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Our position

# The use of persistency and mobility criteria in chemicals regulation: AmCham EU comments

A narrow regulatory focus on persistence-only is not justifiable and can undermine innovation to produce materials that support societal sustainability goals

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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.

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# Introduction

Several Member States are gathering information that will be used to prepare an analysis of restriction options for 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. The AmCham EU Environment Committee has examined the treatment of PFAS from different perspectives. This paper addresses the regulatory focus on persistency and mobility criteria.

# Persistence on its own is not enough to regulate a substance

REACH has regulated Persistence so far in the context of PBTs and vPvBs where Persistence (P) must be associated with Bioaccumulation (B) and Toxicity (T) (or very Persistence (vP) must be associated with very Bioaccumulation (vB)) to justify qualification as a substance of very high concern (SVHC). There is no indication in REACH that Persistence alone justifies risk management measures.

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, hazardous analysis etc. in order to characterize the risk and, if confirmed, adopt risk management measures. Considering the wide variety of persistent substances (including PFAS), the level of priority in the assessment and management of persistent chemicals should vary not only on the basis of their respective level of persistence, but all other relevant factors. Indeed the suggestion by Ian Cousins for regulation based only on persistence include consideration of other criteria (e.g., socioeconomic, possible health risks).[1,2] Therefore, any regulation based only on persistence factor would be overly simplistic and would need to include other relevant and explicit criteria.

As with many chemicals used in our daily lives, PFAS have been detected in the environment at low levels, but presence does not equal harm. In the Call for Evidence on PFAS (page 1),[3] reference is made to persistence leading to an irreversible presence in the environment, to contamination of untreated water, but nothing on health or environment hazards/effects, except that some PFAS are “suspected to be toxic”. This tends to show that persistence is only a measure of exposure. 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. This article of REACH leaves no room for the precautionary principle (since it requires demonstration of an unacceptable risk) and if it would be interpreted otherwise, the Commission Communication on the precautionary principle[4] would apply that require measures taken on the basis of that principle to be temporary and proportionate to the risks involved, which would not justify a complete restriction.

**AmCham EU therefore believes that persistence on its own is not sufficient to regulate a substance being manufactured, imported or used in products.**

[1] I. Cousins, G. Goldman, D. Herzke, R. Lohmann, M. Miller, C. Ng, S. Patton, M. Scheringer, X. Trier, L. Vierke, Z. Wang, and J. DeWitt, ‘The concept of essential use for determining when uses of PFASs can be phased out’, *Environmental Science: Processes & Impacts,* 2019 (11), viewed on 13 July 2020, available at: https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h#!divAbstract.

[2] I. Cousins, C. Ng, Z. Wang, and M. Scheringer, "Why is high persistence alone a major cause of concern?" *Environmental Science: Processes & Impacts,* 2019 (5), available at: https://pubs.rsc.org/en/content/articlelanding/2019/em/c8em00515j#!divAbstract

[3] ‘Call for evidence supporting an analysis of restriction options for PFAS’, *Bundesanstalt fur Arbeitsschutz und Arbeitsmedizin (BaUa), Swedish Chemicals Agency (Kemi), Norwegian Environment Agency, Ministry of Environment and Food of Denmark – Environment Protection Agency, Netherlands National Institute for Public Health and the Environment – Ministry of Health, Welfare and Sport,* 2019, Accessible at: https://link.webropolsurveys.com/Participation/Public/33cd7e34-f2be-4dac-b10c-faa159f17bf5?displayId=Ger1990245

[4] ‘Communication from the Commission on the precautionary principle’ COM/2000/0001 final, *European Commission,* 2 February 2002, available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF

# Persistence is what enables durability and high performance of applications of high societal value

Persistent substances (including PFAS) can also be durable, which contributes to high performance applications of high societal value necessary to modern life (e.g. medical devices and medicines, aerospace and automotive applications, renewable energy, EEE and semiconductor applications, construction materials, refrigeration systems and others). This durability of products directly contributes to the circular economy by expanding the lifecycle of products. **An overly narrow regulatory focus on only persistence will undermine innovation to produce materials that support societal sustainability goals**. Furthermore, the narrow focus on persistence only would also likely lead to restrictions and bans of the alternatives, because in many respect they would require similar propreties to perform the same functions.

