Compliance & Risks

Webinar

Global *PFAS Updates*

Is Your Company Prepared for the **Regulatory Crackdown?**

11th September, 2024

→ | complianceandrisks.com

Q&A Session

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Compliance & Risks

Meet the Team

Cathy Phillips
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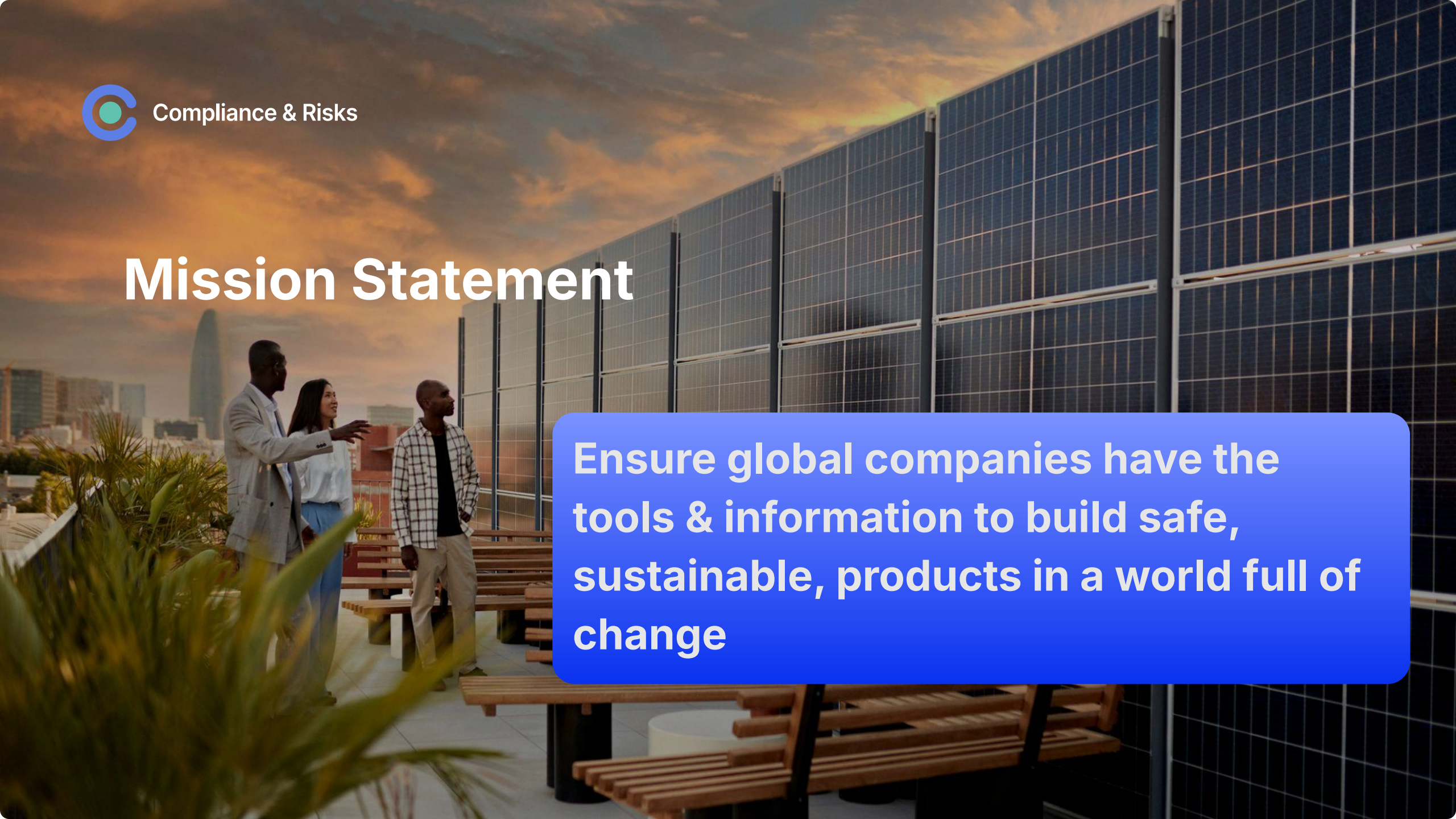
Product Marketing Manager


Compliance & Risks
Mission Statement
Ensure global companies have the tools & information to build safe, sustainable, products in a world full of change

