# TSCA Section 8(a)(7) Rule: Reporting and Recordkeeping Requirements for PFAS

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
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# Background

# Authority

- The Fiscal Year 2020 National Defense Authorization Act (NDAA) amended TSCA section 8(a) by adding section 8(a)(7)

- TSCA section 8(a)(7) requires EPA to promulgate a rulemaking requiring manufacturers (including importers) of a perfluoroalkyl or polyfluoroalkyl substance (PFAS) in any year since January 1, 2011, to submit a report to EPA containing information outlined in section 8(a)(2) for each year since January 1, 2011

# Rule Development

- EPA published the proposed rule on June 28, 2021, and the public comment period closed on September 27, 2021
  - Following public comments and additional information on the scope of potential reporting entities, EPA could no longer certify that the rule had no significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA)
- EPA convened a Small Business Advocacy Review Panel under the RFA: April – August 2022
  - The Panel and small entity representatives provided EPA with information and feedback on behalf of small businesses
  - The Panel Report and Initial Regulatory Flexibility Analysis were published for a 30-day public comment period: November–December 2022
- EPA published the final rule on October 11, 2023
  - Final rule considers input from all public comment periods and the Panel
  - Rule codified at **40 CFR 705**

# TSCA Chemical Substances

TSCA defines a “chemical substance” as any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical

- Includes organics, inorganics, polymers, and substances of unknown or variable composition, complex reaction products, and biological materials (UVCBs)
- *TSCA section 3(2) generally excludes activities including, among others, food, food additives, drugs, medical devices, cosmetics and pesticides*
- If a portion of a manufacturer’s production is not subject to TSCA (for example, if the use is regulated under the Federal Food, Drug, and Cosmetic Act), then the production associated with the non-TSCA use will not be reportable

# TSCA Chemical Substances in Articles and Mixtures

- EPA has the authority to require reporting, recordkeeping, and otherwise regulate chemicals under TSCA, including when they're in articles or mixtures

- *Article* means a manufactured item which:

  (1) Is formed to a specific shape or design during manufacture;

  (2) Has end use function(s) depending in whole or in part upon its shape or design during end use; and

  (3) Has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design. (40 CFR 705.3)

# TSCA Chemical Substances in Articles and Mixtures

- *Mixture* means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined. (TSCA 3(10))

- If an article or mixture is comprised of two or more reportable PFAS, the manufacturer must report on each PFAS

# Overview of Final Rule

# Scope of PFAS

- For this rule, PFAS is defined as including at least one of these three structures:
  - R-(CF2)-CF(R’)R’’, where both the CF2 and CF moieties are saturated carbons;
  - R-CF2OCF2-R’, where R and R’ can either be F, O, or saturated carbons; and
  - CF3C(CF3)R’R’’, where R’ and R’’ can either be F or saturated carbons.

- Any **TSCA chemical substance** meeting this definition which has been manufactured in any year since January 1, 2011, is reportable. Manufacturers don’t need to report on substances that do not meet this structural definition.
  - Fluoropolymers may meet this scope

- From the known TSCA universe, EPA has identified at least 1,462 PFAS under this structural definition, including:
  - All PFAS listed as active on the February 2023 TSCA Inventory
  - All PFAS with TSCA section 5 (new chemicals) low-volume exemption (LVE) claims

# Reporting Entities

- Any person who has manufactured (including imported) a PFAS meeting the structural definition at any time since January 1, 2011, is required to report to the extent the information is known or reasonably ascertainable
- Persons who have only processed, distributed in commerce, used, and/or disposed of PFAS are not required to report under this rule, unless they also have manufactured (including imported) PFAS for a commercial purpose
- No reporter exemptions to this rule
- No minimum volume or concentration exemption – any amount of PFAS known to be manufactured is reportable
- Certain waste management sites
  - Sites that import municipal solid waste streams for disposal or destruction are excluded from reporting those amounts of PFAS imported in MSW for disposal/destruction

