wiley

ARTICLE

TSCA and PFAS – Important New Developments

June 18, 2021

This article was originally published in Wiley's The WELL blog.

Per- and Polyfluoroalkyl Substances (PFAS) broadly refers to the family of perfluoroalkyl and polyfluoroalkyl substances. These man-made chemicals were developed in the 1940's and PFASs have been used to greaseproof, waterproof and give non-stick properties to food packaging, containers, cookware and consumer products. Today, they are known as "forever chemicals" due to their longevity in the environment and the human body (persistence and bioaccumulation). Two of the most studied are perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Longer chain substances stay around longer and along this spectrum, PFOA and PFOS are considered in that category, with carbon chains of C8 and above.

Governments around the world are targeting PFAS for restrictions, including the US government and some states. Due to contamination incidents in drinking water sources, several states have set PFAS health limits for drinking water supplies and EPA is expected to follow suit. There is also an undeniable push to classify certain PFAS as hazardous under CERCLA.

The pressure to regulate PFAS contamination in environmental media is significant alone. In the last several weeks the Environmental Protection Agency (EPA) has made several important announcements to increase regulations on PFAS. This week, we summarize three of these actions taken under EPA's Toxic Substances Control Act (TSCA) authority and provide our take on them.

1. **EPA announced that it will no longer accept low volume exemption (LVE) submissions for PFAS**

Authors

Martha E. Marrapese
Partner
202.719.7156
mmarrapese@wiley.law

Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

The LVE exemption (40 C.F.R. § 723.50) provides for an expedited review for substances to be manufactured or imported in quantities of 10,000 kg per year or less. The information companies have to provide is similar to that needed for the standard premanufacture notification (PMN), except that companies must abide by the manufacturing, processing and use conditions described in the submission and notify EPA of any changes. EPA can find the chemical may cause serious human health or environmental effects, or result in significant exposure, and deny an LVE request. In this way, LVEs can be highly customized and restrictive grants for commercializing a chemical. Nonetheless, EPA has determined that, due to the scientific complexities and hazard potential associated with assessing PFAS "the agency generally expects that pending and new LVE submissions for PFAS would be denied." Basic message: don't bother submitting a PFAS LVE. In addition, EPA has put holders of PFAS LVEs on notice that they may be approached to voluntarily withdraw a previously granted LVE.

2. **The guidance on the PFAS SNUR for articles containing PFAS in surface coatings has been withdrawn**

Under TSCA, long chain PFAS chemicals can no longer be manufactured or imported for virtually any use, even as part of an article. Finding that compliance guide issued by its predecessors in January 2021 on whether certain imported articles were covered by the SNUR "inappropriately narrowed the scope and weakened the SNUR", the Biden-Harris Administration has unilaterally withdrawn the guidance and removed it from the EPA website. As a result, companies are on their own to determine, with their trusted TSCA experts, whether a coated article containing long-chain PFAS as a surface coating requires EPA review to be imported into the United States. This determination requires consideration of coatings "on any surface of any article, whether the coating is applied to the interior facing surface or the exterior surface of an article or has been cured or undergone a chemical reaction," as well as "all coating layers and their chemical components, even when they are not the outermost layer of an article."

3. **EPA published a proposed rule for comment to require section 8(a) reporting for PFAS. Comments are due 60 days after upcoming publication in the Federal Register.**

Section 8(a)(7) of TSCA requires EPA to finalize a rule by January 1, 2023 requiring "each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011" to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards. This legal requirement is a one-time reporting obligation.

Companies will have a year to prepare these reports, and they will need it: the rule necessitates capturing ten years' worth of information on the manufactured PFAS in the United States. In addition, all existing environmental and health effects information for the reportable substances and mixtures containing them will need to be submitted to EPA as part of this exercise. Such exercises can lead to the discovery of information that may have needed to be submitted earlier under TSCA's section 8(e) significant risk reporting provisions and also should be reviewed for privacy and health data protection requirements, since reportable information includes toxicity information as well as range-finding studies, preliminary studies, OSHA medical screening or surveillance standards reports, and adverse effects reports.

The proposed rule defines reportable PFAS as "any chemical substance or mixture that structurally contains the unit R-(CF2)-C(F)(R')R'." Both the CF2 and CF moieties are saturated carbons. None of the R groups (R, R' or R'') can be hydrogen." It includes lists of specific reportable PFAS substances on the Inventory either by CAS number or TSCA Accession number, as well as LVE grants for PFAS chemicals. According to the proposed rule, there are 1,346 PFAS listings on the TSCA Inventory as of April 2021, with less than half (669) of them flagged as active in U.S. commerce.

The information that needs to be reported includes a significant amount of downstream processing and use information on these chemicals, similar to that required for TSCA Chemical Data Reporting (CDR). In fact, if any of the information required by the new rule has already been reported through CDR companies do not have to supply the same information again. However, they are obligated to fill in any gaps. The proposed rule also has similar if not identical provisions for up front confidential business information (CBI) substantiation and for the reporting standard, which is to provide information "to the extent known to or reasonably ascertainable."

The proposed rule includes several areas for comment, two of which we flag here for consideration–

- The reporting obligation is limited to manufacturers – which includes importers. There are no proposed exemptions from reporting for de minimis quantities or importers or articles. Indeed, an area ripe for comment is the inability to assess the impact of this rule on small entity importers of articles because imported articles are generally exempt TSCA reporting. EPA's per-firm costs for reporting are estimated to range from $16,864 to $92,390. EPA is seeking comments on whether imported articles containing PFAS should be within scope.
- EPA's request for comment on whether environmental and health effects information should be within the scope of the rule, which appears largely procedural since this is a required reporting element, bears further study. Comment consideration should be given to the scope of reportable information, minimizing duplicative submissions, distinguishing hazard classifications within the class, as applicable, and the use of a single template for reporting.

The PFAS regulatory universe has many moving parts, but these actions demonstrate the powerful authority EPA has under TSCA to collect information which may ultimately inform regulatory actions to manage PFAS in all aspects.