



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 705

[EPA-HQ-OPPT-2020-0549; FRL-7902-04-OCSPP]

RIN 2070-AK67

### TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment

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

**ACTION:** Proposed rule; Notice of data availability.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the availability of and soliciting comment on an Initial Regulatory Flexibility Analysis (IRFA) and Updated Economic Analysis following the completion of a Small Business Advocacy Review (SBAR) Panel for the Toxic Substances Control Act (TSCA) proposed rule for reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (PFAS). The EPA seeks public comment on all aspects of the IRFA and Updated Economic Analysis, including underlying data and assumptions in developing its estimates, as well as on certain items presented in the IRFA for public comment and related to the protection of Confidential Business Information.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0549, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Stephanie Griffin, Data Gathering and Analysis Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1463; email address: [griffin.stephanie@epa.gov](mailto:griffin.stephanie@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. Background**

In the *Federal Register* of June 28, 2021 (86 FR 33926 (FRL-10017-78)), EPA proposed a rule pursuant to section 8(a)(7) of the Toxic Substances Control Act (TSCA). Section 7351 of the FY2020 National Defense Authorization Act (NDAA) amended TSCA by adding section 8(a)(7), which obligates EPA to promulgate a rule by January 1, 2023, that requires each person who has manufactured a chemical substance that is a PFAS in any year since January 1, 2011, to report and maintain records, for each year, information described in TSCA section 8(a)(2)(A) through (G).

EPA's proposed rule would require all manufacturers of a chemical substance or a mixture containing a chemical substance that is a PFAS (including article manufacturers (including import)) in any year since 2011 to report certain information to EPA related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal (*i.e.*, the section 8(a)(2) requirements). EPA also proposed a five-year retention period for all relevant records following the submission period. Based on information available to EPA at the time of the proposed rule's publication, EPA certified that the proposed rule did not have significant impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA).

After being extended 30 days (86 FR 41802, August 3, 2021 (FRL-7902-03-OCSPP)),

the comment period for the proposed rule closed on September 27, 2021. EPA received 110 unique comments on the proposed rule representing a wide range of views. Many commenters asserted that the proposed rule lacked sufficient data to support its estimates of burden and cost, including those of small entities and article importers, such that EPA could not certify its final rule will not have a significant impact on a substantial number of small entities under the RFA. Based on public comments and additional data sources on PFAS-containing article importers, EPA convened an SBAR Panel for the proposed rule and has prepared an IRFA under the RFA, 5 U.S.C. 601 *et seq.*, and evaluated the economic impact of the proposed TSCA section 8(a)(7) rule on small entities, as well as any significant alternatives to the proposed rule that may minimize significant economic impacts on small entities while accomplishing the Agency's objectives.

EPA has updated its estimate of costs for the proposed rule as proposed from approximately \$10.8M to \$875M in social costs, as well as from \$948,078 to \$1.5M in agency costs. As discussed further in the IRFA, the affected small businesses subject to the rule are expected to incur \$863,483,965 in costs for this one-time reporting. EPA is considering changes to the final rule from the regulatory proposal based on updates to the economic analysis, small business impact analysis, and significant regulatory alternatives presented in the IRFA, as well as regarding the treatment of confidential business information (CBI) for PFAS.

Since publishing the draft Economic Analysis, EPA has also updated the discussion of the benefits of the proposed rule. The IRFA details the many activities in the Office of Pollution Prevention and Toxics and in other offices across the Agency that will use and benefit from the data collected under this proposed rule. The proposed rule will provide information on PFAS to which the Agency (or the public) does not currently have access. By increasing the data supplied to Agency programs, including risk-screening programs across different media, EPA expects to more effectively and expeditiously evaluate any potential risks posed by PFAS. Ultimately, enhancing the risk screening process will have positive consequences for human and

environmental health and may enable a more efficient allocation of EPA's and society's resources. The IRFA also details the potential benefits of the proposed rule to external stakeholders, such as tribal, state, and local governments, non-governmental organizations, and private-sector organizations, based on comments submitted during the proposed rule's public comment period. The proposed rule is an information-collecting rule and does not attempt to reduce risks related to PFAS. The IRFA's benefits analysis does not seek to quantitatively measure the associated benefits and does not formally identify or define the universe of recipients of those benefits.

## **II. Request for Public Comments**

EPA welcomes public comment on all aspects of the IRFA and Updated Economic Analysis, including underlying data and assumptions in developing its estimates, as well as on certain items identified in the IRFA and Updated Economic Analysis for public comment:

- The number of potential small article manufacturers (including import) that may be subject to the proposed rule;
- The number of PFAS for which small entities may submit reports under this rule, including information related to potential outliers of the industry-wide average estimate and the estimated distribution of PFAS per firm;
- The number of hours small entities will spend on understanding the structural definition of PFAS proposed for this rule;
- The number of entities that would be affected by implementing a reporting threshold for this proposed rule of either 2,500 lbs or 25,000 lbs manufactured per year.

