AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

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

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.

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Executive summary

The American Chamber of Commerce to the EU (AmCham EU) welcomes the opportunity to comment on the Green Deal call area 8: Innovative, systemic zero-pollution solutions to protect health, environment and natural resources from persistent and mobile chemicals. Although we support its objective of fostering further research into the health and environmental impact of PFAS substances as well as further development of reliable analytical methods to measure their presence, we are concerned by some statements made by the European Commission in this Green Deal call which we believe ignore scientific facts. From a scientific perspective, 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, vapour pressure, and environmental partitioning are enormously varied.

While from a regulatory perspective, a group approach may speed up the assessment process, in the case of PFAS it would be scientifically inappropriate. **PFAS are a huge and diverse group of chemical compounds consisting of approximately 4,700 individual substances. They are not the same and should not be characterised or regulated as one group**.

It is therefore important to distinguish among 4,700 highly diverse substances. It is possible to scientifically define distinct classes based on physicochemical properties. Broadly, we differentiate between long- and short-chain PFAS and between polymers and non-polymers. Backbone fluoropolymers are a class by themselves, as has been proposed in the publication by Barbara Henry[1]. For fluoropolymers that meet the OECD criteria of "polymer of low concern (PLC)", it is not scientifically appropriate to group them under all PFAS as concern has been shown to be highly correlated to molecular weight. Those PLCs are non-toxic, bio-compatible, non-soluble and immobile molecules so large that they cannot pass through cell membranes. Refrigerants (hydrofluorocarbons or HFCs) are non-polymer PFAS that have already been regulated by the Montreal Protocol (Kigali Amendment) on ozone-depleting substances. The phase-out timeline for HFCs has been agreed upon internationally. Including a different regulation in the Chemicals Strategy for Sustainability would shift the level playing field and lead to duplicative, and potentially conflicting, regulatory efforts.

Scientifically reasonable standards should be applied to read-across and grouping for registration purposes, for restriction/authorisation purposes, as well as for research and analytical purposes. Read-across justification for grouping should be substantiated with the same stringency whether used by industry or the authorities. ECHA already 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.[2] Restrictions in general should be enforceable but even more attention should be paid to it when applied to a group of substances.

When regulating chemicals, a multi-facetted approach must address issues such as persistence, bioaccumulation, biomagnification and mobility, but the link between these properties and toxicity has to be carefully examined. **Regulation by distinct PFAS classes tempered by physicochemical properties is scientifically superior to classification by a broad PFAS group.**

[1] 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

[2] N. Andersson, *How to bring your registration dossier in compliance with REACH Tips and Hints: Part 5*, European Chemicals Agency, 2014.

Background

In December 2019 Commission President Ursula von der Leyen presented the **European Green Deal (EGD)** with a zero-pollution ambition for a toxic-free environment. In its work programme, the European Commission stated it will publish a Chemicals Strategy for Sustainability in Q3 of 2020. As outlined in the Roadmap published by the European Commission on 9 May 2020, the strategy will build on "recent policy evaluations and initiatives associated with the EU chemicals legislation. It will be based on the second REACH Review[3], the Fitness Check of the most relevant chemicals legislation (excluding REACH)[4] and the Communication on options to address the interface between chemical, product and waste legislation[5]. In its Resolution on the European Green Deal adopted 15 January 2020, the European Parliament prompted the European Commission to address all regulatory gaps and to "contribute to the rapid substitution of substances of very high concern […] including […] very persistent chemicals".[6] The European Parliament's ENVI Committee in its draft motion for a resolution on the Chemicals Strategy for Sustainability[7] to be voted in June Plenary 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.[8]"*

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[9]"*

With **read-across** the REACH Regulation 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)'[10], but it requires that a number of conditions are fulfilled:

- 'results must be adequate for the purpose of classification and labelling and/or risk assessment'

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[3] *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Commission General Report on the operation of REACH and review of certain elements, Conclusions and Actions*, COM(2018) 116 final, European Commission, Adopted on 5 March 2018.

