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Our position

REACH Restriction: Essential use criteria in the context of socio-economic impact analysis when unacceptable risk is demonstrated

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Introduction

The American Chamber of Commerce to the EU (AmCham EU) is actively engaged on a number of topics supporting the European Commission's Green Deal ambitions.

The AmCham EU Environment Committee has examined the treatment of Per- and polyfluoroalkyl substances (PFAS) from different perspectives. This paper specifically addresses 'essential use' criteria in the context of socio-economic impact analysis when unacceptable risk is demonstrated.

Concept of 'essential use'

As defined in the REACH legislation, a restriction can only be adopted if it is demonstrated that the substances present "an unacceptable risk to human health or the environment (...) which needs to be addressed on a Community-wide basis"[1]. This burden of proof is placed on the Member States, and has the benefit of protecting consumers and environment where there is clear need to act based on scientific evidence.

Today, however, EU authorities are considering applying the concept of 'essential'/'non-essential' use to justify potential derogations/ restrictions under REACH, for example in the context of the forthcoming REACH restriction on poly- and perfluoroalkyl substances (PFASs). This is despite the fact that there is currently no definition of an 'essential use' under EU law, and such a concept is not sufficiently strong to justify scientific decisions (i.e. substance/substance group restrictions based on non-essential use). Industry acknowledges the high interest of authorities to further investigate this possibility.

REACH does make reference to 'use'; as restriction processes should be based on the risk associated with a given use. The REACH restriction process also creates opportunities to address the criticality of a use, its importance for society, as well as the availability of alternatives which could ensure identical performance within the scope of an application while being economically viable. In addition, Article 68 of REACH mandates the Commission to take into account the socio-economic impact of the restriction and the availability of alternatives, as two key elements essential for determining the content of a restriction.

While establishing the definition of an 'essential use' may increase efficiency during the restriction process, from an economic and social perspective, essentiality should not be looked at in isolation when evaluating/restricting/authorizing substances under REACH. Doing so can only lead to unjustified bans of large families of chemicals, as well as restrictions on uses that may be considered non-essential but that currently do not pose a direct risk or are an alternative to existing chemicals of concern where no more sustainable solution currently exists (eg chemicals used in closed systems).

The chemical industry in Europe and downstream value chains are critical for delivering the building blocks of the EU's Green Deal ambitions. As such, the operational capabilities of companies doing business in Europe should not be hindered based on a definition that could disregard unique applications for which alternatives do not exist. Given the limits of the establishment of a legal definition of essential use, and the lack of a direct link to the REACH Regulation, establishing a common set of criteria for determining 'essentiality of use' may sufficiently address Member State needs during the restriction process.

[1] '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 (Text with EEA relevance)Text with EEA relevance', *European Parliament and Council,* 18 December 2006, viewed on 13 July 2020, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1594660461367&uri=CELEX:02006R1907-20200428.

‘Essential use’ - a sound way forward?

The Royal Society of Chemistry published in the Environmental Science (Process & Impact) online journal an article entitled “The concept of essential use for determining when use of PFASs can be phased out”[2]. The article was written by a Stockholm University professor in collaboration with a Danish University, US research organizations, and research institutes from Norway and Switzerland, a Belgian law and environmental consulting company and the German Environmental Agency (UBA).

The article refers to the Madrid Statement[3], derived from scientific consensus. The Madrid Statement lays out a road map for information gathering in order to prevent potential for harm based on the use of PFASs. The Madrid Statement calls for the international community to cooperate in limiting the production and use of PFASs and in developing safer non-fluorinated alternatives. However, it does not define ‘essential use’ and instead refers to the Montreal Protocol methodology.

The Montreal Protocol focuses on ‘substances that deplete the ozone layer’. It is a global agreement, followed by yearly implementation meetings. It focuses on a phase-out plan for production and consumption of ozone-depleting substances. This document allows for amendments (six implemented until now). The most recent one added a call for the phase-down of hydrofluorocarbons (HFCs) due to greenhouse effects. These were used as a replacement for ozone-depleting substances eliminated by the original Montreal Protocol, in an example of what is often referred to as regrettable substitution. Without further research, there are significant risks of a widespread and scientifically unjustifiable restriction of all PFAS, as a widespread restriction not based on sound science may lead to severe unintended consequences.

