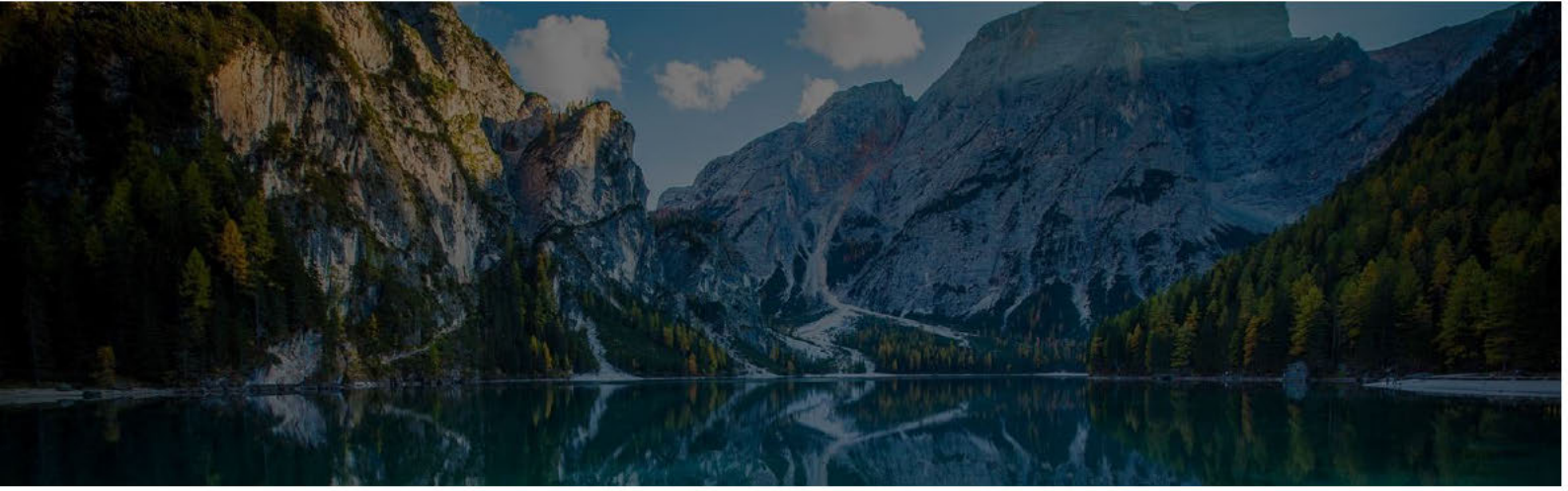
PFAS: The challenge for highly regulated and essential sectors

6 December 2022
Event summary

Organised by

FIPRA | chemsec INTERNATIONAL CHEMICAL SECRETARIAT | efpia European Federation of Pharmaceutical Industries and Associations | ESIA | COCIR Advancing Healthcare



Introduction

Over the last few years, PFAS (per- and polyfluoroalkyl substances) have become a global concern and a priority under the European Union's Green Deal goal to achieve a Toxic-Free environment. Restricting PFAS effectively is far from easy. Challenges in the implementation of PFAS regulations find opposition from PFAS producers and users, political objections, economic challenges, and a lack of consensus as to its grouping and scientific-based hazard qualification. This hybrid event, organised on December 6, 2022, in Brussels, hosted key stakeholders from the industry and NGOs to discuss the associated human health and environmental risks whilst ensuring the continued availability of services and products essential to the wellbeing or welfare of society.

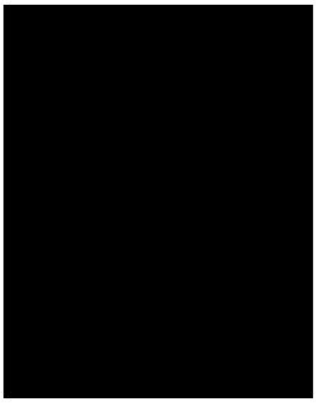
We organised this event in order to have a discussion on highly regulated essential sectors, and what we call the "PFAS challenge". There is no doubt that with everything that has been written, said or published on PFAS in many countries around the EU, there are different ways of dealing with those chemicals.

