledges that the standard SNUR exemptions do not fully align with the Active-Inactive reporting exemptions. In the final rule, EPA is adding an exemption for non-isolated intermediates and expanding the exemption for byproducts for consistency with the PMN exemptions at 40 CFR 720.30(g) and (h)(2) and believes that these exemptions are now consistent with the exemptions from Active-Inactive reporting. As EPA collects evidence of the use of PFAS, potentially including inactive PFAS, EPA may consider making certain exemptions inapplicable in the future. The Agency expects to receive additional information about any ongoing use of PFAS as part of the separate TSCA section 8(a)(7) PFAS reporting rule that was proposed on June 28, 2021 (June 28, 2021, 86 FR 33962 (FRL-7902-01-OCSP)) and finalized on October 11, 2023 (88 FR 70516, FRL 7902-02-OCSP).

*7. Comment:* One commenter stated that the proposal incorrectly estimated the costs related to the submission of a SNUN. The commenter said that the estimated cost of \$26,737 is inconsistent with the Agency's latest proposal for increasing TSCA fees. Another commenter stated that while the user fee may discourage a manufacturer from using PFAS in a significant way, it is likely that the user fee will deter users from submitting a SNUN altogether.

*Response:* EPA disagrees that the proposal incorrectly estimated the costs related to the

submission of a SNUN, and notes that the latest proposal for TSCA fees referenced by the commenter has not been finalized. EPA disagrees with the commenter that a user fee would encourage a manufacturer to circumvent the SNUR. EPA has enforcement mechanisms in place to ensure compliance with EPA regulations.

## **XII. References**

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. “List of Select Chemicals Subject to the Proposed Significant New Use Rule Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory.” October 2022.

2. U.S. EPA. “Response to Comments on the Final Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory Significant New Use Rule (SNUR).” October 2023.

3. U.S. EPA. “PFAS Strategic Roadmap: EPA’s Commitment to Action 2021-2024.” EPA-100-K-21-002, October 2021.

4. U.S. EPA. “Economic Analysis of the Final Significant New Use Rule Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory.” October 2023.

5. U.S. EPA. “List of Select Chemicals Subject to the Proposed Significant New Use Rule Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA

Inventory.” January 2022.

6. U.S. EPA. TSCA Inventory Notification (Active-Inactive) Requirements; Final Rule, 82 FR 37520 (FRL-9964-22), August 11, 2017.

7. Evich, Marina G, Davis, Mary J.B., McCord, James P., Acrey, Brad, Awkerman, Jill A., Knappe, Detlef R.U., Lindstrom, Andrew B., Speth, Thomas F., Tebes-Stevens, Caroline, Strynar, Mark J., Wang, Zhanyun, Weber, Eric J., Henderson, Matthew W., Washington, John W. Per- and polyfluoroalkyl substances in the environment. *Science*. 375: 6580, 1–14. February 4, 2022

8. Organisation for Economic Co-operation and Development (OECD). “Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance.” July 9, 2021.

9. United Nations Environment Programme. Sources, Fates, Toxicity, and Risks of Trifluoroacetic Acid and Its Salts: Relevance to Substances Regulated Under the Montreal and Kyoto Protocols. Report No. 2016-01. February 2016. <https://ozone.unep.org/sites/default/files/2019-08/TFA2016.pdf>.

### **XIII. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

*A. Executive Order 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review*

This action is not a significant regulatory action under Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to Executive Order 12866 review.

*B. Paperwork Reduction Act (PRA)*

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2070-0038 (EPA ICR No. 1188.13) and 2070-0030 (EPA ICR No. 0795.16). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system. 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.

EPA is amending the table in 40 CFR part 9 to list the SNURs and OMB approval number for the information collection activities contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. The Information Collection Request (ICR) covering the SNUR activities was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

EPA always welcomes your feedback on the burden estimate. Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory

Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

*C. Regulatory Flexibility Act (RFA)*

I certify this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are potential future manufacturers (defined by statute to include importers), processors, and exporters of one or more subject chemical substances for a significant new use designated in the SNUR. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, the Agency has determined that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 10 in federal fiscal year (FY) FY2016, 14 in FY2017, 16 in FY2018, five in FY2019, seven in FY2020, and 13 in FY2021, and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$19,020 to \$3,330. This lower fee reduces the total reporting and recordkeeping cost of submitting a SNUN to about \$11,204 for qualifying small firms.

Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that

published in the *Federal Register* of June 2, 1997 (62 FR 29684 (FRL-5597-1)), the Agency presented its general determination that 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)*

This action does not contain any unfunded mandates as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. 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 reasons to believe that any state, local, or tribal government will be impacted by this action. As such, EPA has determined that this final rule will not impose any enforceable duty, contain any unfunded mandate, or the otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

*E. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999) because 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.

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.



Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks 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. Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, EPA’s Policy on Children’s Health also does not apply.

Although this action does not concern an environmental health or safety risk, the designation of certain uses of PFAS as significant new uses ensures the Agency has an opportunity to review and address potential risks associated with such uses before an entity begins commencing any manufacture (including import) or processing of PFAS for that use. Once EPA receives a notification, EPA must review and make an affirmative determination on the notification, and take such action as is required by any such determination before the manufacture (including import) or processing for the significant new use can commence. Such a review will assess whether the use identified in the SNUN may present unreasonable risk to health or the environment and ensure that EPA can prevent future unsafe environmental releases of PFAS subject to the SNUR. As discussed previously, EPA is concerned about the potential for adverse health effects from PFAS for children and will evaluate the risk.

*H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001),

because it is not a “significant regulatory action” under Executive Order 12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This action does not involve any technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation’s Commitment to Environmental Justice for All*

The EPA believes that it is not practicable to assess whether the human health or environmental conditions that exist prior to this action result in disproportionate and adverse effects on communities with environmental justice concerns.

The Agency believes that the inactive PFAS included in this action are no longer being manufactured (including imported) or processed for any uses in the United States. EPA believes that it is not practicable to assess whether this action is likely to result in new disproportionate and adverse effects on environmental justice communities because the Agency is not able to anticipate which chemical substances and uses, if any, will be submitted for a significant new use notice under this action.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 et seq., and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 721**

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

**Dated:** January 8, 2024.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

Therefore, for the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

**PART 9--OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. Amend the table in § 9.1 by adding an entry for § 721.11777 in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

\* \* \* \* \*

40 CFR citation				OMB control No.		
*	*	*	*	*	*	*
<b>Significant New Uses of Chemical Substances</b>						
*	*	*	*	*	*	*
721.11777				2070-0038		
*	*	*	*	*	*	*

\* \* \* \* \*

**PART 721-- SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES**

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

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

4. Add § 721.11777 in numerical order to subpart E to read as follows:

**§ 721.11777 Per- and poly-fluoroalkyl chemical substances designated as inactive on the TSCA Inventory.**

(a) *Definitions.* The definitions in § 721.3 apply to this section.

(b) *Chemical substances and significant new uses subject to reporting.* (1) The 329 chemical substances identified in paragraphs (b)(1)(i) through (iii) of this section, designated as inactive on the TSCA Chemical Substance Inventory as of January 26, 2023, are subject to reporting under this section for the significant new uses described in paragraph (b)(2) of this section. The requirements of this section do not apply to quantities of the substance that are manufactured or processed as nonisolated intermediates, as defined at 40 CFR 720.3(w), or to quantities of the substance that are manufactured or processed as a byproduct, as defined in 40 CFR 720.3(d), which are not used for commercial purposes.

(i) R-(CF<sub>2</sub>)-CF(R')R'', where both the CF<sub>2</sub> and CF moieties are saturated carbons;

(ii) R-CF<sub>2</sub>OCF<sub>2</sub>-R', where R and R' can either be F, O, or saturated carbons; and

(iii) CF<sub>3</sub>C(CF<sub>3</sub>)R'R'', where R' and R'' can either be F or saturated carbons.

(2) The significant new uses for the chemical substances identified in paragraph (b)(1) of this section are: manufacture (including import) or processing for any use.

(c) *Chemical substances not subject to reporting.* The chemical substances already subject to a rule under this part, including § 721.9582, and § 721.10536, are not subject to reporting under this section.

(d) *Specific requirements.* The provisions of subpart A of this part apply to this section.