# Data Elements

- TSCA section 8(a)(2) authorizes EPA to collect information on each PFAS manufactured since January 1, 2011, for each year, regarding:
  - Chemical or mixture identity, trade name, and molecular structure
  - Categories of use
  - Quantity manufactured or processed for each category of use
  - Descriptions of byproducts resulting from the manufacture, processing, use, or disposal
  - Existing environmental and health effects information
  - Number of workers exposed and duration of exposure
  - Manner or method of disposal and any change in manner or method
- Some data elements may be duplicative of information previously submitted to the Chemical Data Reporting rule, Toxics Release Inventory, or Greenhouse Gas Reporting Program
  - Environmental or health effects info also may have been submitted under TSCA section 4, 8(d), 8(e), or in response to enforcement requests under other authorities
  - To mitigate duplicative reporting, EPA is allowing submitters to indicate in the reporting tool if they have provided this information to EPA already, for that year
  - Key difference: this rule requires information for each year in which that PFAS was manufactured, <u>without exemptions</u>

# Streamlined Reporting Forms

- **Article Importers** have an option to provide information through a streamlined form:
  - Chemical identity, chemical identification number, trade name or common name, molecular structure, industrial processing and use information, import production volume, and indicator for whether physically at reporting site, as well as the option to provide any additional information to EPA that the entity may have (e.g., SDS, disposal information)
  - Article importers **do not** need to assert and substantiate CBI claims for chemical identity – EPA will not make any CBI determinations for chemical identity based on article importer forms
- **Manufacturers (including import) of R&D Substances manufactured below 10 kg/year** have an option to provide information through a streamlined form:
  - Chemical identity, chemical identification number, trade name or common name, molecular structure, production volume, indicator for imported but never physically at site, as well as the option to provide any additional information to EPA that the entity may have (e.g., SDS, disposal information)
  - Manufacturers (including import) of R&D Substances manufactured below 10 kg/year will have the option to assert and substantiate CBI claims

# Reporting Standard

- Information is reported **to the extent known or reasonably ascertainable** by the manufacturer
  - "Known to or reasonably ascertainable by" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know
  - "Possession or control" refers to the submitter, or any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question
    - Includes files maintained by submitter's employees who are associated with R&D, marketing, or reasonably likely to have such data, and files maintained by other agents of the submitter

# Reporting Standard

- Includes but is not limited to: information possessed by the manufacturer's employees (e.g., R&D, manufacturing), existing customer surveys, sales reports, SDS or supplier notifications, information learned through technical publications or symposia, may require outreach to other entities (suppliers, customers)
- Case-specific; level of information "known to or reasonably ascertainable" by different companies will vary
- Same reporting standard as other Section 8 rules, including CDR
- No testing or monitoring requirement
- For any manufacturer (particularly article importers) who does not know nor can reasonably ascertain that they manufactured a PFAS and therefore doesn't need to report: EPA recommends documenting the due diligence undertaken, although this is not required

# CBI Requirements

**CBI statutory requirements (from 2016 Lautenberg Act and 2023 TSCA CBI procedural rule):**

- The submitter must substantiate claims of confidentiality at the time information is submitted to EPA, except for types of information listed as exempt in TSCA (e.g., production volume) (TSCA sections 14(c)(2) and (3))
- The submitter must also provide a statement supporting the claim and must certify that the statement is true and correct (TSCA sections 14(c)(1)(B) and (5))
- Information on uses that customarily would be shared with the general public or within an industry or industry sector cannot be claimed as confidential (TSCA section 14(b)(3)(B))
- Information in health and safety studies has limited CBI protection under TSCA:
  - *Chemical identity is always considered part of health & safety study*
  - *CBI protections for health & safety studies generally limited to personally identifying information and process-related information*

# CBI Requirements

**Stipulated the following provisions in the final rule:**

- Generic name requirements
  - Generic names/descriptions for PFAS chemical identities need to contain “fluor”
- Article importers are not required to assert or substantiate CBI claims for chemical identity
  - EPA will not make CBI claim determination for chemical identity based on article importer reports
- Joint submission requirements
  - Manufacturers (other than article importers) who do not know the specific PFAS identity (i.e., CAS name, CASRN, Accession number or LVE number) must initiate a joint submission with their supplier or other entity who is able to identify the specific PFAS and assert and substantiate a CBI claim as appropriate
  - If any entity (other than article importer) reporting the specific PFAS identity fails to assert and substantiate a chemical identity as CBI, EPA intends to start the process of moving that chemical identity to the public portion of the TSCA Inventory, following public notification via EPA’s website of the Accession numbers of PFAS that EPA intends to move to the public Inventory

# Sharing CBI with States & Tribes

- TSCA section 14(d)(4) permits States, Tribes, and political sub-divisions of States to request access to CBI in writing
  - The entity seeking CBI access must show that it can continue to protect the information as confidential. If a State or Tribe requests access and that is granted per statutory conditions, EPA would have an agreement in place laying out how the requestor was going to protect the information.

