

General Comments to the Annex XV Restriction report and Proposal for a Restriction for Per- and Polyfluorinated Alkyl Substances (PFASs) dated 22 March 2023.

PLIXXENT BV is a downstream user of fluorinated gases (“F-Gases”), in particular hydrofluoro-olefins (HFOs) that would be subject to the proposed restrictions. We therefore wish to provide evidence on this subset of substances.

Executive summary

Based on the available evidence, we conclude that fluorinated gases must be fully exempt from the scope of the restriction proposal:

- HFOs have an atmospheric lifetime of days or months and are not classified as (very) persistent under REACH.
- HFO-1233zd do not decompose into Trifluoroacetic acid (TFA) in a significant fraction and HFO-1336mzz decompose in very low yields of TFA and therefore their contribution in the environment is extremely small. Most fluorinated gases have atmospheric decomposition products that are not classified as persistent.
- It has been demonstrated that TFA is not harmful to humans or the environment in the concentrations likely to occur in the decades ahead.
- The grouping of an extremely broad range of substances with very different (eco-) toxicity profiles is in breach with ECHA guidelines on Read Across.
- Persistence on its own is insufficient for a broad restriction as proposed by the dossier submitters.
- The risks of emissions of F-Gases are adequately controlled through existing EU legislation, in particular the F-Gas Regulation (517/2014, currently under review), the WEEE directive (2012/19) and End of Life of Vehicles directive (2000/53).

Furthermore, the available evidence justifies time-unlimited derogations for most uses of fluorinated greenhouse gases:

- Alternatives for F-Gases have not been properly assessed for their environmental impact
- The socio-economic benefits associated with the use of F-Gases outweigh the theoretical cost to society in terms of energy efficiency, public safety.

1. F-Gases are not persistent or very persistent

According to their REACH registrations, all mainstream F-Gases are not classified as persistent. None of them are classified as PBT and/or vPvB. Their toxicity and environmental impact have been thoroughly assessed, both under REACH and in international forums such as the UN Environmental Programme ([UNEP](#)) and the Intergovernmental Panel on Climate Change ([IPCC](#)).

2. Only a few F-Gases decompose in significant fractions to TFA

Referring to substances containing a -CF₃ group (which includes many F-Gases), the dossier submitters state that “most of these substances are expected to ultimately degrade in the environment to TFA”. There is, however, robust evidence that this is the case for just a few mainstream F-Gases (https://www.fluorocarbons.org/wp-content/uploads/2020/10/EFCTC_HFC-and-HFO-Substances-degradation-products-and-TFA-yields-Final-26_08_2020.xlsx). A generalization as used by the dossier submitters is therefore unjustified.

Since there is a limited number of F-Gases that decompose into TFA and the conversion ratios vary between 0% and 100% (theoretical maximum of 2% for HFO-1233zd), the exposure assessment by the dossier submitters (figure 7) is therefore misleading and irrelevant.

3. It has been demonstrated that TFA is not harmful to humans or the environment in the concentrations likely to occur in the decades ahead

According to the [REACH Registration of TFA](#), the substance fulfils the criteria for persistency, but the available data indicate that it is neither fulfilling the criteria for toxic and bioaccumulative (PBT-substances), nor the criteria for very bioaccumulative substances (vPvB-substances) according to REACH directive, Annex XIII and as laid down in the TGD R.11 of the European Chemicals Agency (ECHA).

A recent publication on the mammalian toxicity of TFA concluded that the Margin of Exposure (MoE) to most humans is 4,000 to 476,000 times, indicating that the levels of TFA in the environment are several magnitudes below what would be considered toxic. [Dekant, W. and Dekant, R. (2023). "Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposures." *Arch Toxicol* **97**(4): 1069-1077.]

In a series of reports from 2016 to 2022 the United Nations Environment Programme (UNEP) concluded that TFA has been found at levels that are **below** those that would be considered toxic to humans or aquatic environment and will continue to be below these levels for decades.

