Compliance & Risks

Navigating the PFAS Maze: Your Ultimate Global Regulatory Handbook

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01. About The Authors

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Maitheya Riva is a materials engineer with a strong background in analytical techniques with experience in hazardous chemical testing for regulatory compliance, materials characterization and contamination analysis.

Maitheya is currently part of the regulatory compliance team at RINA where she work mainly in chemical regulation with main focus on RoHS and REACH.

In previous role at RINA she worked as a forensic engineer where she was involved in failure investigations and condition assessment of components for extended life reliability.

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01. About The Authors

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Experienced materials engineer and chemist who is a highly regarded technical expert in global environmental compliance, sustainability and safety.

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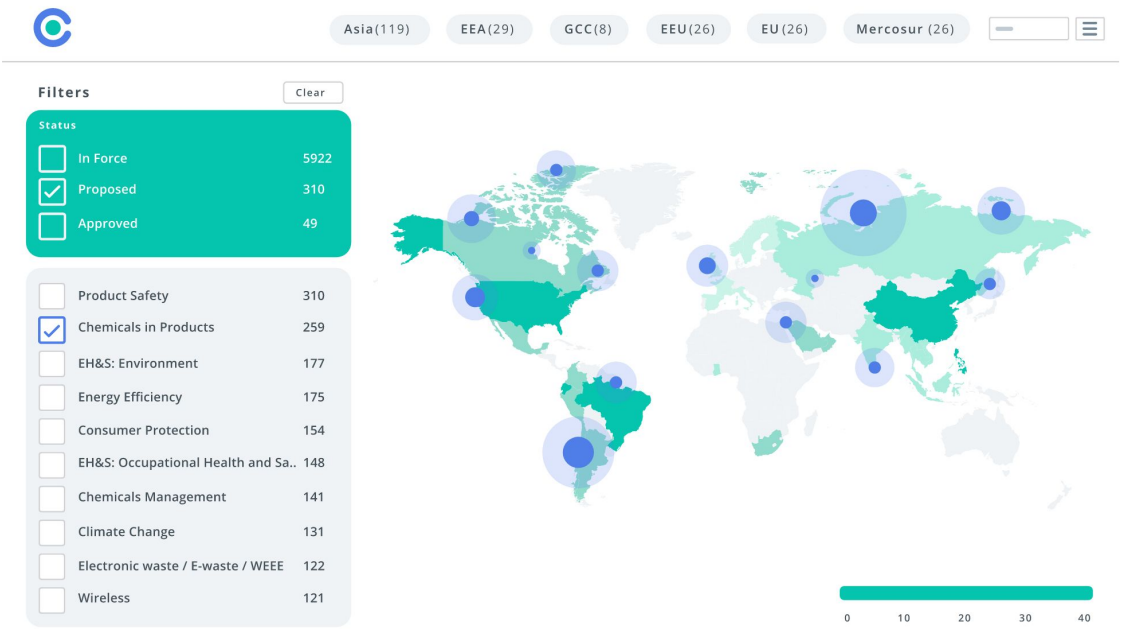

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03. Introduction

The U.S. Environmental Protection Agency (EPA) has released its reporting rule which requires any company which has imported PFAS into the US since 2011 to report on its use. Considering this includes PFAS use in articles, and has no lower limit or de minimis threshold, the rule will introduce new reporting requirements to a wide variety of manufacturers.

On November 22, 2023, Compliance & Risks held a webinar "US PFAS Reporting – What You Need To Know About The Upcoming Requirement," in partnership with RINA, where experts aimed to clarify

- who is obligated to report under the new rule,
- what information will be required
- what proportional actions should be undertaken to ensure compliance.

In response to the numerous queries posed by our engaged audience during the webinar, we've distilled the knowledge shared by our regulatory subject matter experts into this handy document.

This guide serves as your go-to resource for understanding the intricacies of PFAS regulations.