[4] *Report from the Commission to the European parliament, the council, the European Economic and Social Committee and the Committee of the Regions: Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses,* COM(2019) 264 final, European Commission, Adopted on 5 June 2019.

[5] *Communication from the Commission to the European Parliament, the Council, the European Economic And Social Committee and the Committee of the Regions on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation*, COM(2018) 32 final, Adopted on 16 January 2018.

[6] *European Parliament resolution of 15 January 2020 on the European Green Deal* (2019/2956(RSP)), 11 January 2020.

[7] *Draft Motion for a Resolution on Chemicals Strategy for Sustainability* 2020/2531(RSP), European Parliament, 21 February 2020.

[8] *Draft Motion for a Resolution on Chemicals Strategy for Sustainability*, 2020/2531(RSP), European Parliament, 21 February 2020, paragraph 14.

[9] *Draft Motion for a Resolution on Chemicals Strategy for Sustainability* 2020/2531(RSP), European Parliament, 21 February 2020, paragraph 21.

[10] *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.

- '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'

Industry experience is that read-across is rarely accepted by ECHA/Member States for testing/registration purposes, while it is more successfully used in the restriction process (it can be based on similar use, eg paint, but also on substance profiles as was done for cadmium based on the justification that the toxic properties which cause the harmful effects are due to the cadmium ion; the restriction proposal includes all possible cadmium compounds. Elemental cadmium is however selected and presented as prototype for all other cadmium compounds). Another example of similar over-reach was the effort in the past decade to eliminate the use of organochlorine compounds out of an abundance of caution. This proved unworkable when it became clear that some chlorinated compounds play an important role in protecting human and environment environmental health while only a few are problematic. The result was a surgical and measured approach to regulation that achieved the desired goals while avoiding unintended consequences of actions not justified by science.

Increasing numbers of testing strategy proposals based on read-across are being rejected by ECHA, questioning the substance similarity approach. Yet, grouping is not as precise as proper read-across following guidance with good practices. The case of Xylene Isomers (ortho-, meta- and paraxylene isomers will now be tested separately) is a good example which confirms this trend of industry proposals being rejected. On the other hand, unjustified grouping of substances for Annex XVII restriction purposes is becoming more common. This has been the case when Germany and Norway prepared a common REACH restriction dossier for PFOA (Perfluorooctanoic acid), PFOA-salts and PFOA-related substances or in the recent proposal to restrict the placing on the market of undecafluoro-hexanoic acid (PFHxA), its salts and related substances. Similarly, there is an intention by the Netherlands and four other member states to group into one REACH restriction dossier all per- and polyfluoroalkyl substances. This would result in a dossier covering a class of several thousand compounds. The implementation of an Annex XVII restriction must address (1) an unacceptable risk and (2) account for the socio-economic impact of the restriction, including availability of the alternatives. The proposed grouping approach for PFAS is too broad and makes it impossible to demonstrate the conditions set forth in Annex XVII.

Existence of distinct PFAS classes

PFAS are a huge 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:

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

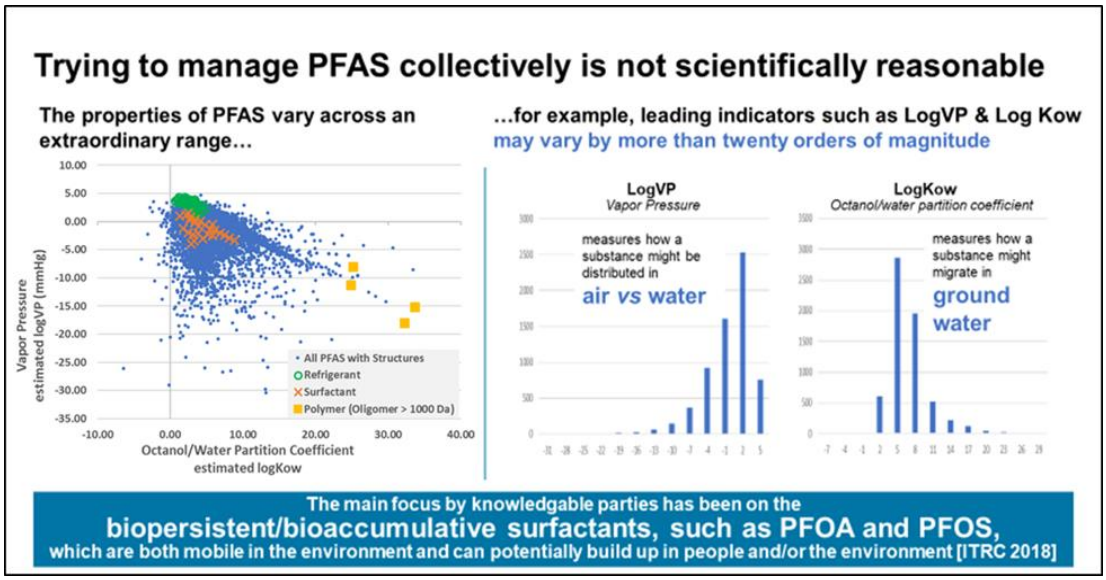

Table: Trying to manage PFAS collectively is not scientifically reasonable[11]

- Some of these materials are persistent, some are not and have been designed to be biologically degradable[12].
- Some of the persistent materials are so inert to oxidative/reductive properties that they look more like the inert minerals found in soil than anything that can get into the food chain.
- The high molecular weight backbone polymers, such as PTFE, FEP, ETFE and PFA, have been widely cited (Henry et al.[13] , ITRC[14], etc.) as being of low concern. To restrict them is to unnecessarily disrupt whole industries without any identifiable hazard.
- Other materials, such as refrigerants are being managed by the Montreal Protocol and subsequent amendments (eg Kigali) that are closely targeting specific issues. To restrict them further is to 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 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 Kow reflecting the likelihood of migration into water versus sticking to soil and becoming part of it. The whole class of PFAS spans more than 20 orders of magnitude in this property.
- The affinity for hydrolysis, based on Kow or acid dissociation constant (Ka), can also signal which potential precursors might be susceptible to degradation and become substances of concern, while

[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, ccessed on 2 June 2020 and available at: https://comptox.epa.gov/dashboard/chemical_lists/PFASOECD

[12] World Health Organization International Agency for Research on Cancer, *Man-made Vitreous Fibres: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, IARC Press, Lyon, France, 2002.

[13] 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

[14] Interstate Technology Regulatory Council, *PFAS – Per- and Polyflouroalkyl Substances: Chemistry, Terminology, and Acronyms*, viewed on 2 June 2020 at: https://pfas-1.itrcweb.org/2-2-chemistry-terminology-and-acronyms/

molecular weight (Mw) 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 vapour pressure which, again, indicates whether something tends to migrate to and remain in water versus being transported in air. Again, vapour pressure, even excluding high polymers, spans more than 20 orders of magnitude (see above figure).

- Other physical properties (eg Koc, 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 high performance of applications of high societal value, necessary to modern life (eg 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.

- Persistence is not a hazard but the property of a substance, like flash point or volatility. Potentially persistence could increase exposure and create hazards, the same way a substance with a low flash point will be hazardous in hot temperature. Persistence is therefore only a measure of exposure. As this exposure may be historical, modern processes may be able to prevent or limit further release. 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.

- There is no precedent for 'banning an element' like the current restriction proposal for fluorine and ECHA should therefore consider:

    - the potential for unintended consequences. Some stakeholders have cited the need for 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, inter alia, result in a ban of all viable refrigerants. The unavailability of air conditioning would expose some sensitive populations to life-threatening uncontrolled temperatures and have a massive impact on transportation and storage of perishable goods, increasing food waste.

    - Banning those types of substances in the EU will lead to an uptake of production in less regulated markets, which, in turn, will have an impact on the EU and the planet.

    - 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.[15]

When regulating chemicals, a multi-facetted approach must address issues such as persistence, bioaccumulation, biomagnification and mobility, but the link between these properties and toxicity has to be carefully examined. **Regulation by distinct PFAS classes tempered by physicochemical properties is scientifically superior to classification by a broad PFAS group.**

[15] 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.