Trusted by the World's Leading Brands

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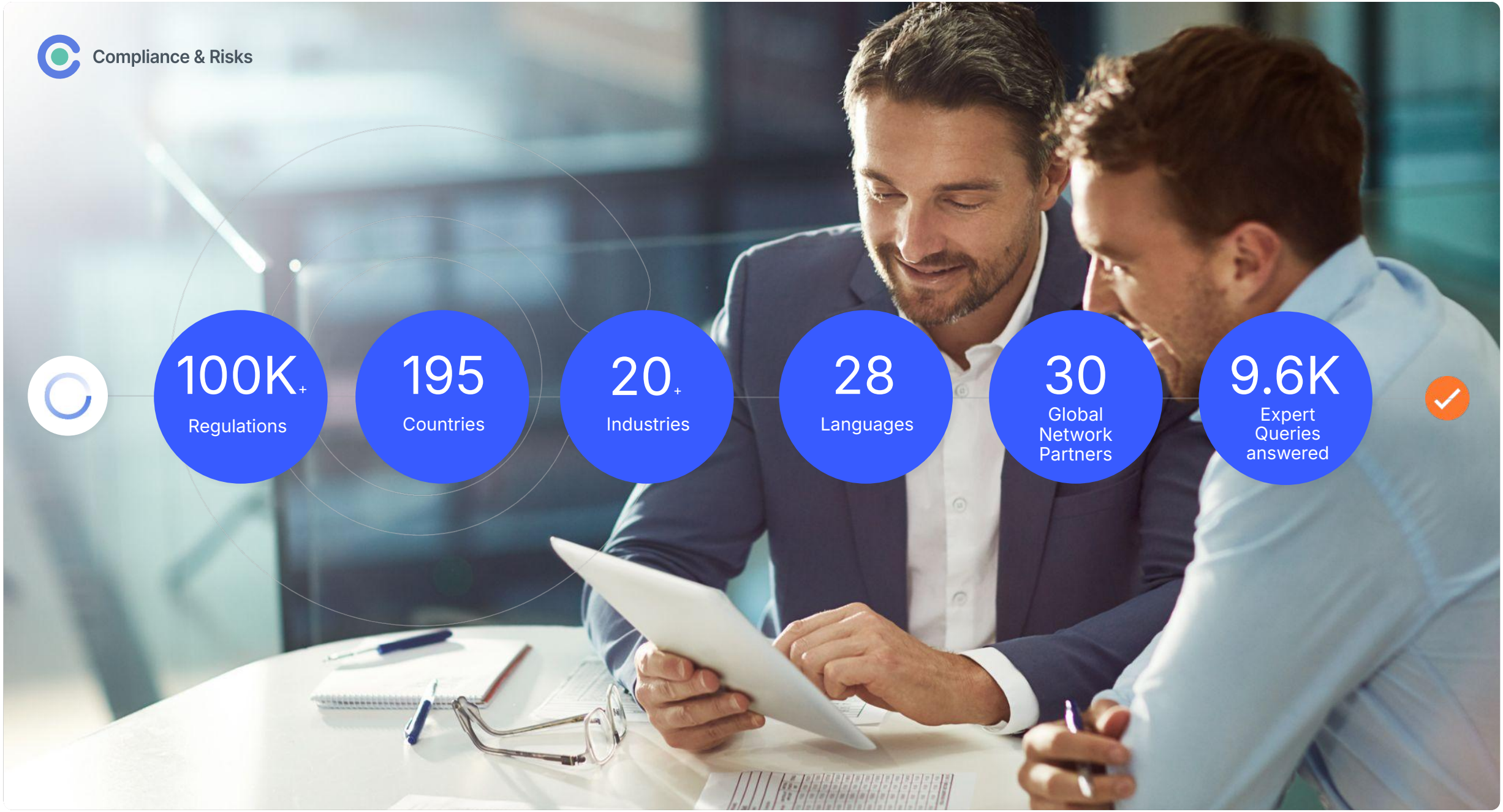
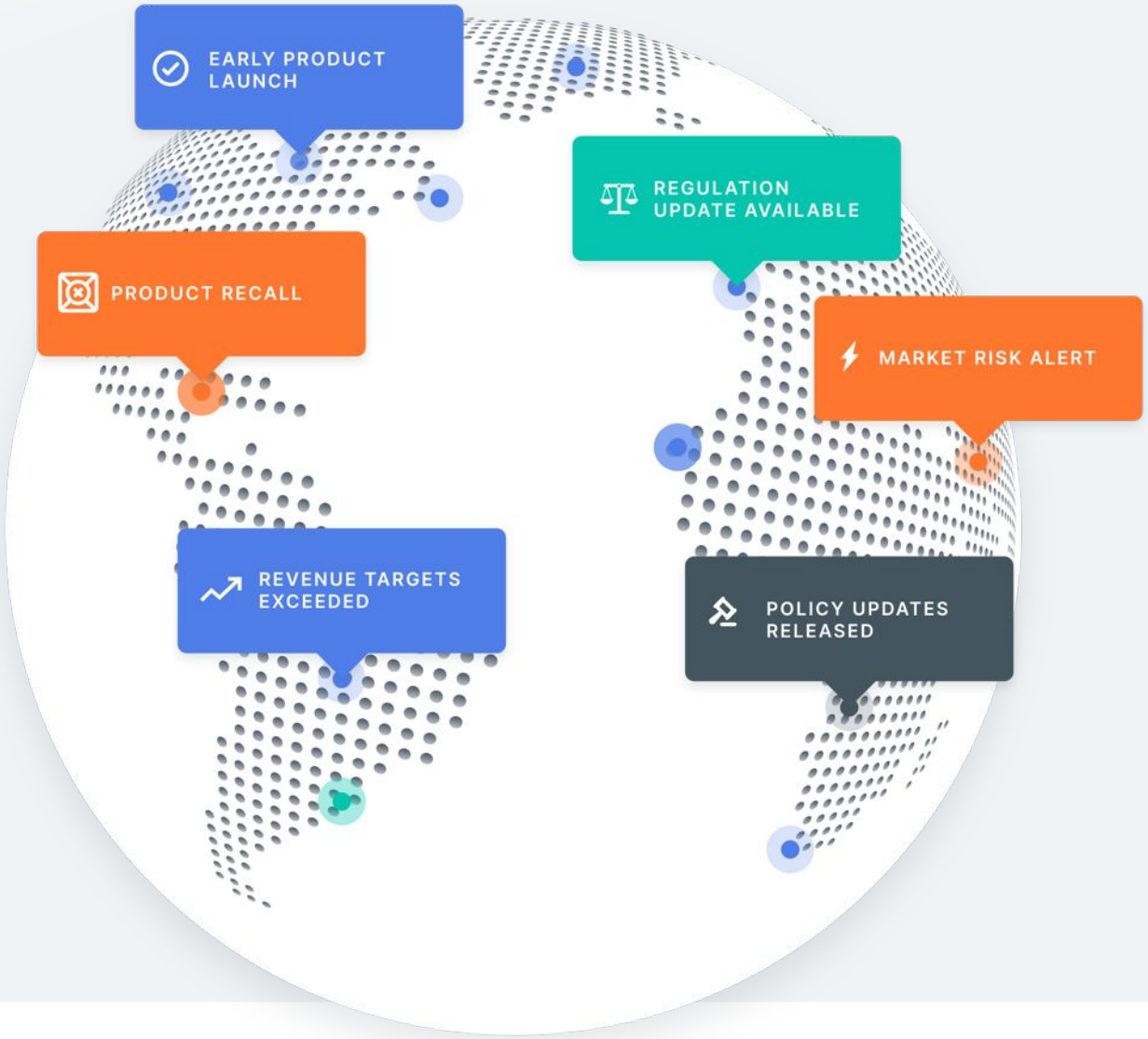