[(<https://ozone.unep.org/science/assessment/eeap>, <https://ozone.unep.org/science/assessment/sap>)]

There is also [overwhelming evidence](#) that TFA is a naturally occurring substance. [EFCTC, Naturally Occurring TFA, https://www.fluorocarbons.org/wp-content/uploads/2020/08/EFCTC-TheEvidenceThatTFAoccursNaturally_A4.pdf]

4. The grouping of an extremely broad range of substances with very different (eco-) toxicity profiles is in breach with ECHA guidelines on Read Across

The [ECHA Read-Across Assessment Framework](#) (RAAF) clearly states that “(a) applying the grouping concept (...) means that REACH information requirements for physicochemical, human health and/or environmental properties may be predicted from information from tests conducted on reference substance(s) within the group, referred to in this document as source substance(s), by interpolation to

other substances in the group, referred to as target substance(s).” A separate assessment should be conducted for each information requirement intended to be fulfilled by the read-across approach.

It is clear that defining PFAS as a group based on the presence of at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it) does not meet the RAAF criteria.

This is also confirmed by the OECD Expert Group on PFAS (including experts from the dossier submitters) which clearly states that “As PFASs are a chemical class with diverse molecular structures and physical, chemical and biological properties, it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner. The term “PFASs” is a broad, general, non-specific term, which does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety. [underlining added, 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.]

5. Persistence on its own is insufficient for a broad restriction as proposed by the dossier submitters

Many materials, natural and man-made (water, steel, concrete, minerals, polymers) are persistent. That in itself cannot be a justification for a broad restriction with time-limited derogations. The burden of proof that a restriction is justified is on the dossier submitters. They assert that “(t)his is the key hazardous property common to all PFASs in this restriction proposal. Consequently, if releases of PFASs are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects become inevitable.” We suggest that the term PFAS is replaced with “concrete, steel, water or silica” and ask the reviewers if they would agree.

6. The risks of emissions of F-Gases are adequately controlled through existing EU legislation

The control on in-use and end-of-life emissions of F-Gases is adequate under a variety of EU legislation and has not been properly assessed by the dossier submitters. For example, the EU F-Gas regulation (517/2014, currently under review) requires regular leak inspections and recovery at end-of-life. Similarly, the Waste of Electronic and Electrical Equipment directive (2012/19) and the End of Life of Vehicles directive (2000/53) address/require the minimization of emissions of hazardous substances.

Moreover, the mainstream F-Gases have been subject to the REACH registration (and evaluation) provisions which require the registrants to submit detailed and rigorous Chemical Safety Assessments, including end-of-life.

In view of their increasing scarcity and relative high market value vs. their assumed alternatives, there are additional and sufficient incentives for the recovery, reclamation and re-use of F-Gases which are a fundamental part of the EU’s Green Deal and its Circular Economy objectives. A prohibition on the placing and use of F-Gases would effectively eliminate the economic incentive for their recovery and reclamation at end of life and could well lead to higher emissions.

7. Alternatives for F-Gases have not been properly assessed for their environmental impact

The dossier submitters refer to the alternatives for F-Gases, notably Carbon Dioxide, and Hydrocarbons (propane, butane and pentanes) as “natural substances”. In fact, these are all produced at an industrial scale. As indicated above, TFA would have a greater claim to the epitaph “natural”. As noted by the dossier submitters, these alternatives are much lower in cost compared to F-gases, and it would have been appropriate to assess their end-of-life emissions since the economic incentive for recovery, reclamation and re-use is virtually absent.

- Carbon dioxide (CO₂, R-744) is currently exempt from registration under REACH. It is a very persistent substance and the single most important contributor to Climate Change. [\[IPCC\]](#) It is also the single most important contributor to acidification of oceans causing irreparable damage to coral reefs and therefore broader sea-life. [\[NOAA\]](#) In concentrations over 5000 ppm it is a life-threatening substance (asphyxiation). [\[UK HSE\]](#).
- Hydrocarbons, notably Propane, Butane and Pentanes are typically produced from crude oil in refineries. They are classified as (extremely) flammable and included in Annex I of the Seveso III Directive (2012/18) on the control of major-accident hazards involving dangerous substances. They are (Very) Volatile Organic Compounds (VOCs) which are associated with air quality (revision of the EU ambient air quality directive 2022/0347(COD)). Their Photochemical Ozone Precursor Potential (POCP) is orders of magnitude higher than F-Gases ([VOCs and POCPs - Fluorocarbons](#)).