Now, four Member States with Norway are working on a REACH restriction proposal for a category of chemicals called PFASs. When we look at the EU PFAS restriction proposal, soon to be published in January, it will create a precedent for the first time for placing such a large class of chemicals through a restriction process.

There is no doubt that other topics will have a big impact - we have been hearing or participating to many events about the Chemicals Strategy for Sustainability (CSS), discussed essential uses, generic risk assessment, grouping of chemicals, as well as discussions between Members States and the Commission on various platforms such as CARACAL and the Rome Council. Those initiatives are linked in many different ways, although we will have to wait to understand the full implications until the REACH revision proposal is published, and eventually adopted.

Meanwhile, the PFAS proposal, following the current REACH restriction process, and given the extraordinary number of substances and uses, is not a minor exercise.

Panel discussion



ChemSec is a Swedish NGO founded by national governments and private charity funds. For the last 20 years, their goal has been to drive political discussion on the most harmful chemicals, supporting companies in their work towards substituting these chemicals in all but essential uses. Tools already developed include the "SIN List", and ChemSec Marketplace as initiatives to help companies find ways to substitute harmful chemicals, and work with policymakers, as well as investors in the context of the ChemScore, the chemicals ranking of companies that aims to strengthen transparency and face up substitution plans on PFAS.

Many scientific reports show the urgent need for change. PFAS are present in our drinking water and our blood. Other recent reports state that we are overstepping planetary boundaries when it comes to chemicals, meaning that "business as usual" is not an option anymore.

Essential uses are an opportunity to focus the PFAS ban on wide dispersive consumer uses which will lead to a better protection of human health and the environment. We can focus on important cases and phase out for the rest of the uses. It's not about the importance of specific products – it is rather about when we can accept very hazardous substances. Essential Use concept needs to be clearly defined for the industry in order to differentiate the "nice-to-have" from the "critical need".

In this context, the PFAS movement, started by ChemSec with other NGOs, consists of more than 100 companies in favour of a broad and strict PFAS restriction, all committed to phase out PFAS.

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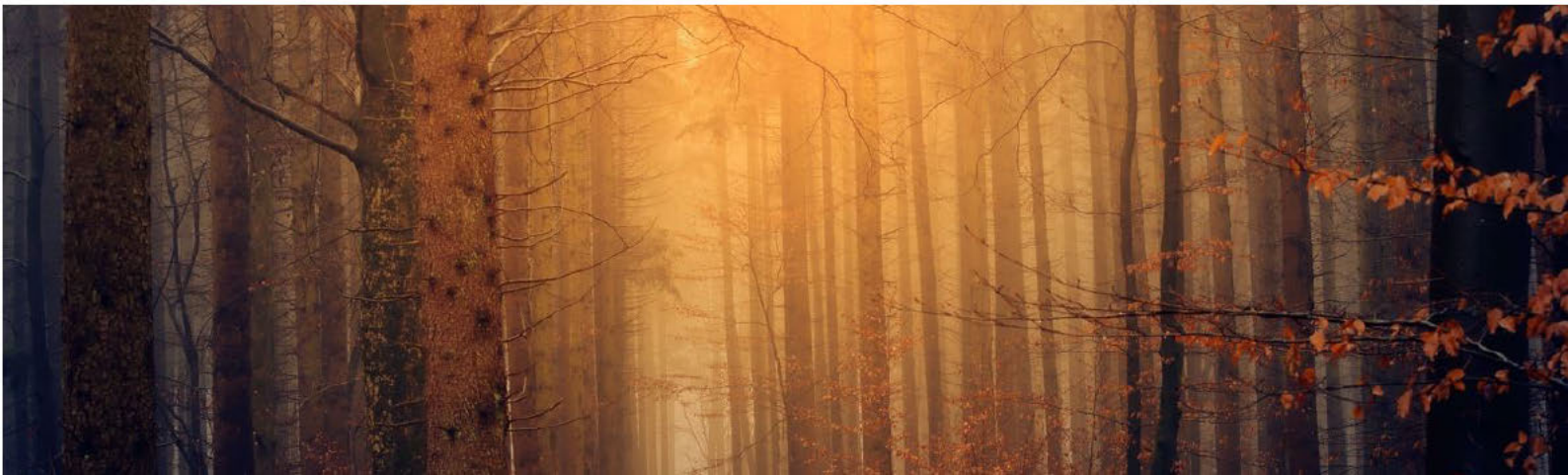


