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Watch**

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Spotlight on PFAS

Regulatory developments from around the world

May 2021



Introduction: Increasing global scrutiny

Over the last year, we've seen increasing global regulatory action on per- and polyfluoroalkyl substances (PFASs), particularly in the EU and North America. For example, the European Commission's recently published chemicals strategy for sustainability – widely regarded as launching the most far-reaching regulatory measures in the EU in over a decade – promises a comprehensive action plan to address this group of chemicals, including phasing them out of consumer products.

Five European countries have agreed to prepare a restriction proposal covering the entire group of more than 4,700 substances, while Echa has announced its intention to restrict their use in firefighting foams.

In the US, there has also been a great deal of regulatory action both at federal and state level. The US EPA is nearing completion

of a proposed PFAS reporting rule under TSCA which will require manufacturers to submit detailed information on these compounds to guide regulatory action.

As the leading global provider of independent intelligence and insight for product safety professionals managing chemicals, Chemical Watch is well placed to help you keep up with PFASs regulation and its impact on your products.

This report aims to give you a taste of the award-winning reporting and analysis that Chemical Watch provides. By signing up to membership, gaining access to our news and attending our events you can keep yourself informed and up to date on the latest developments that matter.

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Our team of expert journalists reports on the biggest global regulatory and chemical management developments every week, helping you to take a proactive approach to compliance and keep track of the issues that are critical to you and your team.

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Oregon advances bill to address classes of chemicals in kids' products

Measure heads to state Senate after clearing House with bipartisan support

21 April 2021



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Oregon lawmakers have advanced legislation to extend the state's list of High Priority Chemicals of Concern for Children's Health (HPCCCHs) and mandate more detailed product reporting, in an effort to strengthen Oregon's leadership among US states in addressing potentially harmful substances in kids' products.

The bill HB 2495, which passed the state House on 19 April, would allow the Oregon Health Authority (OHA) to include whole chemical classes on the HPCCCH list. This could greatly expand the current list of 68 reportable substances beyond those in neighbouring Washington's list and move the state to the class-based approach advocated by California's regulatory scientists.

As states like Washington focus more on per- and polyfluoroalkyl substances (PFASs) and flame retardants, the OHA could prioritise them as well. But "we would not want to get ahead of the process by naming specific classes at

this time," said State Representative Courtney Neron, who sponsored the legislation.

"Children are especially susceptible to exposure to toxic chemicals," she added. "Creating a sensible programme to report and substitute out the most harmful chemicals is important," especially as certain substance classes' potential health effects become known.

Looking at entire classes, however, "could add thousands of chemicals beyond a specific listed chemical" to Oregon's list and complicate compliance, Kelly Mariotti, the Juvenile Product Manufacturers Association (JPMA)'s executive director, said in written testimony on the measure.

In 2015, Oregon enacted the Toxic-Free Kids Act, creating the HPCCCH list and requiring producers to notify the OHA of a listed chemical's name, registry number, quantity and purpose. The statute directs manufacturers to remove or replace high-priority substances in

goods designed for the mouth, children under three-years-old or use as a non-soap cosmetic. The agency recently finalised the rule for phasing out substances.

HB 2495 would undo the existing cap of five substances that it may add to the list when conducting a triennial review. It would have the authority to exclude lower-risk substances in any added chemical classes. The measure would require the OHA to consider adding chemicals of concern listed in Washington state, Maine, Vermont or Minnesota.

The bill also would instruct manufacturers to report biennially the brand name and model of HPCCCH-containing articles sold in Oregon, from 31 January 2024. This is intended to facilitate consumer awareness and would put the state's disclosure mandate on a par with Vermont's.

Manufacturers that eliminate high-priority substances from products would

have to provide a hazard assessment every three years, describing how the article, and any replacement chemicals, are safer. If the OHA rejects the submission, companies could turn in a revised assessment within 180 days. If it approves or fails to act on an assessment, producers could keep selling the product for three years.

Looking ahead

The bill now awaits Senate review. If it clears that chamber and is signed into law, it would take effect three months after the legislative session ends, which is slated for 28 June.

“Requiring safer substitutes and giving consumers the information they need to make informed purchasing decisions will lower health costs in the long run,” according to Morgan Gratz-Weiser, Oregon Environmental Council (OEC)’s legislative director. The bill will help “prevent toxic products from entering our children’s bloodstreams and our landfills” and “serve as an example for other states to take environmental and human health into account when regulating products”.

It “has a good chance of becoming law”, she told Chemical Watch. The 47–8 House vote “shows the bipartisan support for reducing exposure to high-hazard toxic chemicals in our kids’ toys and products”.

By aligning Oregon with other states, Ms Neron added, it would make implementation and disclosure more simple, efficient and cost-effective.

But according to Jennifer Gibbons, the Toy Association’s vice president of state government affairs, the organisation remains “opposed” to the bill, partly because it would stray farther from Washington state’s statute and increase the burden imposed by Oregon’s stringent scheme.

