US PFAS Reporting -What You Need To Know About The Upcoming Requirement







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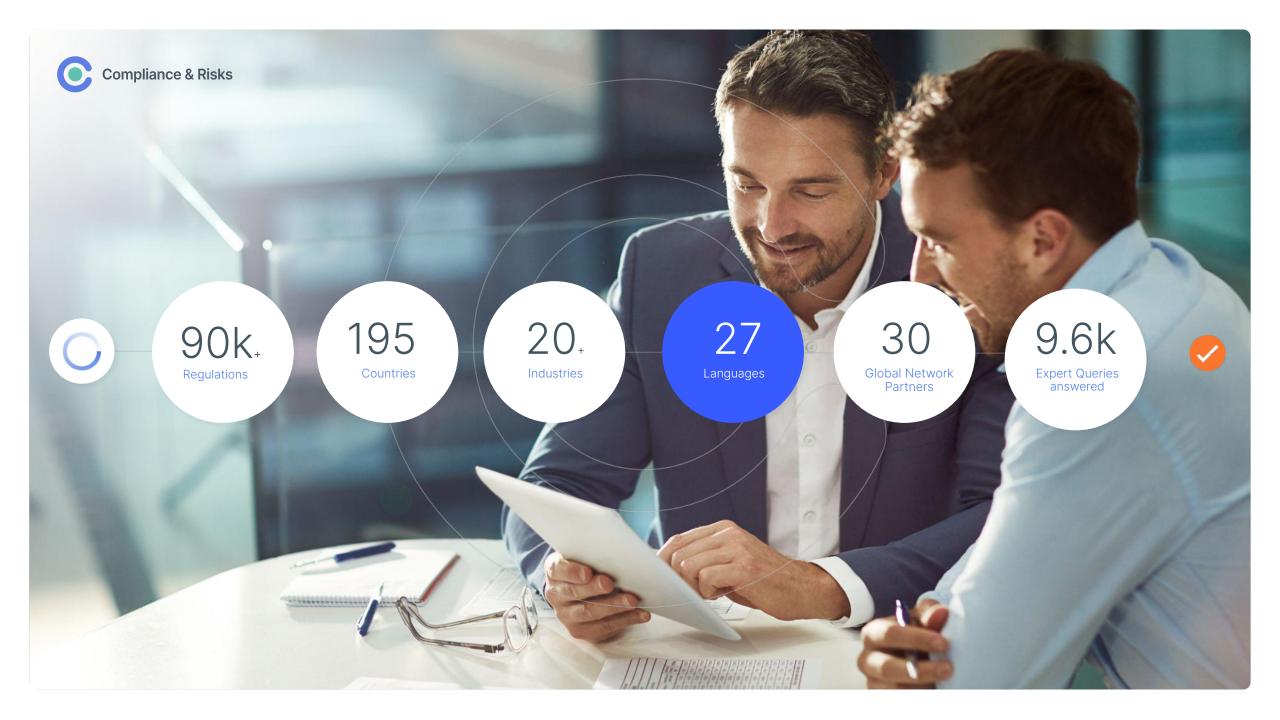


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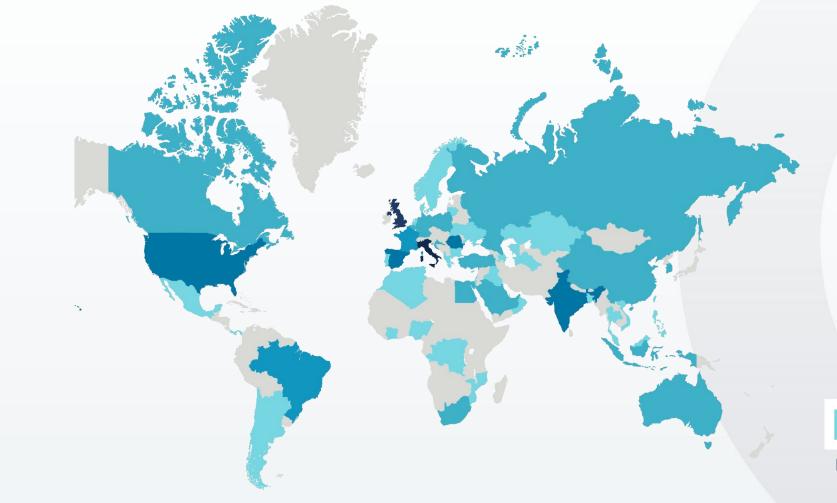
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RINA Overview