# Electronic Reporting

- EPA is developing a new reporting tool for this rule
  - Hosted on CDX with other chemical information systems reporting tools
- Environmental and health effects information must be submitted using OECD harmonized templates where applicable (i.e., the endpoint has an established template)
  - Underlying data or relevant study reports must be submitted as attachments
- Reporters may indicate to EPA if they have already provided a specific data element, for that same year, to EPA under another CDX reporting program to mitigate potential duplicative reporting

# Reporting Timeframe

- Most submitters have until **May 8, 2025** (18 months following the effective date of the final rule) to submit their information to the Agency
  - There is a **one-year information collection period** from the effective date of the final rule for affected parties to familiarize themselves with the rule, identify PFAS they have manufactured, identify any suppliers or other contacts, and to start collecting the required information
  - Following the one-year collection period is a **six-month reporting submission period**. During this time, the reporter submits the required information to the Agency
- Small manufacturers reporting exclusively as **article importers have until November 10, 2025** (24 months following the effective date of the final rule) to report
  - The **one-year reporting submission period** will also start after a one-year information collection period

# Recordkeeping Requirements

- 5-year recordkeeping period following final date of submission period
  - Supports EPA's future activities informed by this data call

# Questions

# Pre-submitted Questions

- *Is [X] a reportable PFAS?*
  - For questions on whether a certain substance (e.g., polymer) meets the structural definition: please reach out to EPA to confirm
    - *You may also consult the 8(a)(7) chemical lists available on various EPA pages: SRS, CompTox Chemicals Dashboard*
  - For questions on whether a substance is covered by TSCA section 3(2) or FFDCA (*"any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device"*): FFDCA's definition is product-specific and is made on a case-by-case basis in a fact-specific inquiry
    - *It's possible that the same PFAS may be used for both TSCA-covered and non-TSCA uses*
- *If I purchase PFAS from a domestic supplier and incorporate it into a product that I sell, do I need to report?*
  - If an U.S. entity manufactures (including imports) PFAS, including the import of a PFAS-containing article, then it is required to report under this rule. Entities that **only** process, use, and/or dispose of PFAS do not need to report.

# Pre-submitted Questions

- *If there isn't yet an analytical test method for a PFAS, how do I determine whether I have imported it and need to report?*
  - The reporting standard is known or reasonably ascertainable information. If a manufacturer does not know nor can reasonably ascertain whether they have manufactured a covered PFAS, they need not report.
  - Manufacturers do not need to test products to determine whether they need to report. However, if product testing has been done previously, those results may be considered known or reasonably ascertainable information.
  - However, if you know you have manufactured a covered PFAS, but aren't sure which one specifically (or of the trade name), you need to report. In that case, you will report a generic name/description with as much structural information as possible.

- *I'm an article importer but do not know whether my imports contained reportable PFAS. What happens if my overseas supplier can't be reached or is non-responsive?*
  - EPA does not expect the scope of KRA information to look the same for all entities. Factors influencing this scope include (but are not limited to) the importer's size and resources, the number of suppliers, the importer's current relationship with suppliers, the supplier's responsiveness.
  - As above, if a company can't determine/reasonably ascertain they have manufactured/imported a PFAS, they need not report.
    - *However, EPA encourages companies who have attempted to reach out to suppliers and other entities for information to document their efforts*

# Audience Questions?

## Additional Resources

- Reporting instructions and small entity compliance guidance: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping
  - Q&As are forthcoming
- TSCA Hotline:
  - Email: tsca-hotline@epa.gov
  - Phone: 800-471-7127, Monday—Friday, 8am—6pm Eastern time
- Central Data Exchange (CDX) user guide: https://cdx.epa.gov/about/userguide

# Appendix

# Data Elements (1/5)

(A) THE COMMON OR TRADE NAME, THE CHEMICAL IDENTITY, AND THE MOLECULAR STRUCTURE OF EACH CHEMICAL SUBSTANCE OR MIXTURE FOR WHICH SUCH A REPORT IS REQUIRED.

- Chemical name (multiple if mixture)
- Generic name(s) if chemical name(s) is CBI
- Chemical ID(s) (CASRN, Accession Number, LVE case number)
- Trade name or common name
- Representative molecular structure, if not a Class 1 substance on the Inventory (attachment)
- Physical state of chemical or mixture

(B) THE CATEGORIES OR PROPOSED CATEGORIES OF USE OF EACH SUCH SUBSTANCE OR MIXTURE.