WHAT WE DO

Unlocking Market Access

Keep on top of regulatory changes and their impact worldwide. Early warning alerts, impact probability, productivity workflow tools and so much more.



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RINA Overview

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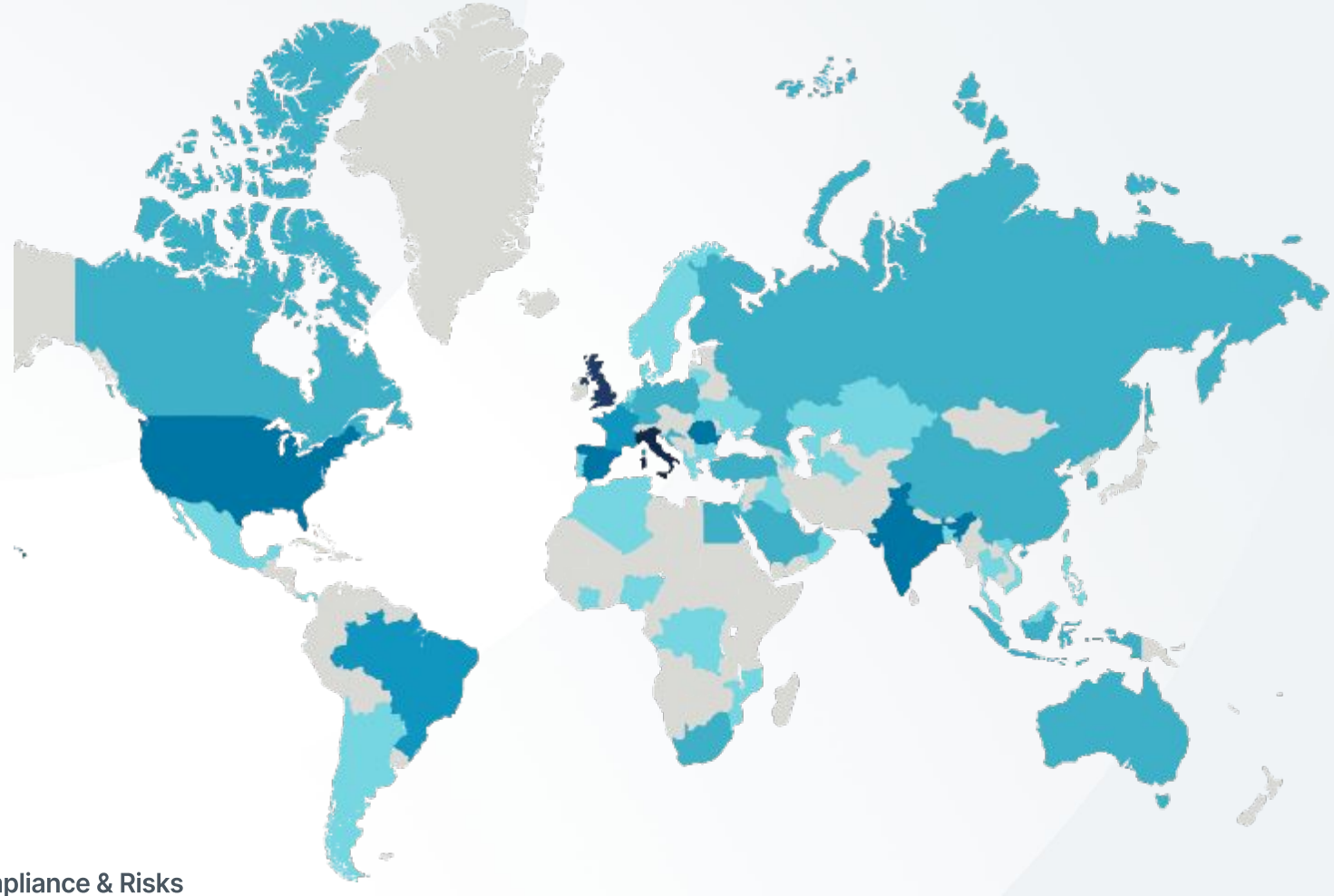
RINA Worldwide



