

Q: Do you have remarks on the scope (definition of the PFAS?)

The Dossier Submitters decided to cover more than 10 000 PFAS substances by grouping PFAS substances on grounds of their structural similarities (primarily related to the alleged "very persistent" property of the substances)¹. The used definition is aligned with the OECD definition, despite it *"does not conclude that all PFASs have the same properties, uses, exposure and risks"* and *"is not connected to decisions on how PFASs should be grouped in regulatory and voluntary actions"*². In this respect, we do not support this approach, since persistence alone should not be considered sufficient to justify a restriction in absence of additional classified hazards/properties (e.g., bioaccumulation, toxicity) and if an unacceptable risk is not demonstrated.

However, with this approach, the Dossier Submitters indirectly assume that all PFAS share the same physchem properties, hazards and risk profile. Many PFAS substances, however, have different properties and should be differentiated one from another.

Similar conclusions have been derived from a panel discussion on PFAS grouping summarized in a paper by Anderson *et al*³, which highlights the following:

- *Most experts agreed that "all PFAS" should not be grouped together for risk assessment purposes.*
- *Most experts agreed that "persistence" is not sufficient for grouping PFAS for the purposes of assessing human health risk.*
- *Most panelists agreed that it is inappropriate to assume equal toxicity/potency for PFAS without confirmatory information.*

Therefore, it appears that combining 10 000 substances altogether is scientifically incorrect. As a result, the scope of the restriction Proposal is not defined in sufficient detail and is not in line with the requirements of Annex XV.

Furthermore, this approach runs counter one of the guiding principles for the preparation of Annex XV, i.e. enforceability⁴. Given the broadness of the definition, it would be difficult for relevant actors to comply with the restriction,

¹ Annex XV PFAS REACH restriction Proposal, p. 21

² OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.

³ Anderson et al. Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts, 2022. <https://doi.org/10.1016/j.yrtph.2022.105226>

⁴ ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 66

and consequently, for the enforcement authorities to supervise and enforce the proposed restriction.

Additionally, given the large grouping of substances, the scope of the Proposal is unclear, as defined in by the Restriction Task Force of ECHA . In this regard, it might lead to difficulties for the Committees when analysing the stakeholder comments and preparing their opinions which may relate to specific PFAS substances rather than the whole group.

Q: Please indicate your sector and describe briefly the Restriction impact/influence on your sector.

Sector: Chemical Industry - Manufacturing of Fluoropolymers and F-Gases

Impact. All PFAS as per definition, unless explicitly derogated, will be banned as from July 2027, if above a certain concentration. Thus, most substances will be completely banned after a transition period (if at all). Fluorinated polymerization aids used in the manufacturing of PTFE, PVDF and FKM will be directly banned (despite the non-availability of alternatives). Fluoropolymers are in scope of the restriction proposal. Only on-site isolated Intermediates (monomers) are exempted. According to the current proposal, specific F-gas uses would be subject to either a 18 months transition period, or 18 months + 5 years derogation or 18 months + 12 years derogation, depending on the use considered, resulting in entire industries faced with the challenge to continue to supply their products to critical sectors such as food preservation, building insulation, data centers, fire suppressants, medical applications or air conditioning in the automotive sector (including electric vehicle heat pumps) without potential available alternatives.

Expected impact downstream: For Fluoropolymers in semiconductors (case study automotive), The European semiconductor manufacturing industry is severely impacted without access to PFA and other fluoropolymers. The removal of PFA from the semiconductor supply chain will directly cost the European economy over €66 billion. Over 21,000 individuals will lose their jobs throughout the supply chain under a non-use scenario

Case study for PFA in automotive (A complete ban of PFA in Europe)

- Economic contributions of €206 billion in profits
- 100% reliant on semiconductor chip imports
- Negative balance of payments

Case study for PFA in automotive (A complete ban of ALL fluoropolymers in Europe)

- Could result in cessation of both industries
- Resulting profit losses of €206 billion
- 1,890 enterprises would likely cease trading and close

→ Total economic loss of more than 439 Bn Euro over the assessment period over the assessment period

F-gases are used in a wide array of applications. Many of these sectors have long and complex value chain endorsement periods implemented to ensure the safety of operators and consumers alike and may have technical feasibility issues to implement alternatives. Below are the impact of the ban of F-gases on two critical sectors for the European economy responsible not only for employment but also contributing to meeting the European decarbonization goals.

For F-Gases, for example used in mobile air conditioning (MAC) in internal combustion engines (ICE) and heat pumps (HP) in battery electric vehicles (BEV): HFOs are used in tight systems as a refrigerant in mobile air conditioning and/or heat pumps in automotive (in both light and heavy-duty vehicles). The European automotive manufacturing industry is severely impacted without access to F-gases. The ban of F-gases used the automotive industry will directly cost the European economy billions of Euros and hundreds of thousands of jobs throughout the supply chain under a non-use scenario.

