TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances: Proposed Rule

U.S. ENVIRONMENTAL PROTECTION AGENCY

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CHEMICAL WATCH PRESENTATION

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Background: What are PFAS?

- Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that includes PFOA, PFOS, GenX, and many other chemicals.
- PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s.
- PFAS can be found in a wide variety of consumer products (e.g., food packaging, cleaning products, paints, certain fire-fighting foam) and industrial uses (e.g., chrome plating, electronics manufacturing).
- There is evidence that exposure to PFAS can lead to adverse human health effects.
- For more information, please visit www.epa.gov/pfas.

Background: Rulemaking 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 rule~~making~~ by January 1, 2023, requiring manufacturers (including importers) of a 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.

Overview of Proposed Rule

Scope of PFAS

- The proposed scope of PFAS for this rule~~making~~ are substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen.
  - Any TSCA chemical substance* meeting this definition which has been manufactured in any year since January 1, 2011, is reportable.

*Under TSCA, a "chemical substance" means: any organic or inorganic substance of a particular molecular identity, including — (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical. (B) Such term does not include— (i) any mixture, (ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide, (iii) tobacco or any tobacco product, (iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.] and regulations issued under such Act), (v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and (vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act [21 U.S.C. 453(e) and (f)]), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act [21 U.S.C. 601(j)]), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act [21 U.S.C. 1033]).

Scope of PFAS

- EPA has identified at least 1,364 PFAS under this structural definition, including:
  - All PFAS listed as active on the February 2021 TSCA Inventory
  - All PFAS with TSCA section 5 (new chemicals) low-volume exemption claims
- To assist companies with identifying PFAS, the rule and docket supporting files will include lists of PFAS on the TSCA Inventory or submitted as new chemical low-volume exemptions, and structural diagram examples to capture any PFAS that could not be specifically listed due to CBI 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
- No reporter exemptions ~~to~~ in this proposed rule
  - Unlike the small manufacturer exemption from ~~other~~ chemical reporting rules under TSCA section 8(a)(1), section 8(a)(7) specifically states that "each person who has manufactured a chemical substance that is a [PFAS]" shall be subject to the rule.

Data Elements

- TSCA section 8(a)(2) authorizes EPA to collect information on each PFAS 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 proposed data elements are similar to information required for the 2020 Chemical Data Reporting (CDR) cycle (e.g., production volumes, worker exposure information)
  - Key difference: this rule requires information for each year in which that PFAS was manufactured, without exemptions
  - To mitigate duplicative reporting, EPA proposes to allow submitters to indicate in the reporting tool if they have provided this information to EPA already, for that year

Electronic Reporting

- EPA will create a new reporting tool for this rule
  - Hosted on CDX with other chemical information systems reporting tools
- EPA is proposing to allow reporters to 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
- Environmental and health effects information would be submitted in the format of OECD harmonized templates when applicable (not all data endpoints have established templates)
  - Underlying data or relevant study reports would be uploaded as attachments
- CBI claims and substantiations would follow requirements and procedures under TSCA section 14

Recordkeeping Requirements

- Proposed 5-year recordkeeping period following final date of submission period
- Rationale:
  - Consistent with CDR rule and some other 8(a) chemical-specific reporting rules
  - Retention requirement corresponds with statute of limitations for violations
  - Supports EPA's future activities informed by this data call

Impacts of Proposed Rule

- 234 respondents are expected to report under this one-time data call
  - Expected respondents identified in the Chemical Data Reporting database and extrapolated to include manufacturers not in CDR database
- Estimated total industry burden and cost:
  - $9.8 million
  - 122,104 hours (no annualized capital or operation and maintenance costs)
- Economic costs include rule familiarization, form completion, CBI claim substantiation, electronic reporting, and recordkeeping activities.
- Benefits EPA by providing information on PFAS which the Agency does not currently have

How EPA May Use These Data

- **Support implementation of TSCA**
  - Informs development of potential existing chemical risk management efforts
  - Informs TSCA new chemical reviews (e.g., health/environmental effects info submitted may provide read-across data for new chemical analogs)
  - Informs the understanding of new analytical methods
  - Informs future TSCA section 6 activities
    - Support prioritization, scoping and risk evaluations
    - Apply to criteria for TSCA high/low prioritization
- **Share with other EPA offices:** Section 9 of TSCA mandates that EPA share certain information collected under TSCA with other EPA offices.
  - Supports other EPA programs (e.g., contaminated site work, solid waste disposal, drinking water management)

Projected Schedule

- *NPRM published on June ##, 2021*
- **60-day public comment period until August ##, 2021**
- Statutory deadline for promulgation of the rule is January 1, 2023
- Proposed 6-month deferral of data submission period after effective date of final rule
  - Allow EPA to finalize reporting software with required data elements
  - Allow companies to become familiar with rule and begin data gathering
- Proposed 6-month submission period
  - Reporting deadline will thus be one year from effective date of rule

Federal Register Notice: NPRM

- Published in the *Federal Register* on June ##, 2021 [FR citation]
- 60-day public comment period ends August ##, 2021
- **Comments must be submitted via** regulations.gov**, using this rule's docket number: EPA-HQ-OPPT-2020-0549**
- EPA specifically requests comment on:
  - Identifying chemicals subject to reporting (i.e., specific PFAS and whether to include imported articles)
  - Considerations for the economic analysis
  - Submission period
  - Potential duplicative reporting concerns
  - Scope of "existing environmental and health information" collected
  - Additional data elements or information collected
  - EPA's use and publication of non-CBI data
  - Joint submissions allowed when necessary
  - Small manufacturer considerations (i.e., regulatory and non-regulatory assistance and outreach)

Appendix

Proposed 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 (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

Proposed 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]
- Maximum first 12 months production volume
- Maximum yearly production volume in any 3 years
- Site-limited
- Maximum quantity stored on-site at any time from 2011-2023
- Total volume recycled (on-site) from 2011-2023

Proposed 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 they are 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)

Proposed 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)

Proposed 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

CBI Requirements

- CBI statutory requirements (from 2016 Lautenberg Act):
  - The submitter must now 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))