RINA Worldwide



3700+ Staff

170+ Offices

65+ Countries

LEVEL OF RINA PRESENCE:







RINA Tech UK Ltd – Regulatory Compliance Group

We support authorities, manufacturers, importers and distributors of products, to identify, understand and meet technical and environmental legislation.



Global Market Access

- Low Voltage
- Electromagnetic Compatibility (EMC)
- Pressure equipment
- Radio Equipment
- Medical Devices
- Machinery
- Hazardous Area (ATEX)
- Substances (RoHS/REACH/CLP/BPR/POPs/Cal. Prop. 65)
- Ecodesign
- Electrical waste (WEEE)
- Batteries
- Conflict Minerals
- Transportation





US PFAS reporting-What you need to know about the upcoming requirement





Types of products PFAS are used in

Technical Characteristics Indicating their potential use:

Temperature stability | Durability | non-stick/low surface energy | Repellence-water/dirt/oil | Chemical resistance/Inert | Biologically resistance | UV resistance



Smudge resistant touch screens

Flexible plastic Cable and wire insulation Conduit and conduit connectors



Circuit board films Cleaning fluids for microelectronics Semiconductor manufacturing aids

Hydraulic fluids Hoses Tubes Flexible ioints Pipe & tank linings



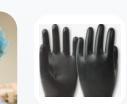






Potting Gels





Paints

Non-stick coatings Stain-resistant sprays and treatments Self-cleaning coatings for weather







Stain Resistant Fabric Treatments



Bushes and Bearing surfaces







Do you know where PFAS are within your product ranges?

- a. We have identified all PFAS uses.
- b. We have identified an estimated >80% of PFAS uses.
- c. We have identified an estimated > 30% of PFAS uses.
- d. We know PFAS is used within our products but haven't yet identified where they are used.
- e. We have not started collecting information on PFAS.

Poll #1

Choose the option that represents your company's current status regarding PFAS in products.





US PFAS Activities



US Environmental Protection Agency (EPA) PFAS Roadmap

The framework outlines EPA's planned approach when reviewing new PFAS and new uses of PFAS to ensure that these chemicals and uses do not present unreasonable risk to human health and the environment.

Often challenging as there can be insufficient information to precisely quantify the risk they may pose- only a small fraction have been well studied.

Research to develop the understanding of PFAS and increase effectiveness of interventions Toxic Substances Control Action (TSCA) prevention of PFAS entering the environment

Reporting under Section 8(a)(7) Toxic Release Inventory (TRI)



US PFAS Activities



The New PFAS framework

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The EPA have introduced a new registration requirement for new PFAS, or new uses of known PFAS, introduced on the US marked.

This will be a risk-based approach depending on whether the PFAS is a persistent, bioaccumulative and toxic (PBT) chemical on a case-by-case basis using the reasonably available data. The assessment will evaluate the process/application/product in which the PFAS is used and the mitigation measures in place.

If it is not a PBT, it will be reviewed through the typical New Chemicals Review Process.



PFAS Definition

US Definition

Any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three sub-structures:

- R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons
- R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons
- CF3C(CF3)R'R", where R' and R"" can either be F or saturated carbons.

If the substance is found to not be a PFAS or PBT, it will be reviewed through the typical New Chemicals Review Process

EU Definition >>10,000 substances

Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/CI/Br/I attached to it)



Are you an importer or a manufacturer of PFAS in the US market?

a. Yes

b. No

c. Not sure

Poll #2

Choose the option that best represents you.





If yes, are you aware of the US reporting requirements?