For F-Gases, for example used in in-situ spray foam applications (e.g. building insulation): HFOs are used as blowing agents in polyurethane in-situ spray foams used primarily for insulation applications. To achieve goals in the European Green Deal and Renovation Wave strategy, in-situ spray foams are essential for the renovation of Europe's building stock thanks to their low thermal conductivity meaning it can resist heat transfer resulting in a lower u-value and a better-insulated product. The ban of F-gases used in the in-situ spray foam industry will directly cost the European economy billions of Euros and thousands of individuals will lose their jobs throughout the supply chain under a non-use scenario.

Q: Do you have specific remarks on the restriction text and its exemptions.

The Dossier Submitters distinguish between "sufficiently strong evidence", "weak evidence" and "inconclusive evidence" for each of the proposed derogations. The methodology followed is questionable in as much as those

levels of evidence are arbitrary and were not used equally to support the restriction, in certain cases relying on weak evidence to support a transition without derogation and in other cases not including information provided as part of the First and Second call for evidences.

Moreover, the Dossier Submitters failed to take into account the concept of "essential use", as this was announced in the 2020 Chemical Strategy for Sustainability ("CSS"), and the PFAS restriction was envisaged there as a kind of case study for the concept. Similarly, the Dossier Submitters have not proposed a derogation for transported isolated intermediates. Although not explicitly provided in REACH, practice leans towards allowing for this derogation. In fact, there are examples for which RAC proposed to exempt from a restriction transported isolated intermediates used under strictly controlled conditions (e.g. PFOA and PFHxA).

Additionally, we would like to comment on specific Dossier Submitters' claims, listed in the table below:

Dossier Submitters' claim	Our view of the claim
PFASs should be managed together as a group	Physchem properties, hazard classification and risk profile of individual PFASs are different, as well as exposure/emission patterns. A grouping approach is therefore questionable
Very persistent chemicals should be regulated on the basis of their persistence alone	Persistence alone should not be considered sufficient to justify a restriction in absence of additional classified hazards/properties (e.g., bioaccumulation, toxicity) and if an unacceptable risk is not demonstrated
It is not possible to demonstrate safe use of PFASs	Safe concentration levels have been derived for Chemours Substances requiring a risk assessment
Emissions are a proxy for risk	The F-gas regulation (EU 517-2014) foresees specific measures for emission control and reduction, hence the risk is adequately controlled.
F-gases are in scope of the Dossier Submitters proposal	F-gases risk to be double regulated in Europe (F-gas regulation) but also globally (Kigali amendment to the Montreal Protocol)
Derogations are based on the availability of alternatives	Tradeoffs of alternatives are not clearly discussed (flammability, toxicity, energy efficiency,..)

5-year and 12-year Restriction options are proposed	Restriction option timeframes are defined without taking into consideration the specificities of each application
Unclear whether destruction and recovery of F-gases fully prevent emissions of fluorinated substances in these waste treatment processes	Recovery, recycling and Reuse (RRR) of F-gases are provisions already set in the F-gas regulation, guaranteeing the circularity of F- gases.

Moreover, the restriction proposal does not assess the potential impact of a restriction on the achievement of the EU Green Deal objectives in the framework of the Socio economic and cost benefit analyses. F-gases are essential to achieve key initiatives under the European Green deal, such as: EU building decarbonization, sustainable mobility, Fit for 55, REPower EU and farm to fork.

Are you concerned by an exemption?

We are concerned by most of the fluoropolymer and F-gas restriction options. both enable a broad array of diverse applications and derogations will create catastrophic disruptions throughout the different value chains ultimately impacting the European consumer. This complexity implies that application needs to be reviewed on a case-by-case basis.

As an example, for fluoropolymers, the Dossier Submitters have proposed a derogation for fluoropolymers used in the proton exchange membrane ("PEM") into fuel cells applications for 6.5 years after the entry into force. However, they have not considered the derogation for PEM in electrolyser for hydrogen production. Without the latter, the derogation may be deprived of its effet-utile, namely devoid of its practical application.

As an example for F-Gases, in the automotive industry, for already developed vehicles, a transitional period of 15 years is needed until the end of the production of these vehicles. A re-development of these vehicles is not possible from a technical and economic point of view. If alternatives have been identified as potentially suitable, for new vehicles whose development begins today would be on the market in 6 - 7 years (for trucks 10 -12 years) at the earliest. Under this condition the suppliers would need to be prepared to produce potentially unique

components on an industrial scale, where the development timeline is not included above.

