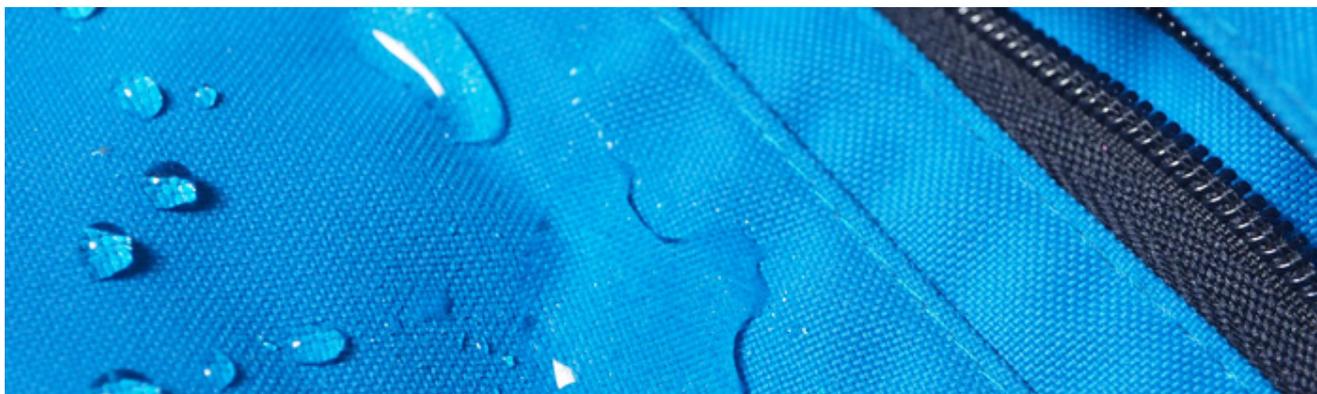


Expert Report: PFAS reporting – what business needs to know and how to start preparing for the US EPA’s new rule

11 November 2021

The agency must promulgate its new reporting rule by January 2023. Jeremy Esterkin at Morgan, Lewis & Bockius, and Jason Conder from Geosyntec Consultants, say those subject to the rule need to plan now for what is coming



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As the EPA works to finalise a [new TSCA rule](#) requiring manufacturers, producers and importers of per- and polyfluoroalkyl substances (PFASs) to submit at least a decade of retrospective reporting on PFAS usage (TSCA Section 8(a)(7)), businesses anxiously await decisions on key elements of the regulations. While some components of the rule are prescribed by statute – such as the reporting timeframe and the kinds of information that must be reported – the EPA is currently considering critical details in response to public comments.

As written, the [scope of the proposed rule](#) could be staggering. It contains no exceptions for de minimis manufacturers or small businesses; it does not exempt “articles;” it incorporates a definition of PFASs that could include thousands of individual chemicals; and it requires reporting a detailed checklist of information that could, in many cases, be very difficult or impossible to obtain.

This rule will impact businesses both large and small across many industries. Depending on who you ask, there may be several hundred or several thousand PFAS chemicals that have been, or are currently in, commercial use. The unique water repellent and surfactant properties

of PFASs are beneficial in any number of applications, and since the first PFAS chemicals were synthesised in the 1940s, products containing PFASs have been used by a wide spectrum of industries, from aviation and aerospace to paper and packaging, semiconductors and textiles.

By law, the EPA must promulgate the new rule by 1 January 2023. Those who are (or might be) subject to the rule can make good use of the time between now and then to begin laying plans – not just for ensuring compliance, but also to prepare for events that might follow submission of the required report.

Who will be required to report?

Under the proposed rule, retrospective reports will be required for any entity that imported, produced or manufactured one or more PFAS chemicals at any time between 1 January 2011 and the date the final rule takes effect. The scope of entities required to report is considerably broader under the proposed rule than under TSCA’s chemical data reporting (CDR) rules. Perhaps most significantly, businesses that manufactured or imported a product containing a PFAS chemical (an ‘article’) could be subject to the rule, as distinct from only those that manufactured or imported a PFAS chemical product on its own. Another important distinction is that small-volume manufacturers, or those with total combined sales below

certain dollar thresholds, are not exempt from the reporting requirements.

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The absence of these exemptions in the new reporting rule is not an oversight. The EPA has acknowledged that the inclusion of articles could create significant challenges, and has requested public comment on that question in particular (potentially signalling some flexibility on this issue in the final rule). The agency has also indicated that although it may have some leeway to ease compliance burdens for smaller importers, manufacturers and processors at the margins, it cannot exempt them entirely because its hands are tied by the authorising statute. Potentially affected entities – including small businesses and others who would not ordinarily be required to report under TSCA – should anticipate that the final rule will offer few, if any, carve outs.

What substances will the new rule cover?

The definition of a PFAS chemical varies not just among US and international regulations, but within the scientific community as well. Some define it as a molecule with at least one carbon atom bonded to three fluorine atoms. Others posit that any molecule with a single carbon atom bonded to two fluorine atoms and two other atoms is a PFAS. The definition that the EPA adopted in the proposed rule is more complicated: it states that a PFAS is any chemical that contains a perfluorinated methylene group ('-CF₂-') that is bonded to a second carbon atom that is subsequently bonded to at least one fluorine atom, but not to any hydrogen atoms. The agency included in the proposed rule a list of 1,346 chemicals that are considered to be PFASs for reporting purposes. The list, however, is expressly non-exhaustive; thus, it is up to each reporting entity to determine if it manufactured, produced or imported any chemicals that meet the definition.

