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What will the US EPA's implementation of Congressional Directives to collect PFAS data mean for business?

The US EPA's proposed per- and polyfluoroalkyl substances (PFAS) reporting rule would impose a myriad of obligations on business, and apply to those not usually subject to TSCA's requirements, says Lawrence E Culleen, partner at law firm Arnold & Porter

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The US EPA has proposed a regulation that would require extensive reporting by any entity that presently, or during the preceding ten-year period, has manufactured or imported a chemical, mixture, or manufactured a product containing any one of thousands of per- or polyfluoroalkyl substances (PFASs).

Congress ordered the EPA to impose such reporting requirements as part of a provision buried in legislation to fund military spending in the US (the National Defense Authorization Act [NDAA] for Fiscal Year 2020) and to do so not later than January 1, 2023. The action is proposed under section 8(a) of TSCA, which Congress substantially amended in 2016.

While Congress specified that the agency rule must eventually require "each person who has manufactured a chemical substance that is a [PFAS] in any year since 1 January 2011" to report information described in TSCA section 8(a)(2)(A)-(G), the choices the EPA has made with regard to defining the scope of the rule, and the substances and information that must be reported, will greatly affect the compliance burden that entities subject to the rule will face.

Those choices will also greatly affect opportunities for exposure to EPA enforcement actions that could be brought against entities that might not have an awareness of TSCA.

As proposed, the rule would impose myriad obligations and apply to businesses that typically are not subject to TSCA requirements. Thousands of entities located in the US that routinely import everything from garments that might be treated with a water-repellent coating, to complex products that contain many hundreds of individual component parts (such as televisions, machinery, automobiles, and even aircraft) that commonly rely on small quantities of PFAS in such components, will need to develop an acute awareness of the rule's requirements.

Affected businesses will need to consider now when to begin making timely inquiries of their suppliers if they hope to avoid potential violations of a final rule that can result in penalties that can exceed $40,000 per day, per violation.

Vast number of chemicals subject to proposed requirements

The scope of the proposed PFAS reporting rule is broader than periodic TSCA section 8(a) reporting requirements such as chemical data reporting (CDR), which is familiar to traditional manufacturers and importers of chemical substances and mixtures. The proposed PFAS rule would require reporting by entities that currently or have

previously manufactured (including imported) a PFAS, in any quantity, between 1 January 2011 and the effective date of the final rule.

In contrast to the proposed rule, the CDR obligation is imposed on manufacturers in four-year cycles and covers only the period of time between submissions. CDR reporting also exempts many substances and entities from reporting. For example, CDR reports are generally not required if a substance is manufactured or imported in quantities less than 25,000lbs annually.

Furthermore, the proposed PFAS reporting rule will gather much more information on those substances than the EPA obtains in the four-year CDR reports. A key feature of the proposal is that the agency intends to gather a potential treasure trove of previously unreported data on health and the environmental effects of PFASs.

Exemptions common in other TSCA rules omitted

The proposed PFAS rule will exclude from reporting PFASs produced solely for use as a pesticide or in food, food additives, drugs, cosmetics, or medical device uses. However, the scope of the proposed rule will surprise many when they realise the regulation will require reporting on PFASs when manufactured for virtually any other use, including when present as an unintentional impurity or byproduct of manufacturing or disposal, and when imported as a component in manufactured products, referred to as 'articles'. This might include articles containing any of thousands of PFASs that could be present as part of surface coatings applied in manufacturing processes abroad.

There is no exemption offered for substances produced only in small quantities (such as laboratory reagents, and other substances used only for research and development efforts) or for chemicals unintentionally present in another product or mixture. The EPA also has elected not to exempt small businesses that are manufacturers of PFASs or importers of materials containing the substances.

The proposed rule contains pages and pages of lists of the specific identities of the substances for which reporting is required. However, it puts businesses on note that the printed lists might not include every substance for which reports must be submitted. Therefore, the agency has proposed that the rule should include the following definition of PFAS:

- per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R"; and
- both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R', R") can be hydrogen.