The intention of this publication is to:

1) Develop the concept of essential use based on an existing approach described in the Montreal Protocol;
2) Apply the concept to various uses of PFASs to determine feasibility of elimination or substitution of PFASs in each use category; and
3) Outline the challenges for phasing out uses of PFASs in society.

The paper develops three categories of use (see Annex I for more detail): Non- essential, Substitutable and Essential. While making an assumption that:

- It is neither feasible nor reasonable to assess the essentiality of all PFAS uses in one go;
- The phasing out of a substance is possible because it is not necessary for betterment of society in terms of health and human and environmental safety or because functional alternatives exist;
- Some uses of PFAs are considered vital with no alternative; and
- Essentiality is not considered permanent – it entails the constant effort to look for alternatives.

[2] 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

[3] A. Bulm, S. Balan, M. Scheringer, X. Trier, G. Goldenman, I. cousins, M. Diamond, T. Fletcher, C. Higgins, A. Lindeman, G. Peaslee, P. de Voogt, z. Wang, and R. Weber, ‘The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)’, *Environmental Health Perspectives,* 1 May 2015, viewed on 13 July 2020, available at: https://ehp.niehs.nih.gov/doi/10.1289/ehp.1509934

The paper recognizes two legal instruments to regulate PFAS like substances: EU REACH[4] and UN Stockholm Convention on Persistent Organic Pollutants[5].

Most importantly, after an in-depth analysis, the authors themselves recognize the imperfections of their approach:

- This essentiality should not be considered permanent but instead a constant pressure is needed to substitute; and
- The authors give various examples of 'grey areas/grey zones' due to the generic definition of essentiality that is presented in this paper (grey areas/zones represent examples where a particular use cannot be clearly assigned to be eg 'essential' or 'non-essential').

They conclude that in order to avoid/minimize 'grey areas/zones', clear criteria and processes need to be defined/developed (eg based on technical performance standards).

AmCham EU proposal for a way forward: set criteria for essentiality instead of a definition of essential use

'Non-essentiality' is not a condition to drive REACH restriction process decisions

The discussion around the concept of essentiality has emerged relatively recently and, to date, has not produced a clear definition of essential and non-essential uses, but rather many 'grey zones' and 'areas for future research'. AmCham EU members believe that any restriction process should be triggered only if a risk associated with a given use has been identified. The European Commission can adopt a restriction only 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". The burden of proof is on the authorities (Member States requesting restrictions), and it is not sufficient for EU authorities to demonstrate that a use is 'non-essential' to justify a restriction of such use under REACH.

Benefit of having a clear set of criteria in place for an 'essential use definition'

We do not see that the REACH restriction process would be directly improved by developing a generic definition of 'essential uses'. Developing this definition would not bring any additional value to the existing authorization and restriction processes under REACH. As an alternative, industry and authorities could benefit from a harmonized set of criteria to be considered when assessing essentiality for substances that are subject to the restriction process. These should be used in the context of the socio- economic impact analysis when unacceptable risk is demonstrated.

Having such criteria in place would enhance the focus of the restriction scope and help to avoid decision making based on 'grey zones'.

- Essentiality criteria should include socio-economic impacts and the availability of alternatives delivering the required performance to justify exemptions from a restriction that is otherwise justified only by the unacceptable risks of a substance;

[4] 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 (Text with EEA relevance)Text with EEA relevance'.

[5] Covers exempted uses (similar to essential-use, exemption from restriction granted for 1-5y and can be prolonged)

- Essentiality criteria and socio-economic impact must allow for flexibility to allow a holistic consideration of what is 'essential' (including, for example, technological developments or pandemic response). Among other factors, this should include an assessment of the substance's ability to deliver critical functionality and output to sectors of 'systemic relevance',[6] and/or essentiality to the functioning of 'critical infrastructure' sectors[7] for the benefit of society;

- Essentiality also has a production asset dimension. If only essential applications are allowed, companies may not be able to respond to a medical/environmental emergency by shifting production to producing more of the essentially required products (e.g. medical, hygiene, PPE); and

- Essentiality should not be looked at in isolation when evaluating/restricting/authorizing substances under REACH.