Dive in, explore, and equip yourself with the insights necessary to navigate the evolving landscape of PFAS reporting.

Together, let's contribute to a safer and more sustainable future.

You can also watch our webinar on-demand to learn more about PFAS obligations and how you should respond as a business.

04. FAQS

This chapter serves as a comprehensive repository of insights gleaned from our recent webinar, "US PFAS Reporting – What You Need To Know About The Upcoming Requirement," where our Knowledge Partners, RINA, addressed queries from a diverse audience.

Navigating the expansive landscape of PFAS regulations demands clarity, and within these pages, we have distilled the collective wisdom of regulatory experts into a curated list of FAQs.

From understanding reporting obligations to grappling with the consequences of non-compliance, this guide is your key to unraveling the complexities of PFAS regulations, ensuring you stay informed and compliant in an ever-evolving regulatory environment.

Q) Is the landscape of currently utilized PFAS extensive, considering the new registration requirement for new PFAS or new uses of known PFAS?

A) It is not fully known what PFAS are being used which is why there are reporting requirement being put in place. It is known however, due to PFAS being observed broadly in the environment that they are of concern due to their persistence

Q) Do we need to report small samples of PFAS containing products that we received from vendors overseas and were used for our internal R&D and product development?

A) R&D products are in scope of the reporting requirement. You should confirm if your supplier is the importer or its your company of those products, as the responsibility of the reporting falls on the importer.

Q) It is mentioned in TCSA Section 8 (7) that the EPA will provide a list with 1462 PFAS substances, do you know where it will be published?

A) The list is not currently available and there is no indication of a timeframe on when this is going to be made available.

Q) How deep in the BOM of the equipment are PFAS reporting necessary?

A) Reporting is required on all components of your equipment as there is not de minimis threshold for TSCA section 8(a)(7) reporting.

Q) If articles containing PFAS are purchased in the USA but exported for use outside of the USA do these need to be reported?

A) There are no requirements for reporting on export of PFAS to outside of the USA.

Q) Regarding a machinery manufacturer utilizing PFAS-containing components, particularly those sourced internationally and domestically, is it necessary to report all these articles? This encompasses both the articles manufactured within the United States and those imported.

A) Yes, both imported and manufactured PFAS containing articles are in scope of reporting. However, you are in scope of the reporting *only* if you are either the manufacturer or the importer.

Q) If a piece of machinery is imported into the USA and some of the components within that machinery contain PFAS does this need to be reported? If so, for the quantity reported, would it only be the number of pieces of machinery reported or do the specific components within that machinery need to be identified and reported?

A) The requirement is to report: PFAS use (down to the article level if this information is available), production volumes, disposal, exposures, and hazards.

Q) What concentration of PFAS impurity or by-product need to be reported to the EPA?

A) There is no lower limit threshold for the reporting for TSCA section 8 (a)(7) and there is currently no concentration limit for impurities.

Q) US TSCA PFAS Reporting: Do PFAS in articles (e.g. in a sealing ring) have to be considered for the "designation indicating, for each PFAS at each site, whether any imported PFAS is ever physically present at the reporting site"?

A) Yes

Q) Is there already a deadline for PFAS restriction in Minnesota?

A) There is currently no Minnesota specific restriction outlined or ready for implementation, It is suggested that the "Minnesota's PFAS blueprint" is reviewed and monitored for updates.

Q) Are we concerned if we are importer of PFAS containing PFAS finished goods?

A) Yes

Q) Are O-Rings in an instrument included?

A) O-rings are in scope of the reporting for TSCA section 8(a)(7).

Q) As an assembler of products, if your supplier fabricates intricate articles and a component within the supply chain, obtained from another upstream supplier, contains PFAS, is it necessary for the assembler importing the product into the US to submit a reporting to the EPA for PFAS?

A) If the assembler is the one making the product containing the PFAS available on the US market it is the responsible for the reporting requirement.