Persistent substances and materials provide health, safety, environmental and energy savings benefits. Below is a list of examples for the category of fluoropolymers. Fluoropolymers are critical components in numerous technologies, industrial processes and everyday applications. They are used in many sectors in Europe, including transport, chemicals & power, electronics, food & pharma, textiles & architecture, medical applications, renewable energy[5]:

- Transport: By providing durable and effective protection against heat, aggressive fluids and fuels, humidity, vibrations and compression, Fluoropolymers prolong the useful life of various components critical for performance, emission control and safety in both the automotive and aerospace industries.

- Chemicals and power: Fluoropolymers enable a high level of efficiency and environmental safety in the chemical and power sectors, helping them remain internationally competitive. Uses include piping, vessels, fluid-handling components, filters, vents and cable coatings.

- Electronics: Fluoropolymers are critical to the semiconductor manufacturing process. Fluoropolymers enable improved fire safety, reliability and performance of cables, notably data transmission cables enabling a wide range of ICT2, industrial, automotive, medical imaging and analysis and a huge range of other applications. A combination of high dielectric properties, high heat resistance and fire resistance is necessary to produce acceptable products.

- Medical applications: Fluoropolymers enable excellent performance and long lifetimes in medical equipment such as surgically-implantable medical devices, catheters, guide wires, filters and pumps. This reduces the risks of failure, replacements, cross-infections and clogging of medical equipment, contributing to the avoidance of medical complications and the associated pain and public cost. Many novel medicines contain -CF2 or CF3 functional groups to drive efficacy for specific modes of action.

- Renewable energy: Fluoropolymers exhibit a unique combination of properties within various components in renewable energy installations. They are also used in energy storage systems such as PEM fuel cells and lithium-ion batteries.

- Cooling and refrigeration: CF2 and CF3 elements are components in most refrigerants gases, in HFCs as well as next generation gases like HFOs. Refrigerants have been tightly regulated at international level first to phase out ozone depleting gases, and currently to phase down their global warming power (GWP). HFOs have been developed with ultra-low GWP, which together with energy efficient technology are the result of decades of R&D to find cooling with the least environmental impact.

[5] 'Socio-economic Analysis of the European Fluoropolymer Industry', *Amec Foster Wheeler*, 2017.

As explained in the Amec Foster Wheeler paper, some alternatives might have a similar performance for a particular parameter or property, but it is the combinations or ranges of properties required for the applications that sets fluoropolymers apart from the alternatives.

## Mobility criteria lacks sufficient rationale and has not yet been adopted at European level

The M element has been proposed to address, among other things, potential risks related to persistent substances. However, the PMT and vPvM criteria still lack sufficient rationale and specifity and have not yet been adopted at European level. Application of PMT or vPvM criteria to justify a broad restriction on PFAS under REACH or any other EU regulation would require that such criteria be first adopted at the EU level in a way that is transparent and known to stakeholders.

Furthermore, a direct comparison of PMT/vPvM with PBT/vPvB properties, as it is the case in the PMT/vPvM criteria proposal developed by the German Environment Agency (UBA),[6] equates to comparing Mobility to Bioaccumulation. Mobility is a process whereby a substance is transported between environmental compartments while bioaccumulation is a process in which a chemical biomagnifies in the food chain.[7] These are two different types of assessments, since the first informs on the potential for exposure in an environmental matrix (i.e. water soil) by including key information emissions and environmental partitioning between media, while the second informs in addition on the potential for increasing concentration in the food chain which can cause harmful concentrations in upper trophic level organisms and human beings. These assessments are not informative when performed in isolation. It should also be highlighted that the toxicological assessment in the UBA proposal represents a significant extension compared to the current T criteria set out in Annex XIII of REACH. It also bases the concept of mobility on much disputed Soil Adsorption Coefficient (KoC) values.

[6] Protecting the sources of our drinking water A revised proposal for implementing criteria and an assessment procedure to identify Persistent, Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM) substances registered under REACH, *German Environmental Agency*, October 2017, available at: https://www.umweltbundesamt.de/en/publikationen/protecting-the-sources-of-our-drinking-water-from

[7] "Bioaccumulation, a process in which the chemical concentration in an organism achieves a level that exceeds that in the respiratory medium (e.g., water for a fish or air for a mammal), the diet, or both." Gobas et al, IEAM, 2009.