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PFAS regulatory developments.

September 2023



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Introduction

PFASs are widely used and intentionally added to a range of consumer and professional products, from firefighting foam to food contact materials, cosmetics and many more.

With more than 12,000 chemicals in the class, including a high number associated with health and environmental risks, regulatory authorities have focused on processes to ban or further restrict the use of per- and polyfluoroalkyl substances over the last few years. Their efforts are continuing, driven by increasing public interest in the chemical class and downstream pressure from consumers, retailers and advocacy groups.

In February 2023, ECHA published the highly anticipated EU REACH restriction proposal for PFASs, the most significant regulatory measure targeting the chemical class in any jurisdiction to date. The proposal's potential for significant supply chain impacts have created a huge amount of debate during the public consultation process.

In the US, the EPA's definition of PFASs has been evolving since the release of its roadmap two years ago, prompting discussion and potential divergence within the already challenging regulatory landscape for PFASs. With new evidence also emerging on the risks associated with various types of PFASs, the need to keep track of PFAS regulation is vital for everyone working towards the safe management of chemicals and the use of safer alternatives.

As the leading global provider of independent intelligence and insight for chemicals management and control, Chemical Watch News & Insight is focused on helping product safety professionals managing chemicals stay informed about developments in PFAS regulation and the impact on products. Our award-winning Chemical Watch News & Insight team monitors the latest developments, scientific issues and related business updates. In this report, you will find a sample of the award-winning reporting and analysis that makes our content stand out.

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Read a curated sample of Chemical Watch News & Insight content, featuring some of the 2023 updates and developments relating to PFASs. Washington state eyes reporting for six PFAS-containing priority products. Defers decisions on turnout gear, clothing, floor waxes and polishes

11 August 2023

Washington state has said it is considering PFAS disclosure mandates for cleaning products, ski waxes, certain sealants, nonstick kitchenware and some automotive items under the Safer Products for Washington programme.

The preliminary regulatory determinations of the green chemistry scheme's 'cycle 1.5' reflect the state's unfolding research into safer substitutes for several PFAS-containing priority products, which were designated under a 2022 law to more swiftly prevent pollution from the substance class.

The Department of Ecology's plan to introduce reporting requirements "could change" by the time final determinations are sent to the legislature for approval next year, the agency told attendees at a 10 August webinar. Regulatory options range from reporting requirements to restrictions to taking no action.

Ecology floated the potential disclosure obligations for PFAScontaining ski waxes, car waxes, car washes and cleaning products based on an exploration of safer feasible alternatives (SFAs) begun last October. The agency said it has "not [yet] been able to identify safer alternatives for any complete product category".

Ecology also expects to recommend reporting for PFAS-containing nonstick kitchen supplies and hard surface sealants, two priority products it chose not to examine SFAs for to save resources. The agency said its investigations focused on PFAS functions that were addressed in SPW cycle 1, span multiple articles so as to maximise exposure reduction, or involve formulated articles anticipated to have greater ingredient transparency.

Deferred action on some categories

Meanwhile, Ecology said it would defer decisions on PFAScontaining apparel, firefighting personal protective equipment (PPE), and floor waxes and polishes, pushing any regulatory action to SPW cycle 2. This would allow the agency two more years to study possible replacements.

"Our conclusions for these products are limited by data gaps, and we have efforts underway to fill those," it said. Any

recommendations for a disclosure mandate or ban for these goods would go to the legislature in January 2027.

Furthermore, prohibitions on PFAS-containing glass and floor cleaners could materialise in cycle 2 if current hints of SFAs are confirmed, the agency told Chemical Watch.

During the webinar, Ecology also shared early results from a market analysis on the availability, price, demand and effect of PFAS-free substitutes. It forecasted that cleaning products and clothing would be "the highest-impacted industries" because of their size in Washington state.

Call for input

Ecology has started hazard assessments where enough information exists to see whether potential replacements fulfil the agency's 'safer' standards. But overall, the SFA evaluations have "been very limited" by poor ingredient transparency, it said.

Therefore, the agency said it is "actively soliciting more information", including through six-month data orders and communications to manufacturers.

Ecology noted that it is preparing data orders for the firefighter PPE and apparel sectors. In cycle 1, it issued orders to vinyl flooring companies to shape a restriction on ortho-phthalates.

Draft findings due soon

Ecology intends to post a draft report of cycle 1.5 findings by January for public comment. A final version is slated for June, with a late 2025 rulemaking deadline set by the statute.

"We like to start talking about preliminary conclusions early, so no one is surprised when the draft report comes out," the agency said.