- Industrial processing and use - type of process or use
- Industrial processing and use - sector(s)
- Industrial processing and use - function category
- Consumer and commercial use - product category
- Consumer and commercial use - function category
- Consumer and commercial use - consumer or commercial
- Consumer and commercial use - used in products intended for children
- Consumer and commercial use - maximum concentration in any product

# Data Elements (2/5)

(C) THE TOTAL AMOUNT OF EACH SUCH SUBSTANCE AND MIXTURE MANUFACTURED OR PROCESSED, REASONABLE ESTIMATES OF THE TOTAL AMOUNT TO BE MANUFACTURED OR PROCESSED, THE AMOUNT MANUFACTURED OR PROCESSED FOR EACH OF ITS CATEGORIES OF USE, AND REASONABLE ESTIMATES OF THE AMOUNT TO BE MANUFACTURED OR PROCESSED FOR EACH OF ITS CATEGORIES OF USE OR PROPOSED CATEGORIES OF USE.

- Production volume - domestically manufactured [for each year 2011-2023]
- Production volume - imported [for each year 2011-2023]
- Imported but never physically at site
- Volume directly exported [for each year 2011-2023]
- Industrial processing and use - % production volume [for each use for each year 2011-2023]
- Consumer and commercial use - % production volume [for each use for each year 2011-2023]
- Whether chemical is site-limited
- Total volume recycled (on-site) from 2011-2023

# Data Elements (3/5)

(D) A DESCRIPTION OF THE BYPRODUCTS RESULTING FROM THE MANUFACTURE, PROCESSING, USE, OR DISPOSAL OF EACH SUCH SUBSTANCE OR MIXTURE.

- Byproduct chemical name(s) or description (if unknown)
- Byproduct generic name(s) if byproduct chemical name(s) is CBI
- Byproduct chemical ID(s) if applicable (CASRN, Accession Number, LVE case number)
- Was the byproduct produced from manufacture, process, use, or disposal?
- Was the byproduct released to the environment?
- If byproducts are released to the environment, indicate the environmental media are they released to
- Byproduct volume released [for each year 2011-2023]

(E) ALL EXISTING INFORMATION CONCERNING THE ENVIRONMENTAL AND HEALTH EFFECTS OF SUCH SUBSTANCE OR MIXTURE.

- OECD template (attachment)
- Study report (attachment)
- Supporting information (attachment)
- Other data relevant to environmental and health effects (e.g., range-finding studies, preliminary studies, OSHA medical screening or surveillance standards reports, adverse effects reports)
- Analytical methods used, if any

# Data Elements (4/5)

(F) THE NUMBER OF INDIVIDUALS EXPOSED, AND REASONABLE ESTIMATES OF THE NUMBER WHO WILL BE EXPOSED, TO SUCH SUBSTANCE OR MIXTURE IN THEIR PLACES OF EMPLOYMENT AND THE DURATION OF SUCH EXPOSURE.

- Worker activity descriptions at manufacturing site
- Number of workers reasonably like to be exposed at the manufacturing site, for each worker activity
- Maximum duration of exposure for any worker, for each worker activity (hours/day)
- Maximum duration of exposure for any worker, for each worker activity (days/year)
- Number of workers reasonably likely to be exposed for each industrial process and use
- Maximum duration of exposure for any worker for each industrial process and use (hours/day)
- Maximum duration of exposure for any worker for each industrial process and use (days/year)
- Number of workers reasonably likely to be exposed for each commercial use
- Maximum duration of exposure for any worker for each commercial use (hours/day)
- Maximum duration of exposure for any worker for each commercial use (days/year)

# Data Elements (5/5)

(G) IN THE INITIAL REPORT UNDER PARAGRAPH (1) ON SUCH SUBSTANCE OR MIXTURE, THE MANNER OR METHOD OF ITS DISPOSAL, AND IN ANY SUBSEQUENT REPORT ON SUCH SUBSTANCE OR MIXTURE, ANY CHANGE IN SUCH MANNER OR METHOD.

- Description of disposal process(es)
- Description of any changes to the disposal process or methods since 2011
- Total volume released (land disposal) [for each year 2011-2023]
- Total volume released (water) [for each year 2011-2023]
- Total volume released (air) [for each year 2011-2023]
- Total volume incinerated (on-site) [for each year 2011-2023]
- If incineration occurs, the temperature at which the chemical was incinerated