



## New Approach: Proposed PFAS Regulation Erodes TSCA Exemptions

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EPA's proposed reporting and recordkeeping requirements for Per- and Polyfluoroalkyl Substances (PFAS) under the Toxic Substances Control Act (TSCA) may be notable for what they do not do. In particular, the proposal does not recognize certain traditional exemptions to TSCA reporting.

### Scope of Reporting

The proposed new regulation would require persons that manufacture (including import) or have manufactured PFAS substances in any year since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards. EPA estimates there are 1,364 PFAS compounds that may be potentially covered by the proposed regulation as of April 2021, 669 of which are on the active Inventory (*i.e.*, in U.S. commerce).

If a company does import or manufacture PFAS substances, the following PFAS data would have to be reported to EPA shortly after the regulation becomes final:

- A. The covered common or trade name, chemical identity and molecular structure of each chemical substance or mixture;
- B. Categories or proposed categories of use for each substance or mixture;
- C. Total amount of each substance or mixture manufactured or processed, the amounts manufactured or processed for each category of use, and reasonable estimates of the respective proposed amounts;
- D. Descriptions of byproducts resulting from the manufacture, processing, use, or disposal of each substance or mixture;
- E. All existing information concerning the environmental and health effects of each substance or mixture;
- F. The number of individuals exposed, and reasonable estimates on the number of individuals who will be exposed, to each substance or mixture in their places of work and the duration of their exposure, and;

- G. The manner or method of disposal of each substance or mixture, and any change in such manner or method.

### **Potential Exemptions Narrowed**

The proposal continues one key exemption to TSCA reporting. Data on imported or manufactured materials excluded from the definition of "chemical substance" in TSCA section 3(2)(B) will not have to be reported. Those exclusions include, but are not limited to: any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; any food, food additive, drug, cosmetic, or device, as defined by 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; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code of 1954. Substances which have been manufactured or imported for intended use as any food, food additive, drug, cosmetic, or device, regulated by the Food and Drug Administration, are not chemical substances under TSCA. 86 Fed. Reg. at 33927.

Other TSCA exemptions would not apply if the regulation is adopted as proposed. The exemption for "articles" which had been included in previous EPA reporting regulations under TSCA is not included in this proposed regulation. The import of a chemical substance "as part of an article" is not subject to existing Chemical Data Reporting ("CDR") requirements for that chemical substance. See 40 CFR § 711.10(b). Chemical substances are considered to be imported "as part of an article" if the substance or mixture is not intended to be removed from that article and has no end use or commercial purposes separate from the article of which it is a part.

The rationale for including information on articles raises concerns about the impact of the proposed regulation:

For the purposes of this proposed rule, articles containing PFAS, including imported articles containing PFAS (such as articles containing PFAS as part of surface coatings), are included in the scope of reportable chemical substances. TSCA does not define articles, nor does the statute define articles as a category of substances exclusive of chemical substances. EPA therefore considers its ability to regulate chemical substances to encompass authority to regulate articles containing such chemical substances. Additionally, the Agency would benefit from collecting the requested information on PFAS-containing articles (including articles containing PFAS as part of surface coatings) because the information would improve the Agency's knowledge of various products which may contain PFAS, their categories of use, production volumes, and exposure data. Such data are not currently known to EPA. However, EPA acknowledges that some article manufacturers, including article importers, may not have such information known to or reasonably ascertainable by them and may not meet the reporting standard as described in Unit II.C. To this end, information that helps EPA better understand data gaps is useful information for EPA to have. Therefore, articles are within the scope of reportable substances under this proposed rule, though EPA is requesting comments on whether imported articles containing PFAS should be within scope (see Unit IV.1).

86 Fed. Reg. at 33930 (emphasis added). As a result, components on equipment imports will have to be included in the data filed at EPA, if equipment coatings or compounds include PFAS.

Facilities manufacturing or importing PFAS compounds as a byproduct do not get to apply the byproducts exemption and are also covered by the proposal. Under TSCA, "byproduct" is defined as "any chemical substance or mixture produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture." 40 CFR 712.3(a).

Likewise, TSCA does not carry forward an exemption for "small manufacturers and processors" in the proposal. Virtually any size company involved in the manufacture or import of PFAS compounds would be covered. TSCA Section 8(a)(7).

These changes may increase the universe of covered chemicals by 400% according to some. This reduces the scope of TSCA exclusions recognized for decades.

### **Reporting Deadline**

The proposed regulation would require covered manufacturers and importers to file required PFAS data electronically at EPA "during a six-month submission period, which would begin six months following the effective date of the final rule." Id. Therefore, reporting would be required within one year following the effective date of the final regulation.

This short turn around is based on EPA's anticipation that most operations are now subject to CDR for PFAS. "Since this section 8(a)(7) reporting rule will be collecting similar information as CDR, EPA anticipates many reporters will be familiar with the types of information requested and how to report. \* \* \* Since this proposed rule spans a longer time than the four-year CDR reporting cycle, EPA acknowledges additional time may be needed in the PFAS submission period." Id.

## Health Effects Information

It is also important to understand the information EPA is requesting. The proposal would require all existing information concerning the environmental and health effects of the PFAS chemicals covered by the proposed rule. 86 Fed. Reg. at 33928. It is intended this required information include but is not limited to:

- Toxicity information (e.g., in silico, in vitro, animal test results, human data); and
- Other data relevant to environmental and health effects including range-finding studies, preliminary studies, OSHA medical screening or surveillance standards reports, adverse effects reports.

86 Fed. Reg. at 33931.

## Potential Changes

A good way to anticipate how a regulation may change when it is finally promulgated is to review the areas for which EPA is seeking definitive public comment. Among others, the areas include the following issues:

1. Refining the list of PFAS substances subject to reporting.
2. Considerations for the Agency's economic analysis.
3. Timing of the Submission period.
4. Scope of environmental and health effects information collected.
5. Additional information or data elements to be reported.
6. Lack of a small manufacturer exemption.

## Conclusion and Recommended Action

The Biden EPA is not likely to moderate the proposed PFAS regulation. It will require industry to review purchasing and processing records over the past ten years and submit data on PFAS chemicals imported or manufactured at United States facilities, even if the PFAS are incorporated into articles for sale in commerce.

Facilities may wish to get a head start on the proposed regulation. This can be done by following a simple 3 step program:

- Step No. 1: Perform a chemical inventory on all chemical substances (including articles) manufactured or imported from 2011 to the present, collecting anecdotal information, material data safety sheets (MSDS), and safety data sheets (SDS) for each;
- Step No. 2: From the chemical inventory, identify any chemical substances within the PFAS chain from the MSDS or SDS or manufacturing data; and
- Step No. 3: Prepare a summary of the data required by the new proposal in anticipation of the

regulation being passed as written, paying close attention to anecdotal information on health or toxic effects.

**86 Fed. Reg. 33926 (June 28, 2021)**

*TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*

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