3700+ Staff

170+ Offices

65+ Countries

LEVEL OF RINA PRESENCE:

low → high

Compliance & Risks

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

Agenda

01. PFAS Uses
02. Global Trends
03. PFAS Definitions
04. EU PFAS Proposal, Status & Derogations
05. UK PFAS Restrictions Progress
06. Asia PFAS Restrictions
07. US PFAS Requirements

PFAS Uses

Fire fighting foam
Chemical/biological resistant PPE
Bacteria/virus resistant fabrics
Dirt resistant fabrics
Waterproof fabrics
Stain resistant
Fabric treatments

Circuit board films
Conformal coatings
All semiconductor chips
Cleaning fluids for microelectronics
Semiconductor manufacturing aids

Hydraulic fluids
Gaskets
Seals
Hoses
Valves
Tubes
Sealant
Flexible joints
Pipe & tank linings

Refrigerants/
F-Gases

Batteries
Shock absorbers
Bushes & bearing surfaces

Paints
Non-stick coatings
Stain-resistant sprays & treatments
Self-cleaning coatings for weather resistance

Smudge resistant touch screens

Lubricants
Potting Gels
Adhesives
Greases
Surfactants

Flexible plastic
Cable and wire insulation
Conduit and conduit connectors

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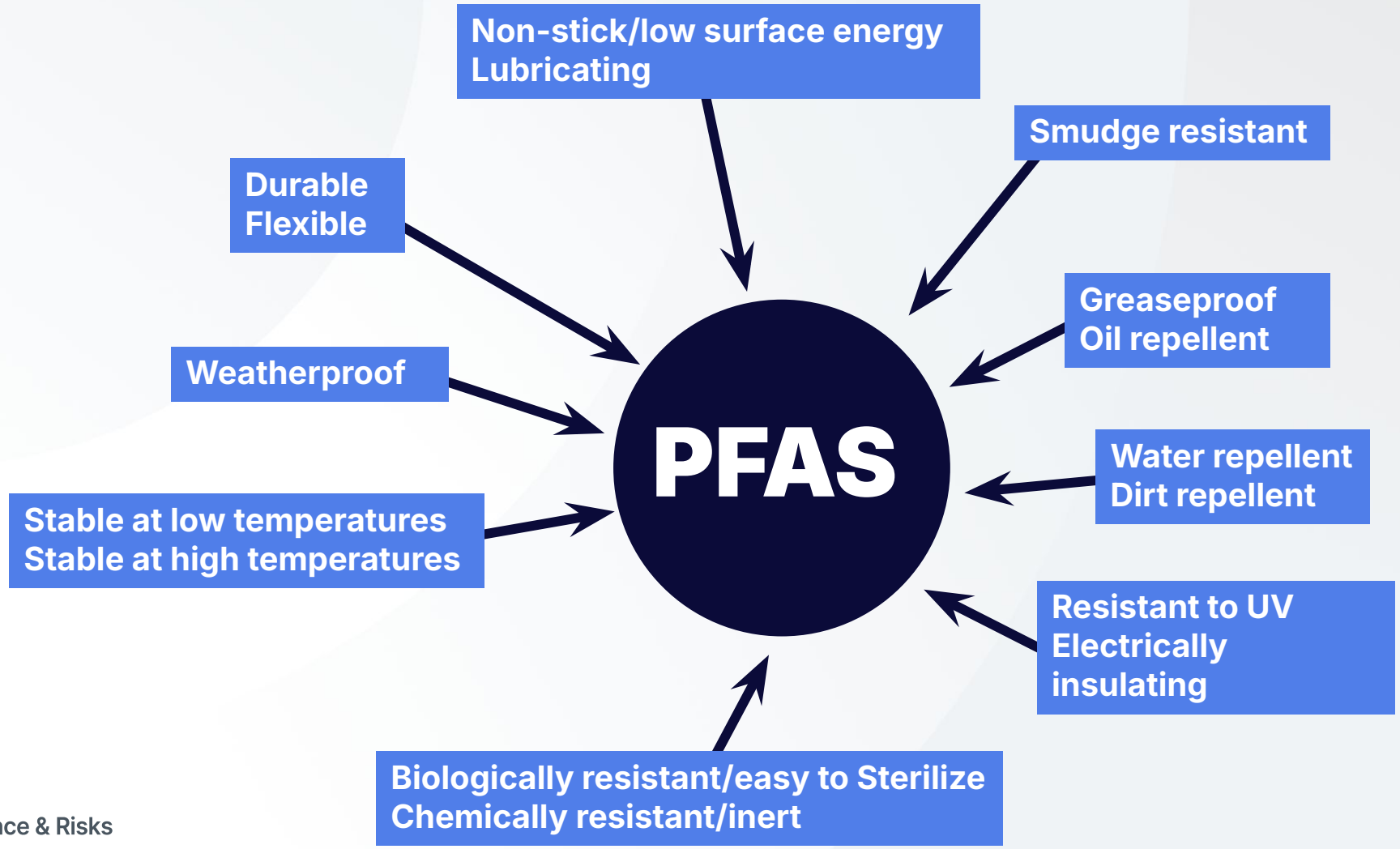
Why Use PFAS?