This is the working definition used by the EPA's Office of Pollution Prevention and Toxics (OPPT) when it was attempting to identify PFASs that appear on the current TSCA Inventory. As a result, the lists which accompany the structural definition are identified as being non-exhaustive. The published list of PFASs potentially subject to the rule includes 1,364 substances on the TSCA Inventory. It also includes all PFASs subject to TSCA section 5 (new chemicals) low-volume exemption (LVE) applications that have been previously granted by the EPA to permit the substances to be produced subject to certain limitations in the US.

As well as the definition and the lists in the proposal, the agency included structural diagrams for PFASs whose Chemical Abstract Services (Cas) registry numbers, or EPA Accession numbers could not be divulged in the publication due to confidential business information (CBI) claims.

Timescale for compliance

The proposed rule would require PFAS manufacturers to report to the agency during a six-month submission period commencing six months following the effective date of the final rule. This potentially provides companies one year following the effective date of the final rule to collect and submit all required information to the EPA. Given the complex nature of the supply chains for the manufacturers and importers of highly complicated manufactured durable goods (such as household appliances, office equipment, transportation equipment, and even military hardware), complying with this timeframe could be very difficult.

Information and data subject to reporting

Congress specified that the information elements listed in TSCA section 8(a)(2)(A)-(G) be collected. Accordingly, the agency has dutifully proposed to require (without exception) reporting of the following:

- chemical name and specific identity;
- trade or common name;
- representative molecular structure;
- physical form of chemical or mixture;
- industrial processing and use;
- consumer and commercial use;
- production volumes;
- whether the substance is imported for use onsite or solely for distribution;
- whether the uses are site-limited;
- the maximum quantity stored onsite at any time;
- total volume recycled on-site;
- byproducts produced during the manufacture, processing, use, or disposal of each PFAS, identifying

information for the chemical and its releases to the environment, if any;
- worker exposure at various sites;
- disposal processes;
- total volume released and incinerated onsite;
- all existing information related to health and environmental effects, using the OECD harmonised templates; and
- other data relevant to health and environmental effects.

Exposure to allegation of other TSCA violations

This last component – data relevant to health and environmental effects -- could have profound implications for submitters of existing data that has not before been shared with the EPA. A separate provision of TSCA (section 8(e)) requires the immediate submission to the EPA of information "which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment". An entity that reports, pursuant to this new requirement, information which the EPA determines qualified for "immediate" reporting under TSCA section 8(e) at the time the data were originally generated, could face exposure to stiff penalties for violations of a provision of the statute which the EPA vigorously enforces.

Level of diligence required

Manufacturers must report information "to the extent that the information is known to or reasonably ascertainable by the manufacturer". This includes "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". The proposed reporting standard is similar to that of the TSCA section 8(a) chemical data reporting (CDR) rule and requires an exercise of due diligence. The EPA notes submitters would need to "conduct a reasonable inquiry within the full scope of their organisation", which could include inquiries outside the organisation to better understand the activities of upstream suppliers or downstream users or employees or other agents. The agency acknowledges in the proposed rule that importers of articles may lack knowledge of importing PFASs and recommends such importers "document [their] activities to support any claims [they] might need to make related to due diligence."

Because submitters may have reported some information required by this rule due to CDR requirements, the EPA proposes allowing reporters to indicate in the reporting tool (CDX) that they previously provided such information through CDR for certain years. The manufacturer would still need to submit any other information required by the final rule.

Confidential business information claims

Similar to other TSCA reporting rules, the agency will permit "a person submitting a report form … [to] claim certain information to be confidential, consistent with TSCA section 14". The EPA will require the submitter to substantiate its CBI claims, although the agency is proposing not to require substantiation for "specific production or import volumes of the manufacturer, as well as the percent production volume for each consumer or commercial use".

Recordkeeping

The EPA intends to impose a five-year recordkeeping period, which begins on the last date of the submission period (one year after the effective date of the final rule).

Request for comments

A rule of this scope and with such profound implications for entirely new segments of the manufacturing and importing communities that do not pay particular attention to TSCA merits attention and public participation. The EPA has identified several issues on which it specifically requests comments. For example, the agency is interested in comments regarding the proposed rule's approach to identifying the chemical substances subject to reporting, whether to include imported articles containing PFAS, the agency's approach to duplicative reporting, and the scope of environmental and health effects information to be collected. The comment period on this very significant proposed rule will conclude on 27 September 2021.

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