Now is the chance for stakeholders to highlight other PFAS-free options that warrant scrutiny, the agency added. "If they're only suggested after we release the draft report, we don't always have time to do an entire evaluation" on them, it said.

European Commission's PFHxA restriction proposal targets only certain uses. Plan deviates from BAUA's broader recommendation because of 'data gaps'

29 June 2023

The European Commission is proposing to restrict PFHxA only in certain uses, instead of a broader restriction recommended by the dossier submitter Germany's Federal Institute for Occupational Safety and Health (BAUA).

The Commission's proposal, published on 20 June, said it considers a "targeted restriction as the most appropriate EU-wide measure to address identified risks". The proposal targets the following uses:

- textiles, leather, furs, hides and outdoor clothing;
- related accessories such as handbags and footwear for the general public;
- paper and cardboard used as food contact materials (FCMs);
- mixtures for the general public;
- cosmetic products; and
- some firefighting foam applications.

BAUA's proposal, submitted in 2019, recommends restricting the manufacturing, use or placing on the market of PFHxA, its salts and PFHxA-related substances, while setting transition periods up to five years for some applications. It also sets limits of 25ppb for PFHxA and its salts and 1,000ppb for related substances used in mixtures and articles.

Opinions from Echa's committees for socio-economic analysis (SEAC) and risk assessment (RAC) supported BAUA's overall proposal to restrict the substances EU-wide. However, the RAC said because of gaps and uncertainties in the dossier's information, the restriction should only apply to uses where it is not possible to implement risk management measures to minimise emissions. SEAC said that coming to a solid conclusion on whether the restriction is proportionate, based on socio-economic considerations, is not possible because of data gaps.

According to the Commission's proposal, PFHxA is not registered under EU REACH but several of its related substances, as well as the ammonium salt of the substance, are registered, in tonnage bands from one to more than 100 tonnes/year.

PFHxA-related substances and the ammonium salt are widely used in many sectors, with large quantities used in paper and cardboard for use as FCMs, in textiles and in firefighting foams.

"The continued use of PFHxA salts and PFHxA-related substances in wide dispersive uses will lead to an increasing environmental stock and further environmental and human exposure," the proposal said.

Consumer products

NGO CHEM Trust said the Commission's proposal "leaves the door open to PFHxA in consumer products that are not covered by this targeted restriction", adding that it also does not restrict production.

The move comes ahead of the broad restriction of per- and polyfluoroalkyl substances (PFASs) in firefighting foams. PFHxA is a PFAS substance.

The Commission said it accepts that a broader restriction dossier for PFHxA, its salts and related substances would be more appropriate for [certain uses of] firefighting foams, "given that alternatives are widely available for training and testing, municipal fire services and civil aviation, restricting these uses should not be delayed".

Member states will now vote on the Commission's PFHxA proposal before it is sent to, and scrutinised by, the European Parliament and Council of Ministers before adoption.

Hong Kong adds PFOA, three other chemicals to hazardous substance list.

19 June 2023

Permits to be required from 20 October

Hong Kong is adding three chemicals and perfluorooctanoic acid (PFOA) to its Hazardous Chemicals Control Ordinance, known as Cap 595.

The manufacture, import and use of hazardous chemicals listed in Schedules 1 and 2 of Cap 595 are subject to permit controls.

The following three substances will be added to Schedule 1:

- hexachlorobutadiene;
- polychlorinated naphthalenes (PCN); and
- decabromodiphenyl ether.
- PFOA, its salts and PFOA-related compounds will be added to Schedule 2.

In addition, short-chain chlorinated paraffins, currently listed in Schedule 2, will be moved to Schedule 1, "for more stringent control".

Companies that manufacture, import, export and use these chemicals must obtain the relevant permit from the Environmental Protection Department from 20 October.

Any person found guilty of not complying with the regulation, will be liable to a maximum fine of HK\$50,000 and one-year's imprisonment.

The Environment and Ecology Bureau said the amendment helps Hong Kong implement the latest changes to both the Stockholm and Rotterdam Conventions for controlling certain persistent organic pollutants (POPs) and hazardous chemicals respectively.

Read the full story ►

McDonald's eliminates intentionally added fluorinated compounds from food packaging in US restaurants.

16 August 2023

Company says it is on course to hit 2025 global phase-out target

Multinational fast-food chain McDonald's says it has eliminated intentionally added fluorinated compounds from food packaging across its restaurants in the US and the company expects to complete a global phase-out by 2025.

In its latest sustainability report, published earlier this month, McDonald's said that globally 96% of its food packaging did not contain added fluorinated compounds – which include per- and polyfluoroalkyl substances (PFASs) – and its "packaging materials comply with state, federal and national-level laws and regulations, including the US Food and Drug Administration (FDA) and EU".