Non-stick/low surface energy
Lubricating
Smudge resistant
Durable
Flexible
Greaseproof
Oil repellent
Weatherproof
PFAS
Water repellent
Dirt repellent
Stable at low temperatures
Stable at high temperatures
Resistant to UV
Electrically
insulating
Biologically resistant/easy to Sterilize
Chemically resistant/inert

What Are the Global Trends on PFAS?

- The PFAS supply chain is responding to the adverse media coverage, legal action and regulatory requirements.
- Alternative PFAS free products increasingly available (example, polymer processing aids).
- PFAS formulation and use is declining, especially in the EU and United States.
- Research on biological action and environmental fate.
  - Results provide increasing body of evidence supporting adverse toxicological effects for particular classes of PFAS.
- Increasing regulatory action around the world
  - Bans on specific PFAS types/product types, reporting requirements to gather information for further regulatory actions.


PFAS

3M sets 2025 deadline to stop making 'forever chemicals'

Company's current net sales of manufactured PFAS, which are linked to cancer and heart problems, are about $1.3bn

Reuters

Tue 20 Dec 2022 15.25 GMT

Different PFAS Definitions

OECD Definition:

Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).

UK Definition:

Any substance that contains at least one fully fluorinated methyl (CF_3-) (without any H/Cl/Br/I attached to it), or two or more contiguous perfluorinated methylene (-CF_2-) groups

EU Definition:

OECD Definition AND

A substance that only contains the following structural elements is excluded from restriction:

CF_3-X or X-CF_2-X′, where

X = -OR or -NRR′ and

X′ = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR′′, -SR′′ or –NR′′R′′′;

and where

R/R′/R′′/R′′′ is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).

US Definition:

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

- R-(CF_2)-CF(R′)R′′, where both the CF_2 and CF moieties are saturated carbons
- R-CF_2OCF_2-R′, where R and R′ can either be F, O, or saturated carbons
- $CF_3C(CF_3)$R′R′′, where R′ and R′′′ can either be F or saturated carbons.

EU PFAS REACH Universal Restriction Proposal

Substances, as a constituent, mixtures, or in articles in a concentration of or above:

- 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)
- 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification)
- 50 ppm for PFASs (polymeric PFASs included)

If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

Manufacturing, use and placing on the market are proposed to be restricted from 18 months after entry into force unless a derogation applies.

EU PFAS REACH Restriction Status

RAC said dossier was too vague (October 2023):

- There has been further information provided by EU Member states in support of the Annex XV dossier.

Challenging for enforcement authorities:

- There is no defined list of PFAS that are included (no list of CAS numbers etc).
- Harmonised laboratory methods and standards needed.
- Common analytical lab equipment might have issues calculating Total Fluorine (TF).

Currently the scope covers:

- Placing on the market of PFAS on its own, in mixtures and in articles.
- Manufacture and use of PFAS as a substance.

But currently not scoped to include… the use of PFAS in existing mixtures and articles.

EU PFAS REACH Restriction Development Discussions

Derogations are still under development with RAC and SEAC, following the consultation responses

Consumer mixtures, cosmetics and ski wax:

- These are areas expected to have very limited, if any derogations.

Metal plating and manufacture of metal products:

- Metal plating PFAS uses included in hard chromium plating and nickel plating. Some of these are being phased out anyway and remaining uses are difficult to substitute.
- Derogations may be agreed where use is unavoidable and identified by SEAC.

17 – 20 September 2024 RAC / SEAC discussions:

- Textiles, upholstery, leather, apparel, carpets.
- Food contact materials & packaging.
- Petroleum & mining.

Next:

- Applications of fluorinated gases.
- Transport.
- Construction products.

EU PFAS REACH Timelines

Timelines are likely to continue to slip due to the complexity and sheer scale of PFAS uses.

- **RAC / SEAC opinions to be published 2025, maybe 2026.**
- **Updated Restriction Proposal later in 2026 / 2027.**
- **Entry into force ~2028 / 2029 (18-month transition period).**

EU REACH Specific PFAS Action: Fire Fighting Foams

Fire Fighting Foams: Legislation expected late 2024, Entry into force during 2025.

Transition to Fluorine Free Foams (F3) draft timelines (may change):

- 18 months for training purposes and municipal fire services
- 3 years most industry & defence
- 5 years for aviation, marine
- 10 years SEVESO Directive sites & offshore

EU REACH specific PFAS Action: PFHxA

Undecafluorohexanoic acid (PFHxA) its salts and PFHxA related substances:

- Applies to PFHxA and substances that degrade into PFHxA (‘PFHxA related substances’).
- Can be in fire-fighting foam mixtures.
- Can be present in articles, mixtures and in another substance as a constituent.
- ≥ 25 ppb all PFHxA & salts. ≥ 1000 ppb for all ‘PFHxA- related substances’.

Used in food packaging, clothing, water/oil/stain repellents.

Proposed Derogations:

- 5 years: hard chrome plating; certain photographic coatings; certain fire fighting foams.
- 7 years: latex printing inks.
- 12 years:vlarge fire fighting tanks, semiconductor uses.