Listing substance classes can obstruct the search for less hazardous alternatives, she added.

The American Chemistry Council (ACC) similarly noted that “regulating chemistries by class is not supported by science.”

Guidance on reporting exemption

Days before the House approved HB 2495, the OHA updated guidance on how to seek an exemption from existing reporting requirements under the Toxic-Free Kids programme. This explains the necessary components of such a request, called a manufacturing control programme (MCP).

Producers with an approved MCP, demonstrating that any HPCCCH contaminant of at least 100 parts per million is “being effectively controlled” will qualify. If an exemption is granted, companies will not need to report products containing the substance or, after their third notice, to eliminate it from products covered under the law.

Join us for the upcoming PFAS Updates 2021 event from Chemical Watch

Following a successful inaugural edition in 2020, this virtual conference will again bring together regulatory authorities, industry and academia for a comprehensive discussion on the latest regulatory developments around the use of PFASs.

Hear experts and stakeholders during the one-day event as they focus on fluoropolymers and their alternatives in the EU, and look at regulatory trends in the US, including the regulation of PFASs as a class.

PFAS Updates 2021
23 June 2021
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Lawmakers reintroduce sweeping PFAS bill in US Congress

House again considers legislation to pause new PFAS approvals, among other measures

14 April 2021



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US lawmakers have reintroduced legislation to broadly regulate per- and polyfluoroalkyl substances (PFASs), including by mandating testing of existing compounds and imposing a five-year ban on allowing new ones into commerce.

Representatives Debbie Dingell (D-Michigan) and Fred Upton (R-Michigan) announced the PFAS Action Act alongside actor Mark Ruffalo and other environmental advocates on 13 April. Like a similar version of the bill that cleared the House of Representatives in 2020, it seeks to put protections in place on new and existing PFASs and tackle environmental contamination.

The current legislation is mostly “identical” to the previous iteration, Ms Dingell said, to “build on our strong bipartisan support from last year”. It would direct the EPA to:

amend section 5 of TSCA to mandate “an unreasonable risk” finding and use

prohibition in response to any PFAS chemical notification submitted under the new chemicals programme for five years;

- amend section 4 of TSCA to require PFAS manufacturers and processors to speedily conduct “comprehensive toxicity testing” for all these chemicals in the environment and products;
- issue guidance for minimising PFAS-containing firefighting foam to safeguard first responders and the environment;
- incorporate into its Safer Choice standard PFAS-free cookware, carpets, rugs, clothing, upholstered furniture and many stain-, water- or grease-resistant coatings, or create voluntary producer labels for these articles; and
- devise a public risk-communication strategy for PFASs in people’s surroundings and products, highlighting ways to reduce exposure.

The bill also preserves a clause instructing the EPA to define all PFASs as hazardous substances under

the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), or Superfund. The House had removed this controversial part from the 2019 version.

PFASs represent a class of thousands of persistent synthetic compounds commonly used by American industries since the 1940s, according to the EPA. Because they repel water, grease, heat and stains, manufacturers often coat goods with these substances. But studies suggest some accumulate in humans and cause cancer and thyroid, cholesterol, immune system and birth weight problems.

“This is an enduring public health and environmental issue”, said Ms Dingell, noting how the compounds are found in everything from food containers to cosmetics. “We need strong federal leadership now to address these pervasive and harmful chemicals.”

She first introduced the PFAS Action Act in 2019. It made it through the House

a year later amid growing attention on the substances and was referred to the Senate Committee on Environment and Public Works (EPW). However, President Trump had threatened to veto the legislation, and it did not advance in the Republican-controlled Senate.

Bill prospects

The lawmakers are hopeful for the bill's enactment, given Democrats' control of Congress, President Biden's focus on the compounds, legislators and communities' increased awareness of PFASs, and time still ahead to expand support.

"I think we're going to see real progress in the Senate", said Scott Faber, senior vice president of government affairs for the Environmental Working Group (EWG).

And the legislation will get signed into law if passed, according to Mr Upton.

"I call on my colleagues in the Senate, Republican and Democrat, to please make this a real priority in this Congress", Ms Dingell added.

But the American Chemistry Council (ACC) objected to the PFAS Action Act, saying it is not scientifically sound and "applies a one-size-fits all approach

to regulating the wide variety of PFAS chemistries" that have distinct environmental and health effects. Since the substances "are vital to enabling our lives in the 21st century", the trade group told Chemical Watch, this approach "would limit consumers' access to important products".

And according to the ACC, new PFASs are already "subject to strict controls under TSCA Section 5(e) orders before they are brought to market". The organisation pointed out that "substantial work" is occurring with industry cooperation on the state and national levels to deal with potential concerns regarding PFASs.