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It is important to clarify that UK REACH refers just to Great Moreover, the question of whether a product contains reportable PFASs begins with an understanding of what chemicals are in the product. In some cases that information may be difficult, if not impossible, to obtain. In other cases, manufacturers and importers may not even realise a product (or a component thereof) contains detectable and reportable PFAS chemicals. Historical documentation, such as ingredient lists or material safety data sheets (SDSs), may leave out information that could be used to identify the presence of PFAS chemicals. This would not be surprising given that many commercial applications of PFASs are proprietary, and/or because the product contains minimal volumes of PFAS chemicals. Alternatively, documentation may refer to PFASs in ways that are not readily apparent, for example, through chemical trade names or codes that must be cross-referenced to other records. It is also possible that products could contain analytically detectable levels of PFASs due to contamination after production, or because PFAS byproducts formed during creation or storage. Reporting entities many of which may be less familiar with PFAS chemistries – will need to educate themselves on the nuances of this subject to avoid inadvertently running afoul of the new rules.

What information will need to be reported?

Because the categories of reportable information are statutorily prescribed, they will not change appreciably when the final rule is published. Reporting entities should be prepared to identify not only basic information such as the identities of the chemicals and amounts used, but also byproducts resulting from manufacturing, use or disposal; information about each chemical's environmental and health effects; the number of individuals exposed and the exposure duration; and the manner of disposal.

Of course, not all of this information will be at a reporting entity's fingertips. The EPA therefore expects reporting entities to make inquiries both within and outside their organisation, to make "reasonable estimates" when the data does not exist, and – when all else fails – to document efforts to obtain it. These diligence standards will be familiar to those who are already reporting usage of other chemicals under the CDR regulations, but for many others (particularly small businesses and manufacturers/importers of articles), the PFAS reporting rule will be their first contact with TSCA. While the EPA has indicated that it may consider measures to reduce burdens on small businesses, the consistency between the proposed diligence standard and the CDR standard suggests that the basic framework is unlikely to change.

What happens next?

Although compliance with these new rules could in many cases be [very taxing](#), those challenges may pale in comparison to what comes next. Businesses will be disclosing more than a decade's worth of data regarding concentrations of various PFAS chemicals in their products, their possible health and environmental impacts, and the number of individuals potentially exposed. The implications are not difficult to foresee.

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First, the data reporting rule is being developed alongside (and will, to some extent, inform) a host of other PFAS-related regulations, both at the state and federal levels. Disclosed information could lead to further inquiries from regulators if, for example, products are suspected of having contributed to exceedances of screening levels and other regulatory criteria that are currently being set for numerous PFAS chemicals. Second, although TSCA permits certain business-sensitive information to remain confidential with appropriate substantiation, the default position is that reported information will be publicly accessible. Information disclosed in a report could influence public perception of the safety of particular products or manufacturing sites.

The path forward

Rather than wait for a knock at the door, many businesses have already begun to plot a course for responding to the challenges that the PFAS reporting rule will bring. The scope of this planning can vary widely, and there is no one-size-fits-all approach. That said, it is universally true that knowledge is power, and reporting entities can best arm themselves for whatever may follow by acting quickly to get a solid handle on PFASs in their products. Businesses that may be subject to the new rule would be wise to take the following steps as early as possible:

- determine whether any current or historical products manufactured or imported contain PFAS chemicals that are likely to be subject to the rule;
- begin the research and analysis necessary to pull

- together the information required to be reported;
- identify the scope of information, if any, that may be reportable; and
- develop plans not just for compliance, but also to manage any foreseeable next steps.

Businesses need not go it alone. Experienced technical experts can help to identify past and current products that may contain reportable chemicals, provide information about chemical characteristics, develop exposure estimates, and assist with other diligence as necessary. Legal counsel with experience in TSCA and PFAS regulations should also be consulted – not only to ensure that the level of diligence and detail in the report is commensurate with the EPA's expectations, but also to help issue-spot and identify areas where a proactive response strategy may be worth further consideration.

For many entities, submission of the TSCA report is unlikely to be the end of their regulatory or legal obligations with respect to PFASs. PFAS regulation is being developed alongside (and sometimes faster than) scientific understanding into the nature and characteristics of thousands of PFAS chemicals. Just recently, the EPA announced a comprehensive plan to use its authority under the Safe Drinking Water Act, CERCLA, the Clean Water Act, TSCA and the Clean Air Act to regulate PFAS – on top of its ongoing research into the use, toxicity and disposition of numerous PFAS chemicals. These actions by the federal government are coextensive with similar efforts that are underway in many states.

As the future begins to come into focus, it is clear that for many companies that have manufactured or imported products containing PFAS, a daunting path lies ahead. Responding to these challenges requires a holistic strategy: one that synthesises current regulatory and legal conditions with entity-specific PFAS use, while staying abreast of seemingly rapid-fire developments in PFAS science, regulation and litigation.

The authors wish to thank Morgan Lewis partners Stephanie Feingold and Yardenia Zwang-Weissman for their contributions to this article. Copyright 2021 Morgan, Lewis and Bockius LLP. All rights reserved. This article is provided as a general informational service and it should not be construed as imparting legal advice on any specific matter.

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