- a. Yes, but I have not started data gathering as yet
- b. Yes, and I have started data gathering
- c. No
- d. Not sure

Poll #3

Choose the option that best represents you.





TSCA Section 8(a)(7) Reporting

Long-awaited rule was first published as a draft in June 2021 after being mandated by the National Defense Authorization Act (NDAA) in 2019.

All PFAS, including articles manufactured or imported into the US (including for distribution) since 1st January 2011:

- No lower limit excluding reporting
- No de minimis thresholds excluding reporting
- Includes impurities, intermediates and by-products. As well as research and development uses and fluoropolymers.

In scope of the reporting requirements are <u>manufacturers and/or importers</u> in the US of PFAS substances.

Only excludes: Pesticides | Food additive | Drug | Cosmetic | Medical Device

Information needs to be submitted to the EPA's central data exchange (CDX) by 8th May 2025 (Nov'25 for small manufacturers) on: PFAS use, production volumes, disposal, exposures, and hazards.



TSCA Section 8(a)(7) Reporting

Information gathering requirements:

- Only related to information in the possession of supplier
- No testing requirements
- Engagement with supply chain is needed
- Activities should be documented to prove due diligence
- Applies to PFAS imported at any point since 2011, including if the activity has ceased.

Streamlined reporting form possible for article suppliers:

- Allows the article volume to be submitted rather than the volume of PFAS contained with the article





Toxic Release Inventory

Relates to listed substance (189 substances) use and emission in the US:

- Listed substances include substances which are used to manufacture polymers, fabrics, coatings and consumer products

- Threshold of 100lbs per listed PFAS or <1% in a mixture* as a de minimis for reporting

There is a proposal that this de minimis should be removed through the classification of chemicals of special concern

Triggering annual reporting requirements by July for the previous year

2021 reporting: 44 US facilities submitted TRI reporting- most of which are chemical manufacturers

*excluding PFOA



US State Requirements

State specific requirements proposed/ passed in 46 states:

Maine and Minnesota are leading PFAS requirements for all products

Most states requirements are limited to listed products which tends to be focused on cookware, furniture, carpets, children's products, food packaging etc.





EU REACH PFAS Restriction

Pre-publication dossier published, covering all PFAS in all uses above extremely low concentrations. It affects PFAS used on their own including intermediate use, PFAS in mixtures, and PFAS in articles including imports.







EU REACH PFAS Restriction

Engagement needs to be prior to restriction publication, which is the opposite to authorisation process

Only excludes: Biocidal products | Plant protection products | Active substances in medicinal products

Derogation listed in the regulation, for 5 or 12 years with an 18-month transition.

If derogation granted:

- Annual reporting obligations (EU and EU importers) to the regulator, and
- Site management plan are required where fluoropolymers and perfluoropolyethers used (in the EU only)





Global PFAS Requirements

UK

Fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (–CF2–).

UK REACH restriction possible focused on:

- Identification of high tonnage uses/emissions
- Substances that are manufactured at ≥1 tonne/year in GB (and so are registered under UK REACH)
- Substances that have been detected in the GB environment.

PFAS that show inert behaviour and are not harmful to the human health are not going to be covered as in scope.

Canada

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Proposed to add PFAS to Canada Environmental Protection Act (CEPA) Schedule 1



How to Respond as a Business

- 1. Engage with your supply chain to start to gather information as soon as possible
- 2. Consider which definition of PFAS to use
- 3. Keep records of due diligence activities
- 4. Start utilising PFAS-free alternatives where possible

Early obsolescence needs to be considered

There are already indications that with the level of concern about PFAS, that suppliers such as 3M are exiting the market, irrespective of legislative requirements

e.g. 3M are set to discontinue the manufacture of all PFAS chemicals by 2025, impacting >20,000 products





Trying to keep on top of it all...