Q) When importing very complex huge systems (e.g. huge manufacturing machine), in which level is the TSCA reporting needed? Article, Product etc?

A) The requirements are for all PFAS to be reported, with no lower limit, therefore the reporting will have to be as in depth as possible.

Q) If our product components contain PFAS are we also considered a manufacturer or importer?

A) If you are the one placing the PFAS containing component on the US market yes.

Q) What is the definition of a "small" manufacturer under this requirement?

A) A manufacturer (including an importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

Q) In the context of US PFAS Reporting, deciphering the definition of "end use" within the article's definition raises questions. Must the reporting obligation fall on the manufacturer of the initial article, such as a sealing ring, or is it incumbent upon the manufacturer of the apparatus, the ultimate end product into which the "first" existing article is integrated?

Additionally, is reporting mandated for imported articles that undergo additional production processes before being authorized for use, as observed in instances like partly completed machinery under the EU Machinery Directive 2006/42/EC?

A) The responsibility of the reporting is on the legal entity placing the PFAS or the product containing PFAS on the US market. If you are the imported of the articles that require further processing, you will still be required to report on the presence of PFAS.

Q) What is the appropriate approach for responding to inquiries about a product that hasn't had PFAS intentionally added but hasn't been tested to confirm their absence?

A) It is correct that PFAS which are contaminants or similar are in scope of the TSCA section 8(a)(7) reporting, but the EPA clarify that testing to demonstrate compliance is not required.
It is suggested that engagement with suppliers for this information is the best course of action.

Q) If we are manufacturing an article outside of the US, do we need to report on PFAS on the TRI list under the EPA PFAS reporting law?

A) No this is not required

Q) Can you please give us the exact legal passage where it's written that articles are included?

A) Reporting is required for all PFAS, as defined in 40 CFR 705, that are chemical substances as defined by TSCA, that have been manufactured (including imported) for commercial purposes during this rule's lookback period.
In section 2.2.1 "If you imported an article containing PFAS, you may use a streamlined Article Import form. This streamlined form does not require all information required for the standard form; when you select "article import reporting" in the section 8(a)(7) reporting tool, the program will show only fields required for this streamlined reporting"

Q) Medical devices are exempt from reporting. Does this include the primary packaging (sterile barrier) of the medical device?

A) If the packaging is also classified as medical devices it is excluded from the scope, but if not then it is included

Q) The threshold for reporting is 100 lbs OR smaller than 1% in a mixture.
If I import products, can I interpret the above thresholds as follows:

1) ***If the total volume of PFAs in my imported products (per product type) is below 100 lbs, I don't have reporting obligations.***
2) ***If the mixture used to manufacture my products (plastic products) is below 1% w/w, I don't have reporting obligations.***

A) This limit of for TRI reporting for substances listed in the 189 TRI listed substances. Threshold of 100lbs per listed PFAS or <1% in a mixture, excluding PFOA as a de minimis for reporting. Please note this threshold is per PFAS and not per product type. For TSCA reporting, there is no lower limit reporting threshold.

Q) If my products do not contain PFAS (above threshold) according to the proposed EU PFAS regulation (REACH amendment) does that mean that I'm fine for the US regulation and don't have reporting obligations?

A) The EU proposed restriction have a minimum concentration of PFAS which could potentially trigger the restriction, as currently written.

PFAS which are contaminants or similar are in scope of the TSCA section 8(a)(7) reporting, but the EPA clarify that testing to demonstrate compliance is not required. However the US does not have a minimum concentration so if any PFAS is present, irrespective of the concentration, this should be reported according to TSCA section 8(a)(7).

Q) Do I have a reporting obligation if I only import a limited number of products that contain small amounts or just traces of PFAS? Is there a threshold for product volume/quantity?

A) There is no lower limit threshold for the reporting for TSCA section 8(a)(7) and there is currently no concentration limit for impurities.

Q) Is testing required for EU, or is gathering information is enough too?