If yes, is the timing foreseen reasonable for your sector?

Assuming entry into force of Annex XVII in January 2026 +/- , all **PFAS as per definition, unless explicitly derogated, will be banned as from July 2027**, if above a certain concentration. Most substances will be completely banned after a transition period (if at all).

Given the short timeframe, should the proposal materialize in its current form, the lack of alternatives in many applications and unrealistic timeline will cause significant effects on the market. (see AoA and other sections for more details)

Defining 12 years as the time necessary for a new technology to be invented, developed to a commercial product, tested and implemented on a wide industrial scale does not take into account the complexity of the F-gas sector and its value chain. The derogation period should be specific to allow the development of alternatives for each application, taking into account the complex and lengthy approval processes needed to ensure safe use and avoid disruption throughout the complex value chain.

Have you conducted an alternative assessment that indicates that the proposed timing is reasonable or not?

Fluoropolymers are specialized high end performance plastics that bring unique combination of properties thanks to their C-F bond. They are expensive to manufacture and process them further. Should viable alternatives exist the market would have transitioned due to economic incentives already. This makes fluoropolymers substances of necessity rather than choice.

For Fluorinated polymerization aids for the manufacturing of PTFE, PFA among others the development of alternative technologies, as effort to improve the overall processes is a continuous effort. No alternatives were identified so far as the usage of non-fluorinated polymerization aids would lead to the formation of PFAS impurities and/or articles not meeting required standards.

For PFA in semiconductors. No alternatives meet the necessary technical feasibility and performance criteria. There are no alternatives identified, and

such alternatives may never be identified. Potentially R&D on alternatives Substitution may require +10 years and 40 years for the process to the current level of manufacturing capacity. The required purity can only be met with Teflon™ PFA. The Purity requirements will continue to decrease as die sizes decrease. Without Teflon™ PFA the ability to produce semiconductor components and infrastructure would not be possible. Significant effects throughout the supply chain and knock-on effects throughout other industries are expected.

Hydrogen economy. Currently **no viable alternatives** to fluoropolymer PEMs are available that can deliver performance requirements equivalent to Nafion™.

F-Gases, used in mobile air conditioning (MAC) in internal combustion engines(ICE) and heat pumps (HP) in battery electric vehicles (BEV):

To date, research has shown that HFO refrigerant technology, in particular HFO-1234yf, provides the safest, sustainable (from a global LCA perspective), and economical solution for both traditional mobile air-conditioning as well as heat pumps, in the case of BEV. **Several alternatives were screened and most were rejected** on the basis of either flammability such as propane), toxicity (ammonia) or relatively high GWP and potential to degrade to TFA. A potential alternative might be CO2 (R-744), however, our assessment indicates that adoption of R-744 as a refrigerant in MAC in ICE vehicles and HP in BEV will result in decreased performance and efficiency at high ambient temperatures, **making it technically or economically not feasible in hot climates**. Particularly in BEVs, the use of R-744 could result in an increase of thermal runaway events, putting users at risks and reducing the longevity of batteries.

The European Green Deal, presented in 2019, has promised to reshape the European Union into a resource sustainable economy and be carbon neutral by 2050, while reducing greenhouse gas emissions by 55% in 2030. In the automotive industry, the Fit for 55 initiative requires all cars or vans placed on the market from 2035 to be zero-emission vehicles. Similarly, the Sustainable and Smart Mobility Strategy aims to have at least 30 million zero-emission vehicles in operation on European roads by 2030. Without the use of BEVs, it will not be possible to achieve these targets. In addition, the RePowerEU plans to make Europe independent from Russian fossil fuels before 2030 following the Russian invasion of Ukraine. Without the use of HFOs to support the transition to BEVs, and without a sufficiently long implementation period that can support

the supply chain to the move to an alternative refrigerant, it is difficult to envision how these goals will be achieved.

F-Gases used in in-situ spray foam applications (e.g., building insulation)

To achieve goals in the European Green Deal and Renovation Wave strategy, in-situ spray foams are essential for the renovation of Europe's building stock. A few alternative blowing agents and insulation technologies were explored, and their performance was compared against F-gas blowing agents and insulation products. A number of these alternatives were rejected before a thorough assessment based on their flammability and toxicity ratings (propane and methyl formate), thermal resistance, and structural integrity (water and cellulose). The shortlisted alternative was rock wool and glass wool (mineral wool), which is not a blowing agent but an alternative insulation technology. The insulation performance of foams produced using HFOs is nearly double those of mineral wool, glass and rock wool. This means that a larger quantity and thickness of mineral wool needs to be used to achieve the same insulation value, which is not always feasible, particularly in renovations. Also, the mineral wool technology requires an additional vapor barrier, which is not the case with in-situ spray foam.