efpia
European Federation of Pharmaceutical Industries and Associations

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe.

In the pharmaceuticals industry, PFAS can be found in the manufacturing process - of industrial use - where all materials are subject to strict control over the full life cycle, in APIs (active pharmaceutical ingredients part of the final product), medical devices (regulated by sectoral regulation) and primary packaging (tackled by the marketing authorization of specific countries). F-Gases also constitute a part of the PFAS restriction, currently used in refrigerants, propellants, and inhalative substances.

PFAS have many definitions, the most important one being the OECD one, used by ECHA for the restriction proposal used in fire-fighting foams. The 2018 definition was broadened in 2021 to include shorter-chain molecules, meaning that the scope has been largely expanded, from hundreds of molecules to thousands of molecules. However, **what OECD did not do is describe a group of chemicals with similar or identical properties that is fit for a regulatory restriction.** It means that **the decision to broaden the definition was not connected to decisions on how PFASs should be grouped for regulatory actions.**

A PFAS restriction is expected to contain the properties of the PFAS which are to be restricted (setting intrinsic harmful properties such as persistent, toxic, endocrine disrupting). **Such a restriction should additionally include proportional measures to address the problem of emissions into the environment**. If emissions can be controlled over the full life cycle of the product, the industry considers it should be exempted from the restriction.

Sectoral legislation should be factored in, especially the medical sector, when they cover mandatory environmental risk assessments. Production and manufacturing materials such as fluoropolymers in industrial uses should also be exempted as they do not become product components. Regarding substitution, a better approach would be based on promoting basic innovation as it allows to phase out harmful chemicals while improving the products.

A simple, applicable, and efficient restriction should include proportional measures to address the problem of emissions of harmful substances in the environment. Derogations should be available for demonstrated low or controlled emissions of PFAS over the full life cycle, as well as essential uses derogations on a case-by-case basis – as a last resort.

A simple, applicable, and efficient restriction should include proportional measures to address the problem of emissions of harmful substances in the environment, which implies finding criteria to identify harmful PFAS and restrict the ones that matter.

The industry recommends avoiding undefined terminology and complexity that leads to uncertainty in implementing derogations. Overlapping of legislations between REACH and other regulations like the pharmaceutical regulation should be likewise avoided. Finally, a point should be made to avoid impacting the EU manufacture of pharmaceutical products and negative impacts on research by restricting the use of the chemicals for innovation.

ESIA

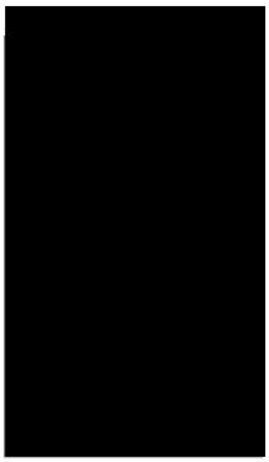
ESIA, the European Semiconductor Association, represents a very research-intensive industry with a sophisticated global supply chain, characterised by a fierce competition and price fluctuations as well as short innovation cycles. Semiconductors are found everywhere, enabling the functioning of a broad range of essential products for society. **EU accounts for 10% of the global production and the industry employs more than 200.000 people in the EU.**

PFAS have many uses in the semiconductor industry, the most important part being the process chemistry for photolithography (e. g. chamber cleaning). They are also used in the manufacturing equipment and chemical distribution systems (especially in fluoropolymer articles for filtering, tubing and linings). PFAS are also found in the facility infrastructures, in water purification, chemical delivery systems and waste management systems and finally, in the products (e. g. wires, cables, circuit boards, batteries).