The EU Member States have voted in favour of restricting PFHxA, its salts and related substances during the European Commission's REACH committee meeting on 29 February 2024.

Currently with the European Parliament for agreement prior to introduction.

UK PFAS Regulation Developments

***Similar* plans to EU, but lagging behind.**

2024 work:

- Restriction dossier on PFAS in fire-fighting foams (FFFs) in progress.
- PFHxA restriction not specifically included in UK HSE plans.
- Still assessing wide dispersive uses of PFAS and PFAS likely to be released from consumer articles.
- UK development of universal PFAS ban is behind the EU.
- Regulators are engaging with industry in a PFAS Forum.

PFAS Regulation in China

The largest manufacturer of PFAS in the world.

PFAS Bans in China:

- Manufacturing of PFOS (1 March 2023).
- Use of PFOS in firefighting foam (31 December 2023).
- Import/export of PFOS starting (1 January 2024).
- More PFAS now being phased out or restricted (PFHxS, PFOA, PFOS in pesticides).
- Regulatory initiatives – New pollutants initiative (2022).
- Revised limits in drinking water standard.

Drivers for change:

- Market access
- National water quality concerns
- Stockholm Convention

PFAS Regulation in Japan: ARMECS

Act on Regulation of the Manufacture and Evaluation of Chemical Substances

PFASs are currently controlled or scheduled to be controlled:

- PFOS and its salts: designated as a Class 1 Specified Chemical Substance in 2010.
- PFOA and its salts: designated as a Class 1 Specified Chemical Substance in 2021.
- Isomeric forms of PFOA and their salts: to be designated Class 1 in late 2024.
- PFOA-related substances: to be Class 1 Specified Chemical Substances in late 2024.
- PFHxS, isomeric forms of PFHxS and their salts: to be Class 1 February 2024.
- Other substances: Ministry of Environment is monitoring developments (Stockholm Convention)

Drivers for change:

- Stockholm Convention
- Food packaging safety
- National water quality concerns

PFAS Regulation in Federal USA

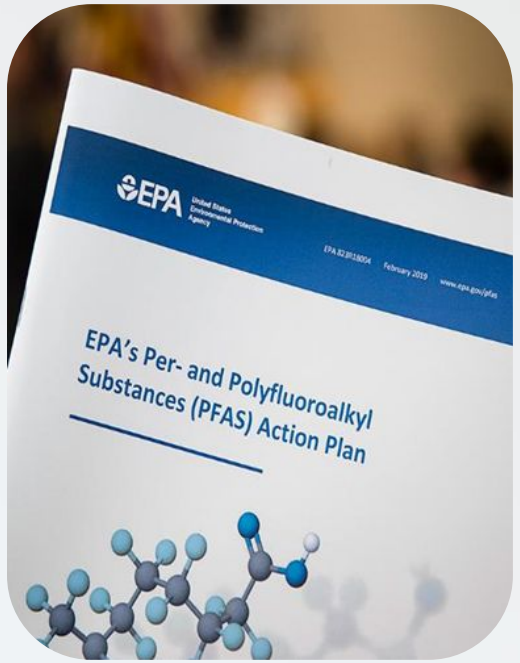
- US EPA roadmap initiative under the Biden Administration.

  Research → Restrict → Remediate

- National PFAS Testing Strategy.

US Federal Regulations:

- TSCA (TRI) for manufactures of PFAS and TSCA Rule Section 8(a)(7) for articles.
- National Drinking Water standard.
- TSCA Significant New Use Rule for Inactive PFAS.
- Resource Conservation and Recovery Act (RCRA).
- Comprehensive Environmental Response, Compensation and Liability Act.

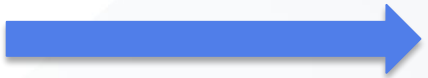


Federal US Regulation Affecting Articles

DATE ROLLBACK

- Requires “any person that has manufactured or imported PFAS substances or PFAS containing articles in any year since January 1, 2011”
- Report starts **July 2025 and finishes by 22 January 2026** for most businesses
- Uses a structural definition (not a chemical substance listing), all chemical entities (polymers, chemical substances, mixtures etc) will fall in scope if they fall under the structural definition. EPA provide a non-exhaustive inventory of PFAS.
- No minimum reporting threshold; all PFAS imports - includes packaging.

Reporting requirements under Toxic Substance Control Act (TSCA) final rule 8(a)(7)



Reporting is required for both imported articles and chemicals, and US manufactured PFAS Exemptions may apply*

** Exemptions: PFAS containing articles from US PFAS supplier; US pharmacopeia: drugs, medical devices; food, food additives; non-commercial R&D*

Federal US Regulation Affecting Articles

DATE ROLLBACK

Requirement	Who	What	When
Reporting	Manufacturer/importer of chemicals	Production volumes, byproducts,	**22 January 2026**
Reporting	Manufacturer/ importer of articles	PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects for any year since January 1, 2011	**22 January 2026**
	Small manufacturer/ importer of articles*		**11 July 2026**
Record keeping	Manufacturer/importer	Retain records that document any information submitted to EPA	**Five years following reporting date deadline.**

PFAS Regulation in US States

Requirement backtrack

Increasing US state legislation: California Proposition 65, Illinois, Indiana, New Hampshire, New Jersey, Colorado, Minnesota (HF2310)

Maine (Public Law 2021, c. 477, amended by Public Law 2024, c. 630) is the most developed so far:

- Maine initially required general notification of PFAS from 1st January 2025, which has been **withdrawn by 2024 amendment**.
- Maine's law prohibits listed products with **intentionally** added PFAS with some exemptions. The prohibited list increases with time.
- Specific products can be exempted through a Currently Unavoidable Use (CUU) reporting program.
- Current exemptions include medical devices, packaging, lab equipment electronics, semiconductors, motor vehicles.