Environmental group highlights widespread PFAS use in building materials

Green Science Policy Institute calls for greater disclosure, switch to alternatives

22 April 2021

Per- and polyfluoroalkyl substances (PFASs) are widely used across the building sector, the Green Science Policy Institute (GSP) said in a report that called on industry to adopt greater disclosure policies and embrace safer replacements.

The publication, *Building a better world*, aims to help industry decision makers "understand where they might be using PFAS so that they can then ask whether all those uses are really necessary" and "drive demand for innovating" substitutes, GSP senior scientist Tom Bruton told Chemical Watch. GSP compiled the report with information from peer-reviewed papers, government publications and company websites to

raise awareness about the substances' "large, lesser-known" implication in the building sector, Mr Bruton said.

The 21 April report highlights a sphere that is increasingly drawing the eye of regulators and retailers (see box).

PFASs offers benefits in a vast range of building components, helping in weatherproofing, preventing corrosion, decreasing friction and achieving resistance to stains, grease and water, GSP said. At the same time, the compounds are highly persistent and can wind up in the environment, indoor dust, food and eventually humans via these materials' production, utilisation and disposal, the advocacy group said.

GSP's investigation discovered PFASs, such as polytetrafluoroethylene (PTFE), polyvinylidene fluoride (PVDF), polyvinyl fluoride (PVF), polychlorotrifluoroethylene (PCTFE), fluorinated ethylene propylene (FEP) and ethylene tetrafluoroethylene (ETFE) throughout the building industry.

The organisation said they can be found in:

- roofing, including metal, asphalt and textile-based roofing and weatherproofing membranes for flat roofs;
- coatings, including paints, wood lacquers, and metal and plastic coatings;
- flooring, including carpets, rugs and resilient flooring;



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to the ACC. They should be “regulated by their specific properties and potential risks rather than by a sweeping, broad-brush approach with the potential to severely impact the functionality and safety of numerous products we rely on”, it said.

- sealants and adhesives, including caulks, O-rings, and grout, tile, stone and concrete sealers;
- glass, including windows, doors, mirrors and lightbulbs;
- fabrics, including furniture, curtains and awnings;
- wires and cables;
- tape, including plumber’s, flashing, fiberglass and film tapes;
- timber-derived articles, including composite wooden sheets and wood fibre insulation;
- solar panels, including rechargeable batteries that store energy;
- artificial turf, including blades and backing; and
- seismic damping systems.

Many of these applications are non-essential, according to GSP, which pointed out less harmful options that exist for most categories.

The National Association of Home Builders (NAHB) and the American Coatings Association (ACA) declined to comment on the findings at this time.

Recommendations

To enable informed decision making that minimises PFASs in buildings, producers should demand transparency from chemical suppliers and disclose substance use to customers, GSP concluded. Manufacturers should implement, and tell suppliers to create, PFAS-free choices, it added.

The construction industry “has the economic power and the technical expertise” to transform the market, the non-profit noted. Increasingly available certifications, transparency schemes, chemical data systems and assessment programmes like ChemFORWARD and GreenScreen for Safer Chemicals can facilitate the process, it said.

Governments can also exert their purchasing power to make companies disclose chemical ingredients and remove inessential PFASs in construction goods, the report says. It suggests governments enhance disclosure via regulation and ban non-vital PFAS-containing articles, too.

The American Chemistry Council, however, objected to evaluating the essentialness of this entire substance class. PFASs provide “significant durability” in construction and the roughly 600 compounds in commerce have been reviewed by the US EPA, the trade group said.

Given “the lack of alternatives that possess the same suite of performance characteristics”, the ACC told Chemical Watch, a class- and need-based view “will lead to unnecessary and unjustified restrictions on large groups of chemicals that do not pose a significant risk to human health or the environment”.

PFASs should be scientifically reviewed by substance and application, according

Action on building materials

US laws do not currently address PFASs in building components as a whole, but many states are taking steps towards regulation in some areas.

California and Washington state have announced plans to examine more closely carpets and rugs containing them. Several other states, including Maryland, Massachusetts, New York, Oregon and Vermont, are considering bills to regulate the substance class in carpets, rugs and furniture, according to Chemical Watch’s legislation tracker.

States could increasingly turn to restricting PFASs in the construction sector, Mr Bruton told Chemical Watch, “especially those uses where there is a direct link to increased exposure”, such as grout sealers, floor polishes and upholstery.

Beyond state-level measures, the PFAS Action Act recently reintroduced in Congress would support PFAS reporting for carpeting, furniture, and stain-, water- and grease-resistant coatings through the EPA’s Safer Choice standard or voluntary manufacturer labels.

And stores like Lowe’s and Home Depot have stopped selling certain home goods containing the compounds, such as fabric sprays and carpeting.