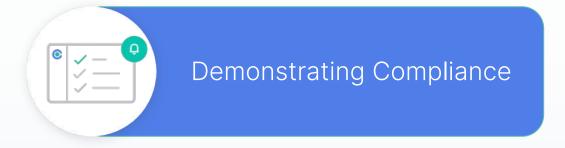




A Smarter Way to Manage Product Compliance

Holistic Market Access Solutions





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For what is required



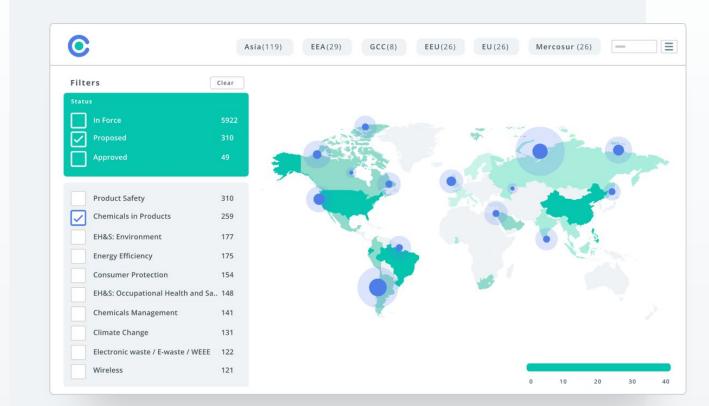
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TECHNOLOGY - C2P

C2P The Key to Unlocking Market Access

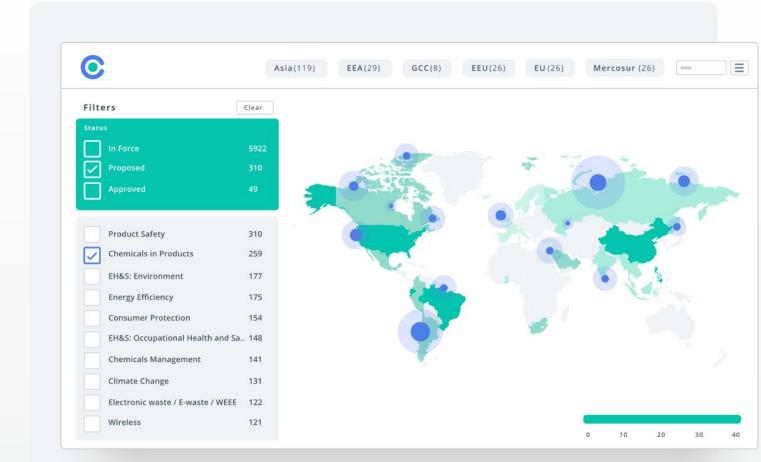
- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- Al powered probability analysis
- Productivity tools to improve team collaboration



TECHNOLOGY - C2P

Manage everything in One Place...

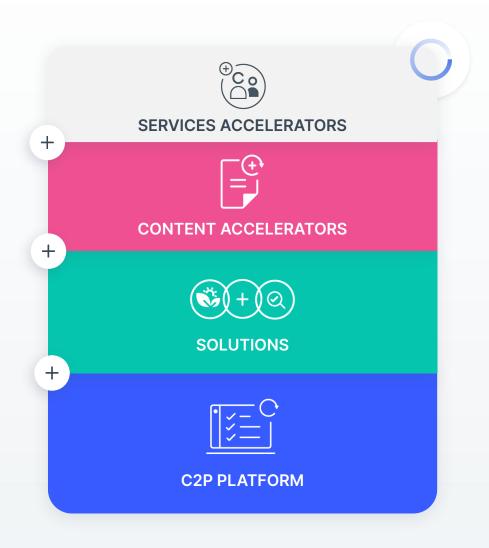
- Design, build, and collaborate on new products with confidence
- Keep all compliance evidence up to date & live linked back to their Regulations, Standards & Requirements
- Continually monitor regulatory changes & keep ahead of proposed changes before they happen
- Integrate with other systems to enable streamlined business processes



TECHNOLOGY - C2P

Tailored to meet your needs...

- Comprehensive capabilities that enable enterprise-wide management of regulations, standards, requirements and evidence
- Add-on packages to accelerate market access through:
 - Use-case specific solutions
 - Global regulatory content
 - Professional services











Thank you!







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