The PFAS restriction is a big challenge for the industry as they are widely used and essential for the processes outlined above. Unfortunately, **the current state-of-play does not allow to cover the manufacturing without PFAS**. The industry, though, remains aware of the environmental impacts of PFAS and started to transit from PFOA and PFOS substances to short-chain PFAS, and will remove PFHxA according to the regulatory timeline. There is great concern regarding the broad scope of the current draft restriction, which needs to take into account the global supply chain of the industry.

The challenge faced by the industry is increased due to the expected rapid growth in EU production in the context of the EU Chips Act, with a market share twice as big in 2030 compared to now (from 10% today to 20% in 2030). It is envisaged that doubling the market share will require a fourfold increase of production given that other regions of the world aren't sleeping (e. g. US Chips Act). This market growth also expects that EU's research and technology leadership on small and fast chips will be strengthened and requires more than €43 billions of policy-driven investment until 2030. **The industry is pulled in two directions with tight environmental restrictions linked to PFAS and F-gases on one hand, and the need for a fast market growth in the EU on the other.**

> *The industry is pulled in two different directions with tight environmental restrictions [...] on one hand, and the need for a fast market growth in the EU on the other.*



COCIR is the trade association representing a specific segment of the medical devices sector (mainly medical imaging and radiotherapy devices).
The Medical Technology sector plays an essential role for the running of hospitals to the benefit of society, improving healthcare through early detection, screening, prevention, and treatment. The **Medical technology industry in the EU is among the most innovative in the world**. In the EU, healthcare drives patenting activity, giving the EU a decisive competitive position globally.

The PFAS restriction is very complex for the sector. Medical imaging and radiotherapy devices can weigh up to 10 tons, made of an extraordinary high number of assemblies and sub-assemblies. Substitution represents a challenge not only for the high number of parts and components but also because we are dealing with multi-level supply chains (11,000 suppliers around the world, and a language barrier that complexifies the process of phasing out a substance). Medical imaging and radiotherapy are high-value devices with low unit sales numbers that also have to comply with sectoral legislation like the Medical Device Regulation (MDR), one of the most complex legislations in Europe.

To sum up, innovation and substitution are long and complex processes due to the long design cycles of our devices. The cost of substitution is very high, and accounts for hundreds of millions per companies to re-design devices to substitute sometimes only a few grams of lead per year (new lead-free chips as an example). **The main impact is however related to R&D resources, exacerbated by the PFAS restriction.**

Substituting identified uses of PFAS requires a case-by-case analysis of potential alternatives, a process that can take years for the efficiency of alternatives to be verified. Alternative materials lead to potential changes to manufacturing and design, and requires rigorous testing, with uncertainty as to the result. Without a practical solution we see a serious risk that medical devices will be from the market (as redesign is not possible, and as suppliers far-away in the supply chain would pose uncontrollable risks of non-compliance).

The proposed solution is called **the "legacy device approach"**, consisting in the application of restrictions to new models while excluding "legacy" ones. This simple and practical solution, already adopted under the RoHS Directive avoids diverting resources from R&D of innovative medical technologies. The legacy approach does not consist in asking for a blanket exemption as we see the importance of phasing out PFAS but shifting the focus on design rather than on the redesign of old models. If legacy devices are excluded, we can use our R&D resources to focus on developing sustainable new products without any of these harmful chemicals present. Transition times will be needed to collect evidence on alternatives and their substitution potential, with a long validity of derogations to continue the search for alternatives and validate them. Derogations for new products would be asked only after the transition period in case technical feasibility of known substitutes is not possible and in order to properly explore and test other alternatives.

> *The legacy approach does not consist in asking for a blanket exemption as we see the importance of phasing out PFAS. [...] if we focus on new products only - if legacy devices are excluded, we can use our R&D resources to focus on developing sustainable new products without any of these chemicals present.*

Panel debate and Q&A session

How do you see a broad PFAS restriction proposal to work in practice and to go through a restriction process as it currently exists?