Comment: Why a pesticide contamination case in the US should concern all of us

The discovery of PFASs in mosquito insecticide raises big questions over product stewardship, says consulting editor, Geraint Roberts

21 April 2021



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Last year Kyla Bennet, a scientist working for a civic society group in Massachusetts, began to ponder why there was an area with drinking water contaminated with per- and polyfluoroalkyl substances (PFASs) that lacked obvious sources of contamination, such as defence facilities, chemical plants or firefighting training sites. Where was the contamination coming from? Could there be a connection to the aerial spraying of mosquito insecticide that occurred every year?

To test the theory, the Public Employees for Environmental Responsibility (PEER) group examined the insecticide, Anvil 10+10, which is stored and transported in high-density polyethylene (HDPE) containers. Tests found PFAS compounds in the pesticide.

Alerted to the results, the US EPA decided to do its own tests, not only

to see if PEER's findings would be confirmed, but also to work out where the PFAS compounds were coming from. The agency discovered that none were approved for use as active or inert ingredients in Anvil 10+10, so it decided to test product samples from different steps in the production/distribution process – and to rinse both the inside and the outside of the HDPE containers, and analyse the rinsates. Testing on a limited number of containers used by one Anvil 10+10 supplier found eight PFAS compounds, including perfluorooctanoic acid (PFOA).

The EPA thinks it has found the source. As a final stage in their production process, the HDPE containers used to store and transport the pesticide were treated inside and outside with fluorine gas, in a reactor. This was done to create a chemical barrier that makes them tough enough to contain liquid chemicals and solvents that would

otherwise react with the container and cause it to buckle, or the product inside to become damaged. The PFAS compounds in the pesticide, says the agency, were formed by fluorine atoms reacting with the plastic, either during the fluorination process or afterwards, and then leaching into the containers' contents.

If this is correct, and fluorinated containers are widely used, mosquito pesticides could be the tip of the iceberg. The PFAS levels connected to the pesticide containers are very low, but we don't know how many containers are leaching PFASs. Millions of acres could be sprayed with pesticides containing PFASs. The EPA says many companies use fluorinated containers to store and distribute pesticides and that "fluorinated polyethylene and HDPE are used for numerous applications such as food packaging". Companies offering fluorinated plastic containers

say that as well as pesticides, the range of products that can benefit from them includes petroleum products, solvents, as well as household and beauty products containing enzymes. According to a post on the website of US firm Berlin Packaging, dated October 2019, "new trending uses" for fluorinated containers include food and beverage containers. The American Chemistry Council says fluorinated packaging is manufactured by numerous companies worldwide and that the US Food and Drug Administration has authorised fluorinated HDPE packaging and several specific fluorinated substances for food contact materials.

Six months on from PEER's test results and we are none the wiser about the scale of the problem. The EPA is testing different brands of fluorinated containers but it is yet to provide evidence that pins down the potential scale of the issue. The chemical, pesticide and agricultural container trade bodies working with the EPA have also not yet provided evidence. Most say that until the local press ran stories about PEER's testing, they were unaware that fluorinated containers might leach PFASs.

The issue has also caught authorities on the hop in Europe, where five

countries are preparing a wide-ranging EU restriction on PFAS compounds. The restriction is likely to encompass the whole lifecycle of PFAS compounds, from manufacturer to use, and from distribution to waste management of products. But the work on packaging is nearly finished and the countries involved have not decided whether to delay its completion until they have worked out if fluorinated containers are a significant data gap. Nor have they decided if the restriction should include unintended sources of PFAS compounds.

Europe's trade bodies also seem to have been caught off guard by events in the US. Despite repeated requests, neither fluorine trade body EuroFluor, packaging trade body European, food industry group Food DrinkEurope, PlasticsEurope or plastic converters association EuPC gave us any information about the fluorinated containers market in Europe.

Nonetheless, they are being used. According to Curtec, a packaging firm based in the Netherlands, some larger distributors offer fluorinated bottles, jerry cans and small packs, which they either buy already fluorinated or have them fluorinated themselves. Curtec used to provide fluorinated drums

for the transportation of liquid Teflon coatings. UK packaging firm Bettix offers fluorinated containers for a range of products including fuels, lubricants, degreasers, agrochemicals, fragrances and flavours, and says it exports the containers to many countries. There may be other suppliers, possibly many.

It is unsatisfactory, to say the least, that it should take a non-profit body, rather than environmental agencies, to look at pollution hotspots and search for discrepancies with obvious sources. Did anyone check to see if the fluorination process or the use phase of fluorinated containers could create unintended chemicals on the surface of the container?

Six months down the line, no one in industry has published detailed information on what it is doing to raise awareness of the issue with members and get better data – neither fluorination technology providers, nor the packaging and pesticide sectors. Where was the product stewardship before this issue came to light? And where is it now?

Council of Ministers presses European Commission to take more action on PFASs, EDCs

Member state representatives call for greater involvement in chemicals strategy implementation

23 March 2021

The EU Council of Ministers has called on the European Commission to take further action on specific chemicals such as endocrine disruptors and per- and polyfluoroalkyl substances (PFASs) under the bloc's new chemicals strategy.