Based on this evidence, we conclude that a ban on the use of F-Gases could lead to regrettable substitution.

8. The socio-economic benefits associated with the use of F-Gases outweigh the theoretical cost to society in terms of energy efficiency, public safety.

As noted in the proposal, the submitters of the restriction dossier recognize that F-Gases have a considerable cost disadvantage compared with the putative substitutes. There must be good reasons why downstream users opt for F-Gases and they have every incentive to minimize their use and emissions.

Contrary to the assertions by the dossier submitters, F-Gases combine unique attributes that are highly valued by downstream users:

- They are safe in terms of toxicological and physical properties.
- They contribute to highly energy efficient Heating, Air Conditioning, Cooling and thermal insulation.
- As a result, the total cost of ownership is considerably lower than the proposed substitutes, due to additional costs required to meet the legitimate safety concerns, especially in applications widely used by the general public, as well as the, sometimes substantial, incremental energy consumption.

Moreover, the dossier submitters have failed to provide an accurate estimate of the cost associated with the continued responsible use of F-Gases.

Similarly, the dossier submitters refer to a table (E.91) presented by EFCTC as evidence of the thermal conductivity of the main options for thermal insulation. The table shows that the next best non-F-Gas substitute for HFO-1233zd has a 30% penalty in energy efficiency.

Delivery of the optimal energy efficiency is critical for the energy transition in the EU (RePowerEU). Forcing downstream users to convert to more energy consuming solutions would require additional investment in power generation capacity, transport and distribution to meet demand at times of peak load in summer (Refrigeration and Air Conditioning) and winter (Heat Pumps). Much of that additional capacity will be sitting idle when demand is below peak load and will place an additional cost burden on society. The associated additional investment will come on top of the already very challenging target of a full conversion to Electric Vehicles by 2035. The dossier submitters have made no effort whatsoever to assess these implications.

UK Approach

In its [analysis](#) of the most appropriate regulatory management options for PFASs, the UK Health and Safety Executive (UK HSE) narrows the definition of PFAS to “fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (–CF₂–)”. It concludes that it would be appropriate to prepare Annex XV dossiers for the restriction of certain PFASs in certain applications.

US Approach

In the US, the Environmental Protection Agency (EPA) uses a narrower working definition of PFAS as “Chemicals with at least **two** adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated” in their [National PFAS testing strategy](#) as well as their [PFAS strategic roadmap](#). Commercially available F-Gases do not qualify as PFAS within the scope of this structural definition. EPA’s use of this working definition provides focus on PFAS of concern based on their persistence and potential for presence in the environment and for human exposure. Regarding degradation products, the EPA Office of Chemical Safety and Pollution Prevention have opined that “trifluoroacetic acid is a well-studied non-PFAS.” The EPA’s [PFAS roadmap](#) aims to research, remediate, and restrict PFAS using science and filling gaps in science where present. In its recently published [Chemical Data Reporting \(CDR\) National Review](#) EPA compared the PFAS data reported for years 2010 and 2019 and in doing so, used the definition of PFAS from the Office of Pollution Prevention and Toxics which excludes commercially available F-Gases.

We wish to point out that the map of the USA (figure 6 in the Annex XV proposal) does not include a single entry point for F-Gases or TFA.

Conclusion

Based on the available evidence we conclude that F-Gases must be exempted from the definition of PFAS in the restriction proposal.

We note that both the UK authorities and the US EPA take a more pragmatic approach and focus on subsets of PFAS that are of high concern, exempting or excluding F-Gases from any proposal for restrictions. We suggest that the dossier submitters review their approach in this context.

In addition, there is sufficient technical and socio-economic evidence to justify time-unlimited derogations for the production, placing on the market and use of F-Gases and products containing or relying on F-Gases.