A) The EU have not published a final regulation amended for PFAS, therefore how PFAS are going to be regulated under REACH and how this will be enforced is still unknown.

Q) Are Medical Device Manufacturers exempt from reporting? Does this include all components which could contain PFAS?

A) Medical devices and any components used in their design are excluded from the TSCA Section 8(a)(7) reporting requirements

Q) One of our significant product categories revolves around apparel, with a specific focus on technical outerwear. Within this category, coatings and laminates are integral, often containing PFAS for waterproofing and breathability.

Notably, in the United States, the regulatory reporting landscape is complex, with individual states taking the lead. This poses a reporting challenge due to the lack of clearly established and postponed requirements.

In such an environment, how can a manufacturer or importer effectively navigate this intricate regulatory landscape?

A) The best approach would be to investigate your use of PFAS substances in your products and collect the relevant information. With this approach you ensure readiness when new requirements are placed on manufacturers/importers.

Q) There was an analysis back in Nov. 2023 which utilized HS classification codes. Would these be another way of isolating product likely within scope?

A) Although HS codes are used to classify products, this would not definitively identify if PFAS are contained within certain products. As such, although they can be utilised as a starting point further information would be required.

Q) Our products contain PFAS but we are not the manufacturers, are we in scope of reporting?

A) If you purchase the products containing PFAS in the US you are not required to report, however, if you purchase from outside the US and import in the US you will be in scope of the reporting requirement from the TSCA Section 8(a)(7).

Q) Is the TRI requirement under a different statute called EPCRA instead of TSCA?

A) You are correct, Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) created the TRI, with TSCA utilising the data for its assessment.

Q) Will the EPA consider our complete test reports for recent years, even if we lack any data for earlier products, as sufficient due diligence?

A) If the data covers products from 2011 then yes, if not then there is the expectation that some additional data would be sought for products which the testing data does not cover (for products since 2011).

Q) Are PFAS screening tests, readily available in the market, a sensible means to verify the accuracy of information provided within the supply chain?

A) There are test to determine if Fluorine is contained within products, which is an indicator of PFAS, but to test if a specific PFAS is present depends on the specific substance being tested for.

Q) Do I bear the responsibility for reporting PFAS manufacture or import associated with an entity that has been sold or divested by part of my company since 2011?

A) The legal entity whom was responsible for the import into the US, or use of PFAS in the US, is the responsible person for reporting. Therefore the specific details of how the legal entities have changed over the divesting would indicate who has the responsibility.

Q) If medical devices include materials like PTFE, does the manufacturer of the devices need to report? Or is that only the responsibility of the extruder of the PTFE?

A) It is the responsibility of the person importing into the US to report, or the manufacturer in the US, assuming that the product is in scope. It is worthwhile noting that medical devices are not in scope of the TSCA section 8(a)(7) reporting requirements.

Q) How are testing labs supporting the EPA regulation when they can only test for a maximum few hundred PFAS when the regulation requires reporting on thousands?

A) The testing for PFAS is continually evolving to meet this demand.

Q) How can we achieve due diligence when we're aware that a garment contains PFAS, but we're unable to ascertain the specific PFAS in the article due to the supplier being out of business?

A) If the garment is being shipped into the US as an article, considered using the streamlined reporting which allows the reporting of PFAS based on the article weight, rather than efforts being made to identify the specific PFAS.

Q) What granularity of detail is required for the reporting. e.g. total imported volume of all products or product/component level?

A) The requirements are for all PFAS to be reported, with no lower limit, therefore the reporting will have to be as in depth as possible.

Q) If PFAS is found in part A of electrical/electronic product A, are you referring to 'the article volume' as the 'weight of electrical/electronic product A x sales volume' or the 'weight of part A x sales volume' in the United States? Which quantity is intended?

A) It would be better that the weight of the part containing PFAS is used as this will allow more accurate reporting, but if this information is not known then the weight of the part A can be used.