Although the Commission's strategy is non-legislative and does not require the Council's approval, member states will largely be responsible for the enforcement of new regulatory measures stemming from it.

The Council's official conclusions on the strategy, released on 15 March, broadly support the strategy's level of ambition, as its draft conclusions in January did.

The conclusions:

- stress the need to ensure PFASs are eliminated unless their use is proven essential to society;
- call on the Commission to regularly update the Council on the progress of its PFAS action plan; and
- ask the EU executive to present "further measures to complement the anticipated PFAS restriction proposal".

On endocrine disruptors, the Council urges the Commission to "strengthen" the European legal framework to enable swift identification under CLP to minimise exposure, and ensure a "high and coherent" level of protection across legislation, especially for vulnerable population groups.

It says it supports the "accelerated development" of test methods to generate data on the chemicals.

The conclusions also state the need to continue to improve the quality of REACH registration dossiers, in particular for substances of unknown or variable composition (UVCBs), and to "carefully examine" the need to register substances that are currently excluded from the process.

Member state involvement

Other changes to the draft conclusions include calls for enhanced member state enforcement capacity and strengthened national market surveillance capabilities and customs authorities.

At an informal meeting of the Environment Council on 18 March, some member states called for the Commission to involve member states more in the strategy's implementation by allowing them to participate in its high-level roundtable on the plan. The Environment Council consists of a group of ministers responsible for EU environment policy.

Czech deputy environment minister Vladislav Smrz said the involvement of national competent authorities in the roundtable would "significantly contribute" to its work, while Danish environment minister Lea Wermelin said it was important that the Council conclusions "emphasise member states' participation and the right of initiative of member states".

In another change from the draft, the Council stressed "the importance of not shifting environmental and health

damage to third countries". During the Environment Council meeting, several member states expressed concern over the bloc's exports to third countries of chemical products which would not comply with EU legislation, with French environment minister Barbara Pompili calling this a "moral issue".

8th EAP

A rift in opinion between the Commission and Council emerged in discussions on the 8th Environmental Action Programme (8EAP), which will set the course for European environment policy to 2030.

The Commission presented a proposal on the programme – which includes a zero-pollution ambition – in October.

The committee of member state ambassadors (Coreper) agreed on a mandate for negotiations on the deal on 17 March, but demanded changes including a mandatory legislative proposal from the Commission in 2025.

Environment Commissioner, Virginijus Sinkevičius, labelled this demand "a major concern" during the Environment Council meeting, saying "such a provision goes against the Commission's institutional prerogatives" and the EU executive's right of initiative.

The Parliament is set to vote on its mandate for negotiations at its June plenary.

RIVM to explore criteria for EU essential use of persistent chemicals

Dutch institute study in parallel with work on PFAS restriction proposal

18 February 2021

RIVM, the Dutch agency jointly working on an EU restriction proposal on per- and polyfluoroalkyl substances (PFASs), has embarked on a project to define criteria for essential uses of persistent chemicals.

The move will help to frame the concept that will be the new basis for phasing out substances of concern under the European Commission's chemicals strategy for sustainability.

The Netherlands is one of five European countries preparing a joint PFAS restriction proposal – a sweeping ban on the substances as a group expected to be submitted to the Commission by the middle of 2022.

The National Institute for Public Health and the Environment (RIVM) is conducting the socio-economic impact assessments of the restriction. Project manager, Martijn Beekman, said it made sense to branch out into a separate study to formulate scientific criteria for essential uses of persistent chemicals, a broader group that includes PFASs.

The Dutch government says PFASs should be restricted in non-essential uses, a position that was embraced by the Commission's chemicals strategy which includes actions to ban PFASs except for uses "essential for society".

The project on essential use by RIVM will be done in close cooperation with the other four countries working on the restriction and with the Commission, Mr Beekman told Chemical Watch.

Currently there are no clearly defined

criteria for essential use, and the concept has proved controversial, causing disagreement in legal circles about whether it can be introduced in REACH without a recast of the regulation. The Commission is expected to put forward its proposed criteria by the end of 2022.

Mr Beekman said RIVM's findings on essential use would contribute to the PFAS restriction proposal, and more broadly to applying the concept to all hazardous chemicals, as set out in the chemicals strategy.

It could have a complementary approach to another group working on essential use criteria for PFASs – the Global PFAS Science Panel, led by Professor Ian Cousins.

The panel has set out to refine an initial scheme that categorised the substances according to essentiality – work that prompted the Commission to adopt the concept in the chemicals strategy.

But RIVM's team of four experts are mainly focused on socio-economic issues, Mr Beekman said, with some members also involved in the restriction proposal.