Additionally, EPA welcomes public comment on items in the IRFA that were not available for public comment during the proposed rule's comment period:

- Regulatory flexibility alternatives, such as exemptions for businesses with less than \$12 million or \$6 million in revenue, exemptions for article importers with less than \$6 million in revenue, limiting the scope of PFAS to a finite list, establishing reporting thresholds, simplified

reporting forms for certain entities (*i.e.*, article importers and manufacturers of research and development (R&D) substances in volumes less than 10 kg per year) (see alternatives in the IRFA (Ref. 1)).

- Reporting exemptions common to other chemical reporting programs, such as for research and development substances, byproducts, impurities, recyclers, and intermediates. EPA particularly seeks information on the potential impacts of such exemptions, which it did not quantify in the IRFA.

- Potentially duplicative or overlapping reporting requirements with this proposed rule (see “Other Federal Rules that may Duplicate, Overlap, or Conflict with the Rule” in the IRFA (Ref. 1)). EPA specifically requests comment on potential duplication with any reporting requirements that have been implemented since the publication of the proposed rule.

EPA also welcomes comments on whether any of the significant regulatory alternatives considered in the IRFA, such as *de minimis* or research and development exemptions, would be appropriate to extend to more broadly to each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011.

Lastly, EPA also welcomes public comment on the following items pertaining to confidential business information (CBI) that are not in the IRFA and Updated Economic Analysis:

- *Treatment of chemical identity claims.* EPA seeks to clarify and add to language included in the PFAS proposed rule based on comments received in response to the TSCA CBI Procedures proposed rule about an entity’s knowledge of a specific chemical identity. PFAS proposed rule Section 705.30(a)(2)(iii) indicates that confidentiality claims cannot be asserted when a response is left blank or designated as “not known or reasonably ascertainable.” EPA seeks to explain how it will handle such a response in the context of a specific chemical identity. If any entity reports a PFAS substance by specific chemical identity and does not claim the specific chemical identity as CBI, EPA expects to determine that the specific chemical identity is

no longer entitled to confidential treatment. However, EPA would not make this determination where an entity attests that it does not have knowledge of the specific chemical identity. Instead, an entity that does not have knowledge of a specific chemical identity must initiate a joint submission with its supplier or other manufacturer. In these cases, the secondary submitter would be responsible for providing the specific chemical identity and for asserting and substantiating any CBI claims concerning the specific chemical identity. See, *e.g.*, 40 CFR 711.15(b)(3); 711.30(c). If an entity (likely an article importer) attests that it lacks knowledge of the specific chemical identity and also that it lacks knowledge of the identity of the manufacturer of the substance, the joint submission provisions would not apply, and the entity would not be able to make or waive a CBI claim for the specific chemical identity.

- *Notice prior to publication on the public Inventory.* The Agency seeks to further clarify and add to language in the PFAS proposed rule at 40 CFR 705.30 to explain which entities, if any, should expect to receive notice before a chemical identity is moved to the public portion of the TSCA inventory. In PFAS proposed rule 40 CFR 705.30(g), EPA indicated that information not claimed as confidential may be made public without further notice to the submitter. EPA seeks to clarify that if a submitter reports a PFAS substance by specific chemical identity, but does not assert a CBI claim on that specific chemical identity, then EPA *will* move that chemical identity to the public portion of the TSCA Inventory without further notice to the submitter. EPA is also requesting comment on aligning this provision in the final PFAS rule with language in the proposed TSCA CBI Procedures rule, by indicating that persons who previously made a CBI claim for the same specific chemical identity will also not receive prior notice before the specific chemical identity is moved to the public portion of the Inventory. See 87 FR 29078, 29081 and proposed 40 CFR 703.5; rule docket including comments available at <https://www.regulations.gov> (docket ID EPA-HQ-OPPT-2021-0419).

- *Generic names without “fluor.”* Generic names must be sufficiently detailed to identify the reported chemical as a PFAS. Specifically, any generic name reported for a PFAS that does

not contain “fluor” in the name would be rejected by EPA as insufficient under TSCA section 14(c)(1)(C). Additionally, any previously existing generic names from earlier TSCA section 5 submissions for PFAS without “fluor” are insufficient. Further, even if a generic name reported under the TSCA 8(a)(7) rule lacks the structural unit “fluor,” the Agency will identify the chemical substance as a PFAS.

### **III. References**

The following is a listing of the documents that are specifically referenced in this document. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. US EPA. (2022). Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances.

#### **List of Subjects in 40 CFR Part 705**

Environmental protection, Chemicals, Hazardous Materials, Recordkeeping, and Reporting requirements.

Dated: November 18, 2022

**Michal Freedhoff,**

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

[FR Doc. 2022-25583 Filed: 11/23/2022 8:45 am; Publication Date: 11/25/2022]