

Our position

Grouping of PFAS

Regulation by distinct PFAS classes is scientifically superior to classification by a broad PFAS group

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

Executive summary

Several Member States are gathering information that will be used to prepare an analysis of restriction options for Per- and polyfluoroalkyl substances (PFAS), and subsequently, a REACH restriction proposal. The American Chamber of Commerce to the EU (AmCham EU) welcomes the openness for stakeholders to provide information to facilitate this process and takes this opportunity to emphasize that while a group-approach can save time and minimize the need for extensive vertebrate testing, it can, if applied too broadly, result in unnecessary restrictions: **PFAS is a large and chemically diverse group of approximately 4,700 substances. These substances are not the same and should not be regulated as one group unless there is adequate and sufficient scientific evidence that this approach can be justified based on the principles of read across highlighted in REACH guidance (R.6.2).** Please also see AmCham EU's Consultation Response to Green Deal call area 8.¹

Background

The European Commission will publish a Chemicals Strategy for Sustainability in September 2020 to help better protect citizens and the environment against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives aiming to address all regulatory gaps and to “contribute to the rapid substitution of substances of very high concern [...] including [...] very persistent chemicals”².

The European Parliament's ENVI Committee in its draft motion for a resolution on the Chemicals Strategy for Sustainability³ echoes above mentioned demand and further

“stresses the need for a more integrated approach towards assessing chemicals with similar hazard, risk or function as a group; calls therefore on the Commission to rely on a grouping approach more widely both in evaluation and in subsequent regulatory actions, to avoid regrettable substitution; stresses that the ‘one substance – one hazard assessment’ approach should not contradict nor prevent the development of a grouping approach to assess families as a whole.”⁴

In addition, the resolution calls for a

“clear action plan and legislative proposals on how to address all persistent, bioaccumulative and toxic, as well as very persistent and very bioaccumulative, and persistent and mobile chemicals, across all relevant legislation and environmental media, including the action plan to phase-out all non-essential use of perfluoroalkylated substances (PFAS) as part of the chemicals strategy for sustainability”⁵

Justification for Grouping and Read-Across

The “Call for evidence supporting an analysis of restriction options for PFAS” presents the intention by Germany, the Netherlands, Norway, Sweden and Denmark to group all per- and polyfluoroalkyl substances into one REACH Annex XV Restriction Dossier. This would result in a dossier covering a class of several thousand compounds

¹ ‘AmCham EU response to Green Deal call area 8: a zero pollution ambition for a toxic-free environment: Grouping of PFAS - Regulation by distinct PFAS classes is scientifically superior to classification by a broad PFAS group’, *American Chamber of Commerce to the EU*, July 2020, available at: http://www.amchameu.eu/system/files/position_papers/green_deal_call_area_8_-_consultation.pdf

² ‘European Parliament resolution of 15 January 2020 on the European Green Deal’ (2019/2956(RSP)), *European Parliament*, 11 January 2020, available at: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0005_EN.html

³ ‘Draft Motion for a Resolution on Chemicals Strategy for Sustainability’, 2020/2531(RSP), *European Parliament*, 21 February 2020, available at: <https://www.europarl.europa.eu/cmsdata/207511/1197279EN.pdf>

⁴ Ibid, paragraph 14.

⁵ Ibid, paragraph 21.

with the potential for persistence of some⁶ of the class being the only aspect of similarity across 4700 substances, not nearly enough to substantiate read-across or demonstrate universal risk to human health and the environment.

Clear, established scientific standards should be applied to read-across and grouping for restriction/authorization, as for registration purposes. ECHA has internal guidance for evaluating the scientific suitability and acceptability of a Registrant's read-across justification (RAFF). The same elements and standards of scientific robustness upheld by the RAFF should also be upheld in a restriction, including that the identity of all substances in the group be specified and well defined; and that comprehensive documentation be provided for the elements forming the basis of the read-across.⁷

With **read-across**, the REACH Regulation (Annex XI, 1.5) already includes a "technique for predicting endpoint information for one substance (target substance), by using data from the same endpoint from another substance (source substance)"⁸, but it requires that a number of conditions be fulfilled:

- 'results must be adequate for the purpose of classification and labelling and/or risk assessment'
- 'have adequate and reliable coverage of the key parameters addressed in the corresponding test method'
- 'cover an exposure duration comparable or longer than the corresponding method if exposure is a relevant parameter'
- 'adequate and reliable documentation of the applied method shall be provided'

Furthermore, decisions to adopt new REACH restrictions must consider *"the socio-economic impact of the restriction, including the availability of alternatives."*⁹ The proposed grouping approach for PFAS, which includes thousands of substances with different properties, combined with even more uses and applications, is too broad. It is questionable whether the conditions required to justify an EU-wide restriction, as set forth in an Annex XV Restriction Dossier, can be considered to be met for so many substances.