'Thinking sessions'

The Dutch institute has organised three online 'thinking sessions' this month to get the ball rolling on the criteria. The first session was on 15 February.

It has invited experts from academia, industry, NGOs, consumer groups and



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consultancies to attend the sessions, bringing together wide-ranging professions, including toxicologists, psychologists, economists and lawyers.

Each session will have around 15 participants, who will be asked to reflect in a "structured way" on two linked questions:

what criteria for defining essential use do stakeholders consider relevant; and

how could these criteria be measured.

Following the sessions, RIVM will address whether a consensus can be found, and what criteria appear to be most important. It will also consider whether available alternatives can be "acceptable" and if all stakeholders should have an equal say in determining essentiality.

Mr Beekman said that while the concept is generally thought of in the context of substances, there should also be a discussion on the essentiality of products – on the "societal value of certain goods".

Guest Column: How does the concept 'essential use of PFASs' fit the current legal framework in Europe?

Can we ensure the idea of 'essential use' doesn't lead to the adoption of intrusive judgements about what society does or doesn't need, asks Jean-Philippe Montfort of Mayer Brown

14 April 2021



Natalia @adobeStock.com

The European Commission's chemicals strategy for sustainability contemplates using the concept of "essential use" to regulate per- and polyfluoroalkyl substances (PFASs) and other hazardous chemicals. In the meantime, five member states are preparing a restriction on all PFASs that also refers to the concept of "essential use".

As delegates heard at last December's Chemical Watch conference, Essential uses of PFASs, many uses of PFASs are indeed essential to society, and some are crucial to achieving some of the Commission's most strategic objectives – Europe's green recovery and digital sovereignty for example.

If REACH is modified, great care must be applied to prevent the concept of "essentiality" leading to the adoption of unnecessarily intrusive judgements concerning what is good or bad for society. Such judgements are, by nature, relative and must remain evolutionary.

While the current legal framework may be open to the introduction of the concept of "essential use", this concept cannot be used to rewrite, or bypass, the existing REACH processes with their checks and balances.

Essential uses in the strategy

The Commission's chemicals strategy for sustainability states that the very large number of uses of PFASs, including some critical for society (medical devices, for example), "show that some of their uses can bring high socio-economic benefits". Such benefits, it says, should be compared with the socio-economic costs of environmental contamination and adverse effects on human health. A concept that could be useful in this assessment with the purpose of reducing emissions, is "essential use", it says.

The strategy provides as an example of a potential "essential use", the use of

PFASs specifically to provide water and oil repellency to textiles for workplace protective clothing. While for consumer use oil repellency could be considered "convenient but not essential", the strategy argues that a high level of worker protection may be considered essential "until suitable alternatives are available".

This is the heart of the debate. What is "essential" versus "convenient", and who is competent to make that determination? If society accepts that mountain guides can have clothes that can sustain the harshest weather conditions, shall it prohibit them for non-professional hikers because for them it is only "convenient"? If so, will the production of such high tech clothes in such a small volume be economically sustainable? Or will the restriction to "only professionals" lead producers to simply abandon the market? Then nobody will benefit from the innovation.

Lessons from Covid-19

The question of “essentiality” is not limited to chemical regulation. It is a concept that was, and remains, referred to by authorities when taking Covid-19 measures. The debates that have taken place in that context can help us understand the issues at stake when using such a concept.

To prevent the spread of the virus, authorities have had to limit human contact and decide which human or commercial activities should be maintained on the grounds that they are “essential”. Everyone can observe how relative and diverse the answers to this question were. Should we only go out of the house to see a doctor and shop for food? Or also to run in the park and walk the dog? What stores are considered essential? Only food shops and supermarkets? What about bookstores? What about museums and theatres? Is “culture” essential? Yes of course, all governments will sing in unison. Yet, the concrete measures applied were different from one member state to another.

Who decides?

The fact that differences of opinion on essential uses exist is recognised by the Commission in its recent paper to the Competent Authorities for REACH and CLP (Caracal). The Commission notes “it is not necessarily evident what use is considered as essential or not by the society, and there may often be differences of opinions”. It adds “therefore, objectivity and relevance of the criteria must be ensured”.

But is objectivity really possible to achieve? And who should be involved in that decision? With regard to Covid-19, everyone could see how much views and decisions diverged depending on whether politicians involved just epidemiologists, or consulted economists, medical and

social workers, psychologists, etc. How do we prevent the concept of “essential use” leading to the adoption of unnecessarily intrusive judgements of what is good or bad for society?

The most hazardous chemicals

Coming back to chemical legislation, the concept of “essential use” was first applied under the Montreal Protocol which regulates substances that deplete the ozone layer. It defines an “essential use” as one that is “necessary for health, safety or is critical for functioning of society” and which has “no available technical and economically feasible alternatives”.