Guiding principles

Companies doing business in Europe continuously seek advancement opportunities. We recognize that it is in the interest of industry to use more sustainable alternatives to existing substances where possible. Companies are already investing in developing alternatives.

This can only be achieved if REACH restriction processes follow guiding principles, in order to contribute to investment certainty:

- Refer to clear criteria and processes;

- Rake into consideration risk and socio-economic impact and technical functionality benefit;

- Socio-economic impact and essentiality considers especially sectors/professions of 'systemic relevance' (eg chemicals) to society and fully recognizes essentiality to maintain the functioning of 'critical infrastructure' sectors (eg medical, transport, I&CT, energy) and society as such;

- Take into account regional differences through exemption;

- Distinguish between technical function of a substance vs. final function of the article (water repellence vs. medical device);

- Be enforceable;

- Allow the use of substances in non-essential uses when evidence exists that there are no unacceptable effects to human health and environment or there are no better alternatives (could be covered by clear exemptions);

- Demonstrated experience from the past shows that society and individual companies need to be ready to respond to medical or environmental emergencies over short period of time (e.g. accidental release of chemicals into environment or outbreak situations). In those cases, companies need to be in a position to promptly offer solutions. This may require significant increase in production capacity for essential products (e.g. medicines, medical devices and packaging, PPE) within very short lead times.

[6] As one example, sectors identified as having 'systemic relevance' in the framework of COVID-19 are listed in the Communication from the Commission on "Guidelines concerning the exercise of the free movement of workers during COVID-19 outbreak (2020/C 102 I/03)."

[7] 'Council Directive 2008/114/EC f 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection', 23 December 2008, viewed on 13 July 2020 and available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2008.345.01.0075.01.ENG, establishes the following definition: "critical infrastructure means an asset, system of part thereof located in Member States which is essential for the maintenance of vital societal functions, health, safety, security, economic or social well-being of people, and the disruption or destruction of which would have a significant impact in a Member State as a result of the failure to maintain those functions."

Therefore, those companies need to have the flexibility to shift manufacturing capacity to e.g. essential medical and PPE applications. If REACH restriction process was to allow only essential uses (e.g. medical/PPE applications) this could lead to situation where today's 'non-essential' uses would be lost, hampering Member States' capability to respond to societal needs.

We believe that applying the concept of essential use to the poly- and perfluoroalkyl substances (PFASs) restriction process is premature, and may set a precedent that will have unintended consequences. The current call for evidence on a broad PFAS restriction coordinated by 5 European states (Germany, Netherlands, Norway, Denmark and Sweden[8]) does not stipulate identified risks per use. Instead, it collects information on a number of uses. Applying this concept to such a large class of chemicals for the first time is a very ambitious task that does not exclude the possibility of unjustified restrictions being concluded and a lack of enforceability.

[8] 'German RMOA-List', *Helpsdesk: REACH-CLP-Biozid*, viewed on 13 July 2020 and available at: https://www.reach-clp-biozid-helpdesk.de/DE/REACH/Verfahren/SVHC-Verfahren/Stoffliste-EN/Stoffliste-EN.html

Annex I

Uses Categories identified by and set out by Cousins et al[9] – including comments

Table 1: Uses Categories identified by and set out by Cousins et al – including comments

Category	Definition	PFAS Example	Comment
Non-essential	Uses that are not essential for health and safety, and the functioning of society. **The use of substance** is driven by market opportunity	Dental floss, water-repellent surfer shorts, ski waxes	Market opportunity - how do you define **Focus is only on use of a substance**
Substitutable	Uses that have come to be regarded as essential because they perform important function, but where alternatives to the substance have now been developed that have equivalent functionality and adequate performance which makes the **uses of the substance** no longer essential	Most uses of AFFFs, certain water-resistant textiles	**Focus is only on use of a substance**
Essential	**Uses considered essential** because they are necessary for health or safety or other highly important purpose and for which alternatives are not yet established*	**Certain medical devices,** occupational protective clothing	**Examples include but are not limited to certain medicines (and Intermediates, Raw Materials, Auxiliaries and Reagents used to manufacture medicines), medical devices,** occupational protective clothing
***This essentiality should not be considered permanent, rather, a constant pressure is needed to search for alternatives, in order to move these uses into cat 2 above**			

[9] Cousins, et al. 2019.