

Cefic input to the call for evidence supporting an analysis of restriction options for PFAS

The call for evidence launched on 11 May 2020 aims to collect information on the manufacturing, use, characteristics and available alternatives of per- and polyfluoroalkyl substances (PFAS). The information gathered will be used to develop a legislative proposal seeking to restrict the manufacturing, placing on the market and use of PFAS within the EU. It is primarily the persistence and potential subsequent accumulation of PFAS in the environment that underpins the restriction initiative.

Cefic asks the initiators of the restriction proposal to consider the elements mentioned below before moving forward. These are cross-cutting and not limited to the debate on PFAS.

The trigger for a restriction: an unacceptable EU-wide risk

The European Commission can only adopt a restriction if it demonstrates that the substances subject to the restriction present “an unacceptable risk to human health or the environment (...) which needs to be addressed on an EU-wide basis” (REACH art. 68).

The burden of proof is on the authorities preparing a restriction proposal. Evidence for the unacceptable risk needs to be clearly demonstrated for all substances within the scope of the restriction, considering the specifics of each identified use, associated risks and enforceability.

REACH does not qualify ‘being persistent’ de facto as an unacceptable risk

The driver for action on the broad group of PFAS seems to be persistency. However, demonstrating that a chemical is persistent is not sufficient to demonstrate an unacceptable risk.

Persistence may represent a concern but does not constitute a hazard or a risk or an effect on its own. Looking at persistence in isolation might give an indication of potential environmental exposure but does not give information on potential harmful effects. Hazard properties, use patterns and exposure characteristics must be considered in order to conclude on any adverse effects as for example is done for persistent, bioaccumulative and toxic substances.

Moreover, a too narrow focus on persistency alone, might undermine innovation to produce materials that support strategic sectors and critical applications. Persistent chemicals allow materials to be fit-for-use under extreme working conditions or to be weather-resistant.

In this context it’s crucial that hazards, risks, functionalities and life cycle impacts are properly assessed for any potential alternatives brought forward in the call for evidence.

Setting the right granularity of grouping to demonstrate an unacceptable risk

Demonstrating an overarching ‘unacceptable risk’ for a group of substances can only work if you set the right granularity of grouping.

Extrapolating conclusions of toxicity and risk assessments of a limited number of substances to a large and structurally diverse group is scientifically invalid. Priority should be given to use actual data over predicted data based on a subset of substances. Some structurally similar chemicals may have different (eco)toxicological and physico-chemical properties.

Clear, solid and established scientific standards must be applied to 'read-across' in line with the ECHA and OECD guidance on chemical categories and criteria for similarity.

Essential use is not part of the EU regulatory toolkit

Although the proposal is still to be developed, the overall objective seems to be to phase out all non-essential uses of PFAS¹. What 'non-essential use' entails is not specified.

We fail to see how the concept of (non-)essential use can be legitimately used under the current legislative framework. The concept does not form part and parcel of the EU legal rules landscape.

As indicated above a REACH restriction can only be triggered by an unacceptable risk. The restriction process does not allow for the regulation of substances on the basis of 'essential use'. Essentiality of a use as such is not part of the decision matrix under REACH and does not form a core plank of REACH governance.

If one would decide to introduce the concept of essential use in the future, many practical and legal issues would need to be addressed, such as:

- Which objective parameters should be considered to assess essentiality of a chemical use in practice?
- How to build in a time dimension as judgement of the essentiality of use will evolve over time? In a dynamic market driven by innovation, how to decide and maintain an up-to-date list of (non-)essential uses? For example, a mobile phone may not have been seen as essential in its early days while it is a technology that has become mainstream and arguably essential by now.
- How to design an essential use approach with due regard to fundamental rights and freedom enshrined in EU and international law?
- How to align measures for the betterment of society – which is the core of some suggested definition of essential use – with principles of non-discrimination and proportionality?

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About Cefic
Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 16% of world chemicals production.

¹ See Council Conclusions 'Towards a Sustainable Chemicals Policy Strategy of the Union' of 26 June 2019 and Q&A section on the call for evidence at the RIVM website.