Earlier this year, a spokesperson for the fast-food chain told Chemical Watch the company was committed to its 2025 deadline, which is likely to precede the most comprehensive ban to date, with the EU planning to potentially place limits on all uses of more than 10,000 PFASs.

Food packaging transition

Several fast-food restaurants have planned to phase out PFASs from their food packaging in the next couple of years. Restaurant Brands International – parent company to Burger King, Popeyes and Tim Hortons – is also aiming to eliminate PFAS by the end of 2025.

Yum! Brands – parent company to KFC, Pizza Hut and Taco Bell – also plans to phase out PFASs from its food packaging by then. Meanwhile coffee chain Starbucks has committed to do the same in all its stores by the end of this year.

US restaurant chains Wendy's and Chipotle completed their transition away from PFASs in their food packaging last year.

US EPA extends planned PFAS enforcement scheme to users.

23 August 2023

Attorneys recommend businesses conduct audits

The US EPA has announced that a new enforcement effort imposing liability for PFAS pollution would target not only manufacturers, but also users of the persistent substances.

The national enforcement and compliance initiative (NECI) for fiscal years 2024-2027 would aid in enforcing hazardous substance listings anticipated for PFOA and PFOS under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), requiring makers and users of the chemicals to fund associated costly remediation.

"This NECI would focus on implementing EPA's PFAS strategic roadmap," according to a 17 August memorandum from the agency's Office of Enforcement and Compliance Assurance (OECA). It would entail "holding responsible those who significantly contribute to the release of PFASs into the environment, such as major manufacturers and users of manufactured PFASs, federal facilities that are significant sources of PFASs and other industrial parties".

Read the full story ►

Canada delays rule restricting flame retardants, long-chain PFASs until summer 2024.

16 August 2023

Planned update to Prohibition of Certain Toxic Substances Regulations sparked 'many' comments

Canada's plans to impose tighter restrictions on long chain PFASs and a pair of flame retardants will not be finalised until next summer "at the earliest", the government has said in a notification to the World Trade Organization (WTO).

Environment and Climate Change Canada (ECCC) and Health Canada proposed an update to the country's Prohibition of Certain Toxic Substances Regulations in May 2022, with plans to finalise the changes by the end of this year.

In its notice to the WTO, however, the government said it had received "many complex and technical comments" on the proposal, "which are being carefully considered". As a result, the government said it now expects to publish the updated regulations in the summer of 2024 "at the earliest".

MEPs pass EU Chips Act but industry warns PFAS ban could impact innovation.

18 July 2023

Semiconductor trade body says 12-year derogation period essential

The European Parliament has voted in favour of legislation that aims to strengthen semiconductor production across the bloc, but the European trade body for the products has warned of the impact on innovation of a blanket PFAS restriction.

During an 11 July plenary session, 587 MEPs voted to adopt the EU Chips Act, while ten voted against and 38 abstained. The legislation wants to address the "vulnerabilities in supply chains exposed by the pandemic" and to combat potential semiconductor shortages. It will include \in 3.3bn for research and innovation.

But the European Semiconductor Industry Association said that per- and polyfluoroalkyl substances (PFASs) remain an integral part of the chipmaking process. Mathias Müller, sustainability and environment, safety and health officer at ESIA, told Chemical Watch that, while PFASs are only used in small quantities in semiconductor production, replacing them altogether is likely to take a significant amount of time. "A blanket restriction of PFAS substances could undo efforts to drive innovation and increase the chip manufacturing footprint in Europe," he said.

Read the full story ►



17 April 2023

PFNA, PFOA and PFOS included on list

Thailand's Food and Drug Administration (FDA) has announced plans to ban the use of 13 PFASs in cosmetics products, even though it found none of the substances were currently being used in this sector.

The FDA announced via a 12 March draft notification (B.E. 2566 – 2023) that the country's Cosmetics Committee had approved the move and the administration was awaiting the green light from the Minister of Public Health before issuing a final version.

Industry: Revoking TSCA PFAS exemptions could push out 'critical' manufacturing. Electric vehicles, clean energy, healthcare, telecommunications among affected sectors

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18 August 2023

The US EPA's plans to make PFASs ineligible for certain exemptions from full TSCA premarket review could drive crucial industries away from the country, several business representatives have cautioned.