Q) Identifying the three sub-structures specified by the EPA as part of the PFAS Definition poses a challenge due to a lack of chemistry knowledge. Is there any assistance available for identification, such as information on listed materials?

A) Unfortunately not completely, however the following list can be a useful starting point
   a) https://comptox.epa.gov/dashboard/chemical-lists/EPAPFAS75S
   b) https://comptox.epa.gov/dashboard/chemical-lists/epapfasinv
   c) https://comptox.epa.gov/dashboard/chemical-lists/epapfas75s1
   d) https://comptox.epa.gov/dashboard/chemical-lists/epapfasinsol

Q) What constitutes effective due diligence regarding state and national PFAS reporting rules? For instance, if our supply chain responds with 'we don't know' during our survey, is that considered satisfactory completion of the task?

A) Under the guidance provided by the EPA asking the supply chain, even if they state they do not know, would be sufficient to allow you not to report any PFAS being used.

Q) Are there reporting requirements for PFAS present in a product, for instance, through components like an O-Ring?

A) Yes, all PFAS uses, even if in articles within complex products are in scope of the reporting, unless the end product is excluded e.g. an O-ring used in a medical device.

Q) Does the import and export of greenhouse gases fall under the classification of "otherwise use"?

A) If the GHG are covered by the structural definition of PFAS being used, then yes this would be in scope of the TSCA reporting requirements

Q) Does the restriction apply to PFAS application on textiles?

A) Yes, all PFAS uses, unless the end product is excluded e.g. an O-ring used in a medical device.

Q) Will there be a more precise definition for the extent of "due diligence" under TSCA reporting?

A) The EPA may provide more guidance in publications closer to the enforcement date. Sign up to our newsletter for more information as we have it.

Q) What is the reasoning behind retroactively dating back to 2011?

A) We haven't been able to find any sources which outline why the date of 2011 was selected.

Q) Does the TRI also exclude cosmetics and medical devices?

A) The TRI doesn't exclude certain product types, but rather has minimum thresholds for reporting as outlined in the webinar.

Q) Does the medical device fall under an exemption at both the federal and state levels?

A) Not automatically, the specific piece of legislation would need to be reviewed to identify if medical devices are excluded.
If you have queries, our team of highly qualified and experienced subject matter experts are on hand to answer your call.

Q) If one processes a resin with and anti-drip agent into a product are you a manufacturer or is the resin manufacturer the reporter

A) If the manufacturer of the resin is in the US then they will need to undertake the reporting (if in scope) but if you use the resin in your products (manufactured outside of the US) and you import into the US then you are obligated (if in scope).

Q) Do we need to report the quantities of PFAs if we utilize a mold release containing them in our plastic injection molding process?

A) If the mold release agent is manufactured by you in the US, or imported into the US- under TSCA section 8(a)(7) then you would have to report. However, if it is used outside of the US and not remaining on your product when imported into the US then reporting would not be required. For the purposes of this answer we have assumed it would be out of scope of the TRI, however this may need to be checked.

Q) If a tool's single component has 2% PFAS, but the overall content of PFAS in the entire tool, where this component is used, is only 0.3%, is it accurate to say that no registration is required in the US?

A) Only the TRI has minimum thresholds for reporting, so if you are referring to the TSCA section 8(a)(7) reporting all uses are potentially reportable.

Conclusion

As can be seen, product regulation regarding PFAS is expanding in the US, as compliance requirements on reporting, restriction, prohibition, and labeling become increasingly complex across multiple states.

This is bolstered by action at federal level where the US Environmental Protection Agency (EPA) announced its framework for addressing new and new uses of PFAS to ensure that, before these chemicals can enter the market, that it undertake an extensive evaluation to ensure they pose no harm to human health and the environment.

PFAS is therefore one of the key topics impacting business now and is predicted to extend through 2024 and beyond.

We are closely monitoring all developments in this growing area on a daily basis and will capture all regulatory updates in our C2P database.

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