	Initial Rules	Future Trends
Scope	Specific products	All products
Requirements	Registration	Disclosure of use or a ban
Substances	Specific PFAS	All PFAS or class of PFAS

PFAS Regulation in Canada

Rapid introduction

- Covers PFAS on their own, in mixtures and in articles (‘Manufactured items’).
- Report PFAS manufactured or imported during calendar year 2023 in specific uses (Schedule 1).
- Reports to be completed by 29 January 2025, via the online portal.

There are de minimis levels based on your annual import or manufacturing activities:

- 10g total of Schedule 1 Part 1 substances: various PFAS, certain polymers, PFAS salts and some fluorosilicones. (273 PFAS)
- 100g total of Schedule 1 Part 2 substances: ethene or propene fluoropolymers or Part 3 substances: F-gases. (39 PFAS)
- 100Kg total of any Schedule 1 substances for any use, in ‘manufactured items’ above 1ppm.
- Imports more than 10g of any one Schedule 1 substance on its own, in a mixture or product at above 1ppm.

PFAS Regulation in Canada

Exceptions:

- PFAS is for personal use.
- In transit across Canada.
- If it has a permit from Crossborder Movement of Hazardous Waste and Hazardous Recyclable Material Regulations.
- Product registered under the Pest Control Products Act, the Fertilizers Act, the Feeds Act; or the Seeds Act.
- If business is a micro business.

PFAS Regulation in Canada

The company must report for each named substance in Schedule 1, in every use for the 2023 calendar year:

1. The name of the substance, and the amount manufactured, imported, used, exported and released (if any).
2. If applicable, the name of the mixture (tradename) or manufactured item (e.g. wire insulation, cordless drill).
3. The application code in which the PFAS is used in, for example:

   C205 electrical and electronics, C207 batteries, C565 medical devices

4. The substance function code, such as:

   U005 anti-adhesive agent, U017 lubricant, U020 photosensitive substances

What Can Industry do About PFAS?

- Understand the PFAS definitions and requirements where you operate and sell.
- Engage with the supply chain to know the identity and amount of PFAS is present.
- Identify the type of PFAS and where it is in your products.
- Assess the risk to your business and manage the risk.
- Keep records of due diligence activities.
- Collate data and comply with legislation on PFAS reporting and phase out.
- Research and develop alternatives to PFAS.
- Redesign to remove the need for the PFAS, use PFAS-free alternatives where possible.
- Keep up to date with the legislation: it is developing rapidly.
- Engage with consultations relevant to you.


PFAS

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Upcoming & Proposed Regulatory Changes

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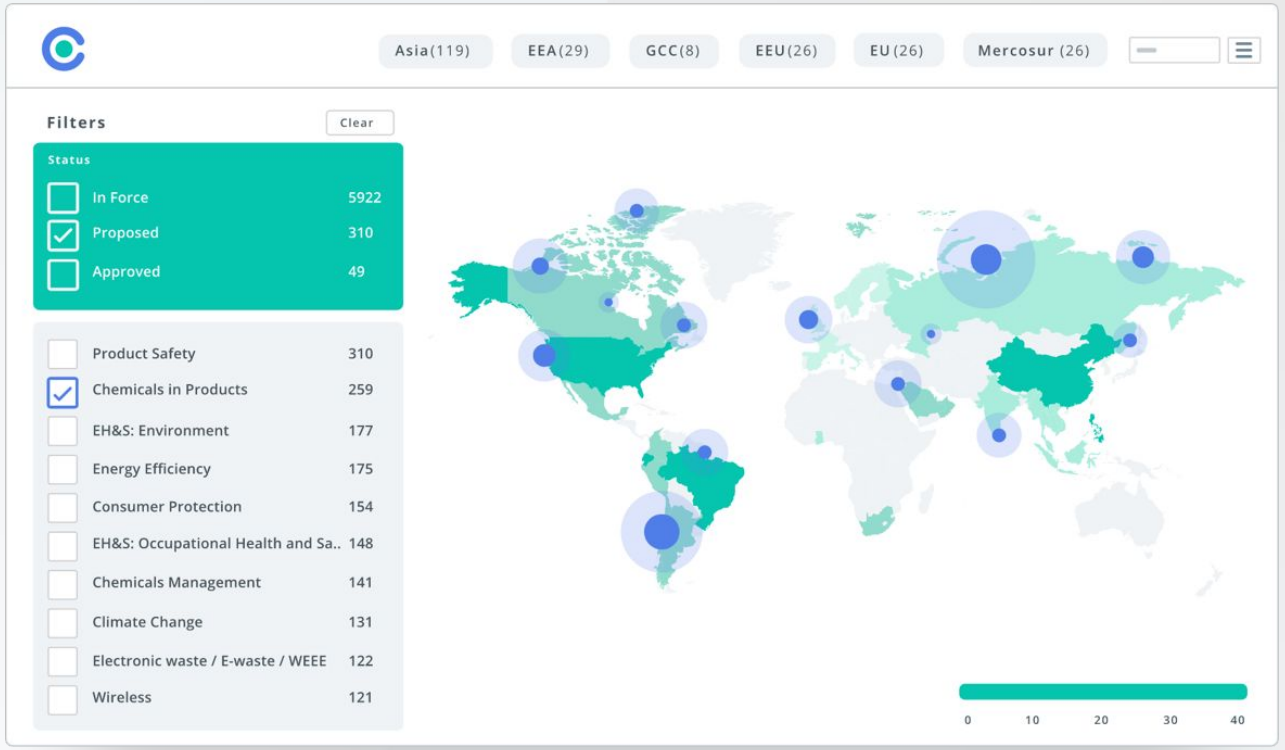
- Batteries
- Brexit
- California Proposition 65
- Carbon Footprint
- Chemicals in Products
- Chemicals Management
- Circular Economy
- Climate Change
- Conflict Minerals
- Consumer Protection
- COVID-19
- Cybersecurity
- Data Protection
- Drinking Water
- Ecodesign
- Ecolabeling
- Electromagnetic Compatibility (EMC)
- Electronic Waste / E-Waste / WEEE
- Energy Efficiency
- Explosive Atmospheres / ATEX
- EU Reach
- Food Contact Materials and Articles
- Globally Harmonized System (GHS)
- Illegal Logging
- Nanotechnology
- Packaging
- Product Safety
- Single-use Plastics
- Transboundary Movement of Hazardous Waste
- Transport of Dangerous Goods
- Water Efficiency
- Wireless