Existence of Distinct PFAS classes

PFAS is a large and diverse group of chemical compounds consisting of approximately 4,700 individual substances. They are not the same and should not be regulated as one group.

Trying to restrict PFAS as a class is not scientifically justifiable because it attempts to classify inert solids, liquids, salts and gases in a single class where intrinsic properties such as hazard, vapor pressure, and environmental partitioning are enormously varied:

⁶ For example, refrigerants reaching the upper atmosphere can degrade by way of photooxidation.

⁷ N. Andersson, 'How to bring your registration dossier in compliance with REACH Tips and Hints: Part 5', *European Chemicals Agency*, 2014, available at: https://echa.europa.eu/documents/10162/13628/09_read_across_webinar_en.pdf/4dbb2e64-408c-4d12-a605-e9f9b75615d8

⁸ 'Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC', *European Commission*, 18 December 2006, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

⁹ Ibid, Article 68(1).

- Some of these materials, such as PTFE parts used in medical applications¹⁰, are intentionally placed into the human body to contribute to human health (e.g. medical implants) and are essentially inert. Others, such as perfluorobutylene, can be harmful to human health. This is not surprising because physical properties such as vapor pressure (Vp), octanol/water partition coefficient (Kow) and others vary tremendously – in many cases by more than 20 orders of magnitude.

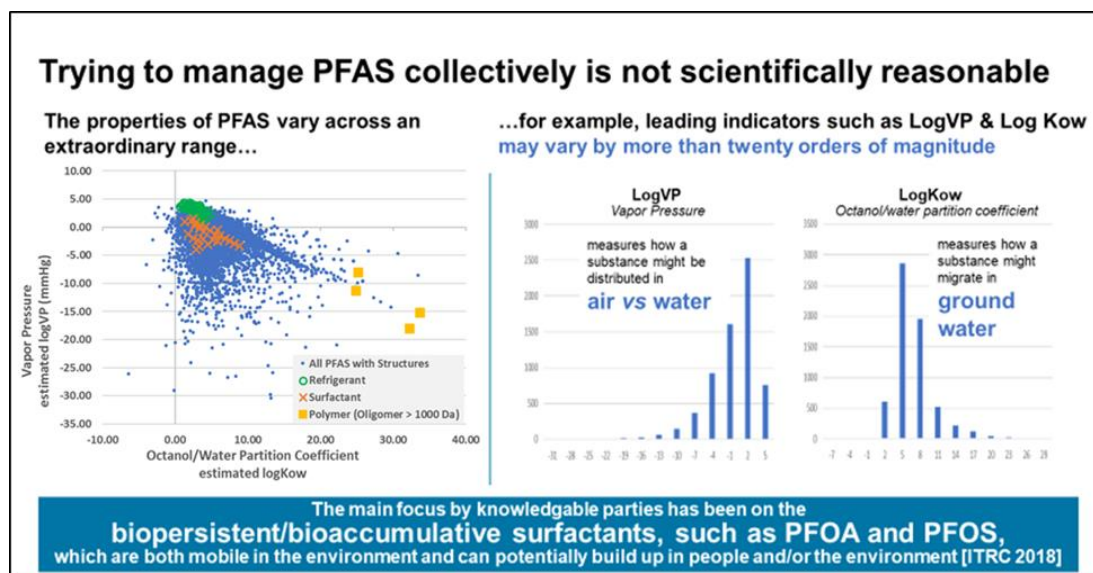


Table: Trying to manage PFAS collectively is not scientifically reasonable¹¹

- Some of these materials are persistent, others are not.
- Some of the persistent polymeric materials are so inert to oxidative/reductive processes that transformation to other forms is not expected to occur under environmental conditions on a timeframe relevant to ecological or human health effects. The persistent materials act more like the inert minerals found in soil, which are unlikely to enter the food chain.
- The high molecular weight backbone polymers, such as PTFE, FEP, ETFE and PFA, have been widely cited (Henry et al.¹², ITRC¹³, etc.) as being of low concern. To restrict them is to unnecessarily disrupt entire industries without any identifiable hazard.
- Other materials, such as refrigerants are being managed by the Montreal Protocol and subsequent amendments (e.g., Kigali) that are closely targeting specific issues. To restrict them further is to

¹⁰ 'PFAS in the Medical Industry', 3M, 9 August 2019, available at: <https://news.3m.com/English/3m-stories/3m-details/2019/PFAS-in-the-Medical-Industry/default.aspx>