The warnings come in response to a TSCA new chemicals framework rule proposed in May. The proposal would expand on current policy by removing low volume exemptions (LVEs) and low exposure and release (LoREX) exemptions for per- and polyfluoroalkyl substances and certain persistent, bioaccumulative and toxic (PBT) compounds. This would mean new PFASs and covered PBTs would have to go through the 90-day premanufacture notice (PMN) evaluation, without the faster route to commercialisation offered by the exemptions.

But trade organisations and companies argue such a sweeping PFAS restriction would prove unjustifiably onerous, stifle American innovation and send important manufacturing sectors elsewhere.

"Having to file a PMN for low volumes of new substances - [with] approvals typically taking 1-2 years - would greatly hinder US innovations" in vital sectors that rely on PFASs, like renewable energy, transportation (see box), healthcare, construction and telecommunications, said Solvay in comments published on 9 August. Businesses "would be inclined to focus research efforts in other regions, where they would be able to quickly" market small amounts of new PFASs, according to the manufacturer.



Insight

What do the EPA's changing PFAS definitions signal for US regulatory efforts? North America desk editor, Julia John,

looks at how the agency's approach to the persistent chemicals has been developing

03 August 2023

The US EPA's definition of PFASs has been evolving since it released a roadmap two years ago to tackle the persistent compounds, with the flux sparking concern from both industry and environmental groups.

EPA officials have long maintained that the agency will not develop a single, agency-wide regulatory definition of per- and polyfluoroalkyl substances (PFASs), due to differing considerations in how to treat the substance class under various statutes such as the Clean Air and Clean Water Acts.

More recently, the EPA indicated it was taking a more granular approach to defining PFASs within the chemicals office. The agency told Chemical Watch that the Office of Pollution Prevention and Toxics (OPPT) replaced the concept of a 'working definition' that spanned TSCA activities, with a 'fit-for-purpose manner' of identifying what constitutes the substances for each regulatory or research action.

The agency's quiet move has already caused divergences between regulatory initiatives. For example, TSCA proposals released this year – including for a new chemicals 'framework' rule and significant new use rules (SNURs) on hundreds of 'inactive' PFASs – rely on a wider definition than the working one underlying a PFAS reporting rule proposed in 2021.

Both definitions are at odds with those followed by other jurisdictions, including the US's closest trading partner, Canada.

Overall, the EPA's decision could further complicate the challenging regulatory landscape for PFASs in the US and beyond.

'An awful idea'

Industry and environmental advocates have taken issue with the absence of a fixed, scientific PFAS definition for the EPA's plans to investigate and regulate the substance class.

The situation could lead to "a lack of clarity about the compliance obligations of regulated entities", according to Molly Blessing, sustainability director at the Household and Commercial Products Association (HCPA).

Implications across borders

Additionally, industry and environmental stakeholders anticipate difficulties resulting from global jurisdictions following separate PFAS definitions (see box).

Canada and the EU have opted to build on a 2021 OECD definition as they look to regulate the substance class. Under a REACH restriction proposed earlier this year, the EU aims to largely ban applications of over 10,000 PFASs as soon as 2026.

Inevitable shift to OECD definition?

According to Lynn Bergeson and Rich Engler of law firm Bergeson & Campbell, the world trade problems stemming from multiple PFAS definitions will probably prompt companies "to adopt the most conservative approach, which will drive an informal global default definition" mirroring the OECD's.

Dr Engler, however, criticised that definition's breadth as "scientifically unsupportable", saying that it lumps together compounds with disparate toxicity and fate simply because of their carbon-fluorine bonds. "It's like saying a porta-john and a 100-floor skyscraper are the same because both have four walls and a roof," he said.

This extract is from a news feature written by North America desk editor, Julia John and is an example of our award-winning global news, insight and analysis that informs product safety strategy. The article is available in full to Chemical Watch News & Insight members.

Definitions

The EPA has historically applied its 'working definition' to identify PFASs on the TSCA inventory, the agency explained in its May proposal for a new chemicals 'framework' rule. That definition, released in 2021, captures more than 1,300 compounds and underpins the agency's proposed TSCA Section 8(a)(7) PFAS reporting rule and TSCA Section 4 PFAS testing strategy.

But environmental advocates have continually pressed for a more far-reaching definition like the one put forward by the OECD in 2021, with one NGO suing the EPA last year to better understand the origins of the agency's definition.

The intergovernmental organisation described PFASs as containing a fully fluorinated methyl or methylene carbon moiety, which encompasses fluoropolymers and a few fully degradable subgroups.

Those criteria align with a sweeping definition typically written into US state-level PFAS legislation, incorporating all compounds with at least one fully fluorinated carbon atom. A similar definition appears in the 2020 National Defense Authorization Act (NDAA) that instructed the EPA to craft its TSCA reporting rule.



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