Manage all your Products & PFAS Compliance in One Place...

- Design, build & 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



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Industry Coverage

Consumer Electronics

Apparel

Household Appliances

Medical Devices

Home Furnishings

Automotive

Textile Manufacturing

Power Tools & Garden Machinery

Leisure & Sporting Equipment

General & Online Retailers

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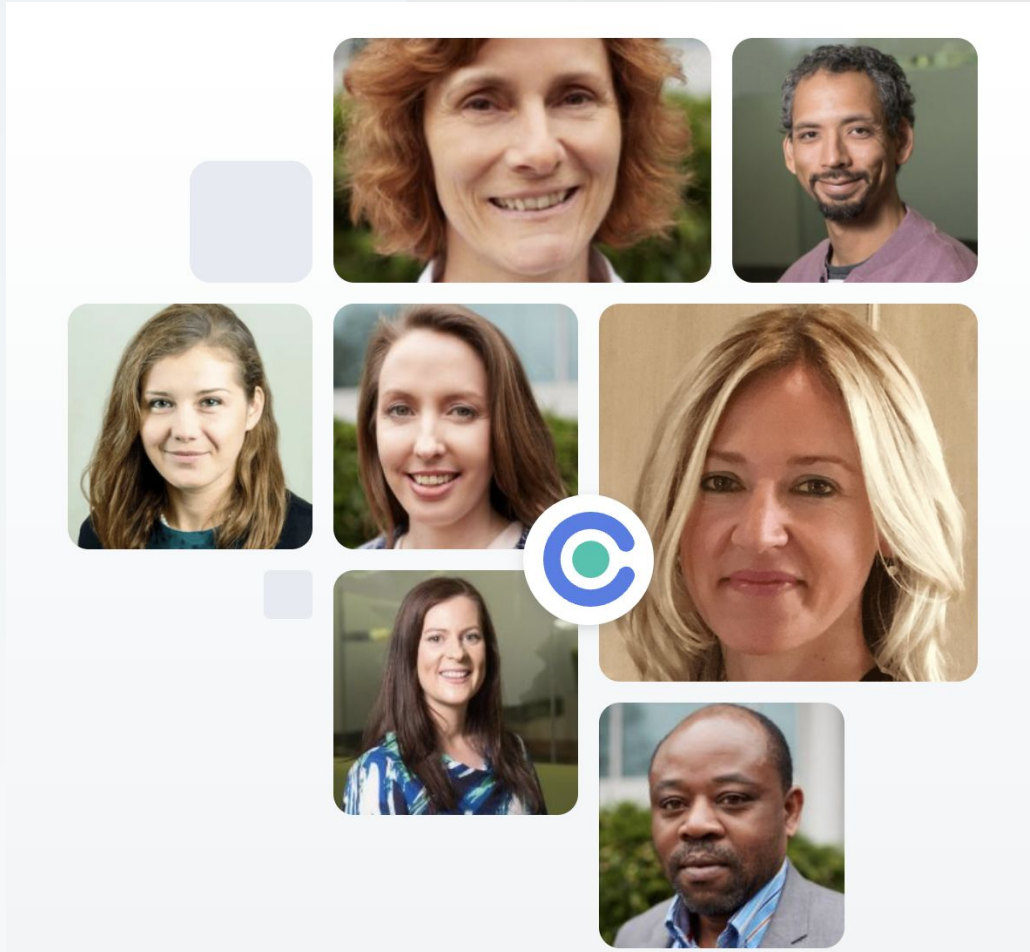

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Questions?

Thank You!

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