Are PFASs comparable to substances that deplete the ozone layer? In its paper to Caracal, the Commission refers to the concept of “essential uses” for “the most harmful chemicals” but offers neither a definition, nor criteria, for what these are. It seems obvious that the first step in creating a new policy based on “essential uses” would be to define the criteria that should be applied to determine which “most hazardous chemicals” should be subject to the policy. Yet, that does not seem to be the Commission’s priority.

‘Essential uses’ in the current legal framework

In the meantime, the REACH Regulation applies as it is and it is in that legal framework that the proposed restriction on PFASs should be considered.

Under REACH, the adoption of a restriction requires authorities to demonstrate that the chemicals they seek to restrict present “an unacceptable risk to human health and the environment”. The burden of proof is on them to do so. And this analysis must take account of the specificity of each chemical substance being considered. There cannot be a

one-size-fits-all restriction that picks up on the characteristics of one PFAS and extrapolates it to all other PFASs without positive demonstration of their hazardous criteria. EU authorities have adopted criteria for read-across between substances that they apply strictly when judging whether test data on a given substance can be used to determine the properties of another substance. There is no rationale for not using the same approach for judging how to read across from one PFAS to another in the framework of a restriction.

Most PFAS are claimed to be persistent or very persistent, and some may be bioaccumulative, but not all. REACH includes criteria for substances that are persistent, bioaccumulative and toxic (PBTs) or very persistent and very bioaccumulative (vPvBs), showing that it is the addition of persistence and bioaccumulation and/or toxicity which is of concern. It remains to be demonstrated that each and every PFAS meets such criteria of concern, or another criteria of concern.

Similarly, Article 68 of REACH requires authorities to take into account socio-economic consequences of the proposed restriction, including the availability of alternatives. This is the legal framework that exists today and in which a PFAS restriction is currently envisaged.

At the Chemical Watch conference, there was consensus that Article 68 does leave some room for the “essential use” concept as part of the socio-economic analysis it requires - and that this exercise is fundamentally different from using the “essential use” concept to overhaul the current legal framework.

Taking into account the socio-economic consequences of a restriction may entail measurable consequences in terms of job creation or loss. It may also entail the loss of availability of products which

serve social needs. In this context, a concept that seeks to define in which conditions a use or a product is “essential” or “convenient” – a “must have” as opposed to a “nice to have” – may find its place. But this can only be considered with due account of the specific risks that this particular use or product raises, and after an assessment of possible alternatives has been made that is as rigorous as that applied to the potentially restricted substance. Great care should be used to ensure that the decision-making process is transparent and non-discriminatory, and that the restrictions remain proportionate.

Conclusion

It may be possible to apply the “essential use” concept under the current legal framework as a qualifier to the analysis that should be conducted as part of the socio-economic consequences of a potential restriction. However, this concept could not be used in the absence of a demonstrated unacceptable risk. Also, the use of this concept should remain within a socio-economic determination as to whether a given use of a chemical that presents an unacceptable risk provides benefits to society that outweigh the identified risks,

and for which there are no technically and economically suitable alternatives. Otherwise, products will be banned on the basis of unnecessarily intrusive judgements of what is good or bad for society, which is by nature relative and must remain evolutionary.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch

New South Wales to ban most uses of PFAS-containing firefighting foams next year

Some exemptions for foams used in response to ‘catastrophic’ fires

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The government of New South Wales in Australia will ban most uses of firefighting foams containing per- and polyfluorinated substances (PFASs) in the state from 26 September 2022. Environment minister Matt Kean said they will also be banned for all training and demonstration purposes in the state from 1 April this year.

The Protection of the Environment Operations (General) Amendment (PFAS firefighting foam) Regulation 2021 will:

- restrict the use of long-chain PFAS firefighting foam; and
- restrict the use and sale of PFAS firefighting foam in portable fire extinguishers.

The EPA is introducing the restrictions in stages over the next 19 months to allow enough time to change systems and practices.

“These changes will make the phase-out mandatory across NSW. We have already seen some businesses and government agencies voluntarily phase out PFAS foam in their products and practices,” said Mr Kean.

However, the Regulation contains an exemption that allows the use of long-

chain PFAS firefighting foam in response to a ‘catastrophic’ fire, defined as one “involving a combustible accelerant, including petrol, kerosene, oil, tar, paint or polar solvents including ethanol”. The NSW EPA is also developing an exemption application process that will enable industry to use the foams in certain other circumstances, for example at high-risk sites.

Nick Zovko, regulatory policy manager at Chemistry Australia, told Chemical Watch that the Regulation is the first step towards achieving the agreed objectives in the National PFAS position statement, which the NSW government has endorsed (see box).

The Department of Defence began phasing out its use of firefighting foam containing specific types of PFASs – perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) – in 2004. Australia had been using the fluorinated firefighting foams since the 1970s.

The state of South Australia was the first to ban the use of PFAS firefighting foams in January 2018, followed by Queensland in July 2019.