¹¹ This information is based on available data from the PFAS EPA Master List, a superset of the OECD PFAS List, and calculated through EpiSuite v 4.11. Please see: *PFAS Master List of PAFAS Substances*, United States Environmental Protection Agency, accessed on 2 June 2020 and available at: https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster, and PFAS: Listed in OECD Global Database, United States Environmental Protection Agency, accessed on 2 June 2020 and available at: https://comptox.epa.gov/dashboard/chemical_lists/PFASOECD

¹² B. J. Henry, et al, 'A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers'. *Integr Environ Assess Manag*, 14, 2018, p. 316-334

¹³ Interstate Technology Regulatory Council, 'PFAS – Per- and Polyfluoroalkyl Substances: Chemistry, Terminology, and Acronyms', viewed on 2 June 2020 at: <https://pfas-1.itrcweb.org/2-2-chemistry-terminology-and-acronyms/>

unnecessarily disrupt complex supply chains and migrations to alternatives that are already in place and have involved significant cost, regulatory processes and disruptions already.

- ECHA has indicated that its concern is around biopersistent and mobile surfactants getting into the food chain, as has been indicated in the PFHxA restriction document. Therefore, the focus should be on physical properties such as lipophilicity reflecting the likelihood of migration into water versus sorption and immobilization within soil. The whole class of PFAS spans more than 20 orders of magnitude in hydrophobic/lipophilic affinities and as such may have considerably different behaviour in these systems.
- The affinity for hydrolysis, based on K_{ow} or acid dissociation constant (K_a), can also signal which potential precursors might be susceptible to degradation and become substances of concern, while molecular weight (M_w) can signal the likely rate of degradation. A similarly large span of these properties is also noted for PFAS.
- Regulation should also focus on factors like vapor pressure which indicates whether something tends to migrate to and remain in water vs being transported in air. Vapor pressure, even excluding high polymers, spans more than 20 orders of magnitude (see above figure).
- Other physical properties (K_{oc} , Henry's law constant, aqueous solubility, etc) also span enormous ranges and change the potential for exposure, a key component of risk management, by 10 to more than 20 orders of magnitude (see above figure).
- Persistence is what enables durability and the high performance of applications of high societal value, necessary to modern life (e.g. medical devices, aerospace applications, renewable energy, EEE, transport). This durability of products directly contributes to increased product safety and to the circular economy by expanding the lifecycle of products and thereby moving away from recycling towards waste prevention.
- Although persistence of a chemical in the environment may trigger a certain level of potential concern, persistence alone is not enough to assess present or future risks to human health and the environment. Once a concern is identified, further risk assessment measures should be taken, such as additional testing, hazard analysis etc. in order to characterize the risk and, if confirmed, adopt risk management measures. Exposure alone or the possibility that exposure may cause unexpected or unknown effects cannot constitute an **"unacceptable risk", which must be positively demonstrated by the EU authorities to justify a restriction under REACH Article 68.**
- The upcoming restriction proposal may have unintended consequences if the grouping is too broad. Some stakeholders have cited the continued evolution of amendments to the Montreal Protocol as a positive example of how industry has continued to innovate to meet societal needs while addressing additional dimensions of concern. This CF2/CF3 restriction could result in a ban of all viable refrigerants. The unavailability of air conditioning would expose certain sensitive populations to life-threatening uncontrolled temperatures and have a massive impact on the transportation and storage of perishable goods, increasing food waste.
- In addition, a broad restriction can result in an unequal playing field for EU companies. The PFAS arena is a microcosm of how regulatory authorities have driven substitution from more biopersistent long-

chain surfactants to less biopersistent short-chain surfactants. This entire substitution process is an example of deep regulatory oversight and control, not a lack thereof.¹⁴

When regulating chemicals, a multi-faceted approach must address issues such as persistence, bioaccumulation, biomagnification and mobility, and to consider their toxicity. **Regulation by distinct PFAS classes, supported by physicochemical properties as well as exposure considerations is more scientifically justifiable than the regulation of all PFAS as a broad group.**

Conclusions

While from a regulatory perspective, a grouping approach may speed up the regulatory assessment process, in the case of PFAS it would be scientifically inappropriate and may lead to overly-conservative and ineffective risk management measures or use restrictions. **PFAS is a large and diverse group of chemical compounds consisting of approximately 4,700 individual substances. They are not the same and should not be characterized or regulated as one group: It is possible to scientifically define distinct classes based on physicochemical properties and we would propose to regulate them accordingly.**

¹⁴ P. Grevatt, 'Per- and Polyfluoroalkyl Substances (PFAS)', Presentation by the US EPA's Director, Office of Ground Water and Drinking Water, to the *National Academy of Sciences, Engineering and Medicine's Water Science and Technology Board* on PFAS on May 17, 2018.