- The political momentum around PFAS allows visibility around the issue, making it clear we need to find ways to find a restriction, so I think that helps. It will be complex, it will be complicated, but it needs to be done.
  [redacted] *ChemSec*

- A targeted approach could be used against a small group of substances or for specific sectors for which a restriction might have a tough impact. And on the other hand, we take a general approach. Restricting critical areas is maybe not the best way to go. In the end, it will be a political decision."
  [redacted] *ESIA*

- Such a restriction could work if it is very simple. If it is complicated from the start, complex derogation processes and unclear environmental impacts, and all of that for legacy devices and other industrial sectors, it will likely fail.
  If we have a non-perfect restriction that works, it is a much better situation than having a restriction that doesn't work. Having a simple framework that is made to work is the way to go.
  [redacted] *Merck KGaA*

- I don't think anyone would disagree that we need to phase out PFAS from our society. What we need is to ensure there is balance and that we don't do it at the cost of healthcare. We need to find ways of doing it, in a targeted approach and in the simplest way we can, using simple tools.
  There is currently no easy way for essential uses to apply for continued use of substances subject to restrictions or authorisations. There must be a better way, either by ensuring that we catch all essential uses or that we have vehicles to ensure we don't take essential uses off the market.
  [redacted] *COCIR*

How would a process with a smaller scope of uses as well as a more limited number of PFAS look like?

A solution would to be to look at specific PFAS according to their properties. Different approaches include tackling PFOA and PFOS, short and medium chain substances that can be considered as the most harmful properties. Still, all those groups cannot be regulated in one restriction.
[redacted] *COCIR*

It makes sense to focus on the most harmful chemicals, because this is where the benefits would be the biggest, but what should be considered is the actual emissions.
[redacted] *ESIA*

Taking into account the precautionary principle, we think that the most persistent chemicals should be included in the restriction. If we have information that some of them do not have harmful properties, we can then have a discussion. But let's not repeat the same mistakes from the past. We need to take action now, and PFAS is a very good example.
We could have derogations for specific product groups where there are essential uses. But we would like to see an incentive to phase out PFAS for all product groups and look for alternatives, to continue innovating and not having a blanket approach.
If X-rays need 10-20 years to find alternatives, that's fine, but the movement towards phasing out PFAS is one of the key issues for this restriction.
[redacted] *ChemSec*

We agree on the need to phase out the group in a precautionary approach.
However, we think the restriction should focus on the industry uses rather than the substances themselves. In this sense the legacy approach allows continued uses of PFAS with a strict control, while allocating resources in finding alternatives following natural innovation cycles.

COCIR

"ECHA should exempt pharmaceuticals as there are sectoral legislation and initiatives that mitigate the environmental impact of APIs, and this is not only related to PFAS. If we don't keep those two separated, there will be a lot of unnecessary complexity.

Merck KGaA

"PFAS are used in cosmetics, in a number of devices, and the PFAS restriction is a way to cover the whole. There are many uses of PFAS, and our first targeted group would be consumer products. There are essential uses where we need PFAS, but we would like to see innovation and substitution, because we need to phase them out.

ChemSec

Engaging with the Audience:

-A representative of the fluoropolymers industry informed that there are currently no alternative available for these chemicals. This emphasizes the importance in restrictions to look at different groups and properties, as persistency is not necessarily a risk.

-A representative from animal health sector explained they follow the One Health approach, taking into account human health and animal health within environment as everything is part of the same ecosystem (e. g. zoonoses).
As animal pharmaceuticals are essential to society, it would be recommended to take a step-by-step as well as place-by-place approach on PFAS in our products globally.

A Commission representative asked how to devise "a restriction that, is effective and that is broad yet not too broad", EFPIA speaker suggested a simpler PFAS restriction framework, with reporting requirements as a middle point, explaining that a non-perfect restriction that works is much better than having a restriction that doesn't work.