Last April, the Australian government also faced the country’s biggest-ever PFAS class action lawsuit, with up to 40,000 people claiming they had been affected by PFAS pollution at and around defence sites, with property values subsequently plummeting.

In February 2020, the government reached an in-principle agreement to settle three separate class actions in Williamtown, NSW; Oakey, Queensland; and Katherine, Northern Territory.

PFAS management plan

In May last year, Australia published a national PFAS position statement as an addition to the Intergovernmental Agreement on a National Framework for Responding to PFAS Contamination, which came into effect in February 2018. The position statement lists a set of nationally-agreed objectives for reducing future PFAS use in the country.

The Australian government said this was the “best way to communicate a nationally-agreed stance on PFAS chemicals of concern, ahead of more targeted and detailed consultation with users of PFASs and other stakeholders”.

Nike to replace ten priority chemistries with 'cleaner' alternatives by 2025

PFASs, bisphenols, VOCs among substance groups retail giant reveals to Chemical Watch

08 April 2021



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Global sporting goods giant Nike has committed to replace ten priority substances or groups of chemicals with 'cleaner' alternatives by 2025.

Because of Nike's market presence as one of the world's largest companies, the move – communicated in its 2020 Impact Report – could see others in the sporting apparel sector, as well as regulatory authorities, further scrutinise and consider taking action on the substances.

Nike's senior chemist and director of Nike's Chemistry Center of Excellence, Professor Renee Hackenmiller-Paradis, told Chemical Watch the ten chemistries are:

- PFASs;
- dimethyl formamide (DMFA);
- dicumyl peroxide (DCP);
- zinc pyrithione (antimicrobial);
- bisphenols;
- formamide;
- formaldehyde;
- NPEOs;
- neoprene; and
- volatile organic compounds (VOCs).

The move will impact the whole industry, said Professor Hackenmiller-Paradis.

"The decisions regarding selection of each priority chemistry was different for all ten – some such as PFCs/PFASs are following through on previous commitments, others are to get ahead of potential future regulatory challenges, such as for zinc pyrithione, while others are setting the stage for additional progress beyond 2025," she said.

To determine which substances to target, Nike used the following set of criteria:

- potential health and environmental impacts based on science-backed information;
- legislative and market access risk, including current regulatory trends;
- volume and variety of use – how and where is the chemical used?
- availability of alternatives – are drop-in replacements currently available or are there process changes that can eliminate the use of the priority chemical?

- realities – can Nike make substantial progress in five years in reducing or eliminating use of the chemical given its current use?

Sources the company used to inform its list of priority chemistries include California's Prop 65, REACH SVHC list and NGO ChemSec's SIN List, along with 25 additional regulatory and organisational substance lists.

A team of chemistry experts across the company then scored and ranked chemicals used to make the materials in its products, to form an initial list of potential priority chemicals.

The ten chemicals or chemical groups selected were determined to be the most urgent and feasible to tackle for Nike's broader 2025 targets, said Professor Hackenmiller-Paradis.

In response to how Nike defines a 'cleaner' chemistry, she said these are alternatives that have less impact on people and the planet.

She added that the company is working to reduce the overall impact of its chemical footprint with a focus on reducing the use of high dermal sensitizers and category one substances classified under the UN's Globally Harmonized System (GHS) of classification and labelling of chemicals. These include carcinogenic, mutagenic, reprotoxic (CMR) substances and those hazardous to the aquatic environment.

It will also reduce the use of substances classified as Benchmark One by the hazard assessment tool Greenscreen, which include CMRs, endocrine disruptors and persistent, bioaccumulative and toxic (PBT) substances.

On why it has set this target now, she said: "Nike is a leader in sustainability and we know we need to do more than just maintain compliance". She added that the target offers an opportunity

to accelerate the adoption of clean, sustainable chemistry that moves the company closer to the "vision of circular design and manufacturing".

'Hindering progress'

Nike's impact report also sets out some of the challenges it faces in ensuring its suppliers comply with its chemical requirements. The report says it "continues to seek a resolution" related to the failure of all companies in the sector to adopt industry-aligned measures on restricted substances. The company stressed this challenge in its 2019 impact report and said it is hindering progress towards meeting its chemical compliance goals.

Professor Hackenmiller-Paradis said the company continues to work with industry groups focused on phasing out hazardous chemistries.

Despite Nike's large market presence, the company shares its supply base with many others in the industry. Because of this, "we cannot affect change alone," Professor Hackenmiller-Paradis said.

In trying to achieve collective results, Nike is focusing on encouraging its suppliers to adopt industry tools, guidelines and approaches to help them move "to a place where we no longer have ... a shared production facility using chemicals for other brands that we restrict".

"We believe the right thing to do is continue our path forward, leading by example and championing collective industry tools and programmes such as those established by the industry programme the Zero Discharge of Hazardous Chemicals (ZDHC)," she said.

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