



## Environment, Land Use & Natural Resources ADVISORY ■

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### EPA Finalizes PFAS Reporting Rule for Manufacturers and Importers of Articles Containing PFAS?

by [Matt Wickersham](#) and [Samantha Van Winter](#)

The EPA has finalized a long-pending rule on reporting and recordkeeping requirements for a class of emerging contaminants known as PFAS (per- and polyfluoroalkyl substances). PFAS are commonly found in many industrial, commercial, and consumer products. Manufacturers or importers will want to look carefully at their inventories to see if they will need to report information under this new rule.

#### **EPA Finalized PFAS Reporting Rule Under TSCA**

On October 11, 2023, the EPA published in the *Federal Register* the [Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances Final Rule](#). The rule was proposed on June 28, 2021, and the final rule was promulgated without significant changes. The rule requires each person that has manufactured (including imported) PFAS or PFAS-containing articles in any year since 2011 to provide information to the EPA on uses, production volumes, disposal, exposures, and hazards. This reporting must include any amount of PFAS that were “known to or reasonably ascertainable by” the manufacturer, even if added accidentally or in trace amounts.

The EPA stated that the information obtained may be used to identify data gaps in the knowledge of commercially manufactured PFAS and will enable the EPA to meet its obligations under the National Defense Authorization Act for Fiscal Year 2020.

#### **The Rule Contains a Structural Definition of Reportable PFAS**

Toxic Substances Control Act (TSCA) Section 8(a)(7) directs the EPA to collect information on chemical substances manufactured for commercial purposes, including chemical substances that are present in a mixture, that are PFAS. Section 8(a)(7) does not define or characterize “PFAS,” nor does it define “articles.”

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This rule includes a structural definition of reportable PFAS, as opposed to a discrete list of specifically identified substances. Under the rule, PFAS are defined as including at least one of the following three structures:

- $R-(CF_2)-CF(R')R''$ , where both the  $CF_2$  and  $CF$  moieties are saturated carbons;
- $R-CF_2 OCF_2 -R'$ , where  $R$  and  $R'$  can either be  $F$ ,  $O$ , or saturated carbons; and
- $CF_3 C(CF_3)R'R''$ , where  $R'$  and  $R''$  can either be  $F$  or saturated carbons.

Notably, the EPA has identified at least 1,364 chemical substances and mixtures that meet this structural definition and will therefore be subject to reporting under the final rule. The EPA will be providing a list of substances that meet this definition that will be made available on the [CompTox Chemicals Dashboard](#). However, this list will not be all-inclusive. A substance that is not included on the list that nevertheless meets the definition of a “chemical substance” under the TSCA will still be subject to the reporting requirement if it has been manufactured for a commercial purpose since 2011. Therefore, manufacturers should conduct analysis based on the definition of a chemical substance and not rely solely on the EPA-published list.

This rule does not require reporting on substances that are excluded from the definition of “chemical substance” in TSCA Section 3(2)(B). These exclusions include: pesticides (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and 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. Further, substances that 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 the TSCA and will not be covered under the reporting rule.

### **Manufacturers of Articles Containing PFAS**

Contrary to typical TSCA Section 8 reporting rules, the EPA has not excluded articles from this requirement. Entities that have manufactured or imported PFAS, including articles containing PFAS (whether imported or domestically produced), since January 1, 2011 are included in the scope of reportable chemical substances.

The Final Rule requires entities to exercise due diligence and to conduct a reasonable inquiry within the full scope of its organization to determine if the entity is subject to the reporting requirement. The EPA acknowledged that these efforts will look different for different entities.

Importantly, the EPA clarified that “entities who solely process, distribute, and/or use PFAS, and do not manufacture (including import) PFAS for a commercial purpose, are not required to report under this rule.” The rule applies only to manufacturers (including importers), not processors.

If a manufacturer does not have actual data (e.g., measurements or monitoring data) to report to the EPA, the manufacturer would be required to make “reasonable estimates” of that information. The Final Rule

states that reasonable estimates may rely on approaches such as mass balance calculations, emissions factors, or best engineering judgment.

The EPA acknowledges that even after conducting due diligence, some entities may not have knowledge that they have imported or manufactured PFAS and therefore may not report under this rule. The EPA advises that these entities document activities to support any due diligence claims they might need to make.

### **Small Manufacturers Are Not Exempt from Reporting**

The rule does not exempt small manufacturers from reporting and recordkeeping requirements. The EPA estimated that approximately 130,000 small businesses may be considered importers of PFAS-containing articles and are therefore potentially subject to the rule. Small manufacturers include manufacturers that fall into either one of two categories:

1. A manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than \$120 million, *and* the annual production volume of a chemical substance is less than 100,000 lbs.
2. A manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than \$12 million.

However, the final rule provides small importers subject to this rule an additional six months to report.

### **Required Information**

The required information must be reported for each year since January 1, 2011. The categories of information to be reported pursuant to TSCA Section 8(a)(7) include:

- Common or trade name, chemical identity, and molecular structure of each chemical substance or mixture.
- Categories or proposed categories of use.
- Total amounts of each substance or mixture manufactured or processed.
- Descriptions of byproducts resulting from the manufacture, processing, use, or disposal of each substance or mixture.
- The manner or method of disposal of each substance or mixture.

### **Timeline for Reporting**

All entities subject to the rule, except small article importers, that have manufactured or imported PFAS in any year since 2011 will have 18 months from the effective date of the rule to report the required forms to the EPA. The reporting deadline for small article importers is 24 months following the effective date of the rule. The final rule will go into effect on November 13, 2023.

Alston & Bird's Environment, Land Use & Natural Resources Group is actively monitoring PFAS-related developments and is available to help clients understand and navigate these new requirements. Get updates on PFAS regulations, litigation, science, and more from our [PFAS Primer](#).

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If you have any questions or would like additional information, please contact your Alston & Bird attorney or any of the following:

## PFAS Working Group

**Meaghan Boyd**  
+1 404 881 7245  
meaghan.boyd@alston.com

**Megan Ault**  
+1 415 243 1056  
megan.ault@alston.com

**Andrew Boyer**  
+1 404 881 7455  
andrew.boyer@alston.com

**Samantha Van Winter**  
+1 704 444 1131  
samantha.vanwinter@alston.com

**Jeffrey Dintzer**  
+1 213 576 1063  
jeffrey.dintzer@alston.com

**Greg Berlin**  
+1 213 576 1045  
greg.berlin@alston.com

**Hannah Hess**  
+1 213 576 2517  
hannah.hess@alston.com

**Shannon Vreeland**  
+1 404 881 7429  
shannon.vreeland@alston.com

**Matt Wickersham**  
+1 213 576 1185  
matt.wickersham@alston.com

**Fiona O'Carroll**  
+1 404 881 4551  
fiona.ocarroll@alston.com

**Ytran Hoang**  
+1 213 576 2610  
ytran.hoang@alston.com

**Kalina Zhong**  
+1 415 243 1018  
kalina.zhong@alston.com

**Gina Angiolillo**  
+1 213 576 2606  
gina.angiolillo@alston.com

**Jay Repko**  
+1 404 881 7683  
jay.repko@alston.com

**Garrett Stanton**  
+1 213 576 1151  
garrett.stanton@alston.com

# ALSTON & BIRD

WWW.ALSTON.COM

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ATLANTA: One Atlantic Center ■ 1201 West Peachtree Street ■ Atlanta, Georgia, USA, 30309-3424 ■ 404.881.7000 ■ Fax: 404.881.7777

BEIJING: Hanwei Plaza West Wing ■ Suite 21B2 ■ No. 7 Guanghua Road ■ Chaoyang District ■ Beijing, 100004 CN ■ +86.10.85927500

BRUSSELS: Rue Guimard 9 et Rue du Commerce 87 ■ 3rd Floor ■ 1000 Brussels ■ Brussels, 1000, BE ■ +32.2.550.3700 ■ Fax: +32.2.550.3719

CHARLOTTE: Vantage South End ■ 1120 South Tryon Street ■ Suite 300 ■ Charlotte, North Carolina, USA 28203-6818 ■ +1 704 444 1000 ■ Fax: +1 704 444 1111

DALLAS: Chase Tower ■ 2200 Ross Avenue ■ Suite 2300 ■ Dallas, Texas, USA, 75201 ■ 214.922.3400 ■ Fax: 214.922.3899

FORT WORTH: City Center Fort Worth ■ Bank of America Tower ■ 301 Commerce ■ Suite 3635 ■ Fort Worth, Texas, USA, 76102 ■ +1 214 922 3400 ■ Fax: +1 214 922 3899

LONDON: LDN:W ■ 6th Floor ■ 3 Noble Street ■ London ■ EC2V 7DE ■ +44 20 8161 4000

LOS ANGELES: 333 South Hope Street ■ 16th Floor ■ Los Angeles, California, USA, 90071-3004 ■ 213.576.1000 ■ Fax: 213.576.1100

NEW YORK: 90 Park Avenue ■ 15th Floor ■ New York, New York, USA, 10016-1387 ■ 212.210.9400 ■ Fax: 212.210.9444

RALEIGH: 555 Fayetteville Street ■ Suite 600 ■ Raleigh, North Carolina, USA, 27601-3034 ■ 919.862.2200 ■ Fax: 919.862.2260

SAN FRANCISCO: 560 Mission Street ■ Suite 2100 ■ San Francisco, California, USA, 94105-0912 ■ 415.243.1000 ■ Fax: 415.243.1001

SILICON VALLEY: 755 Page Mill Road ■ Building C - Suite 200 ■ Palo Alto, California, USA 94304-1012 ■ 650.838.2000 ■ Fax: 650.838.2001

WASHINGTON, DC: The Atlantic Building ■ 950 F Street, NW ■ Washington, DC, USA, 20004-1404 ■ 202.239.3300 ■ Fax: 202.239.3333