

Fluoropolymers Product Group Essential Use

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The REACH regulatory framework has proven its practicability. The search for alternatives and the elimination of chemicals for which unacceptable risks have been clearly identified are already well covered by mechanisms and processes under REACH.

Until agreed and deemed necessary at EU-level, an essential use concept should not be used to regulate the broad and chemically diverse PFAS group of substances.

What European authorities determine as being essential today may not be assessed as being so in other regions of the world and in the future. Differences in interpretation could lead to dispute and potentially lead to the risk that the essential use concept be considered as a technical barrier to trade.

The concept of essential use raises many unanswered questions which still need in-depth debate with all stakeholders.

Essential Use and Substances of Concern

In May 2019, the Cousins et al paper 'The concept of an essential use for determining when uses of PFAS can be phased out'¹ called for a radical new approach to regulating substances of concern, moving away from today's system of chemical regulation based on purely scientific, expert evaluation of the risk, hazard and management of a substance. In June 2019, the European Council called on the Commission to develop an action plan to eliminate all non-essential uses of PFAS². In October 2020, the Commission's Chemicals Strategy for Sustainability³ stated its intention to begin looking at how to "define criteria for essential uses".

The Commission has indicated that criteria will be defined in the period 2021-22 with an aim to ensure that the use of PFAS is phased out in the EU, unless it is proven essential for society. To kick-start discussion, the Commission presented a paper to CARACAL⁴ in November 2020.

¹ <https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h#!divAbstract>

² <https://www.consilium.europa.eu/en/press/press-releases/2019/06/26/council-conclusions-on-chemicals>

³ https://ec.europa.eu/environment/strategy/chemicals-strategy_en

⁴ <https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/f79692a6-c171-4e26-80b4-a4041640df66/details>

REACH Already Regulates Concern

REACH already today provides the tools to address risks arising from specific substances in combination with use: for example, in a REACH restriction, authorities have to demonstrate that a certain substance presents an unacceptable risk to human health or the environment which needs to be addressed on a Community-wide basis, arising from the manufacture, use or placing on the market of substance. REACH restriction provides various formal processes that include checks and balances and consultation processes. The restriction process needs to consider also potential socio-economic impacts, including the availability of alternatives.

REACH has proven to deliver its objectives. This has been re-confirmed by the Commission's own evaluations/review⁵ of REACH. The REACH review highlighted that the current framework is working well, while minor tweaking of the current system can ensure further enhancements/improvement. We do not see that the REACH restriction process would be directly improved by developing the concept of 'essential uses'.

As an alternative an additional impact assessment could further determine the benefits of introducing guiding criteria to help assess essentiality of a use in the context of socio-economic assessments, with the broader Green Deal and societal objectives in mind. This would allow the evaluation of all direct and indirect benefits and consequences of a restriction and would lead to better informed decision making.

Essentiality Should not be Viewed in Isolation

Defining what might constitute an essential (or non-essential) use may be perceived as increasing regulatory efficiency when scrutinizing a REACH restriction dossier, however, from an economic and social perspective, essentiality should not be looked at in isolation when regulating substances.

Considering only the essentiality of chemicals use in isolation, especially through grouping, without due consideration of risk (REACH Art. 68), might lead to unjustified bans of groups of chemistries, as well as restrictions on uses that do not pose an unacceptable risk but are considered non-essential. Essential use should not be a pre-defined political decision. It is of critical importance that the socio-economic assessment carried out by the Socio-Economic Assessment Committee (SEAC) for so called non-essential uses continues to be utilised on a case-by-case basis. The same applies for chemicals that are an alternative to existing chemicals of concern where no sustainable solution currently exists (e.g. chemicals used in closed systems).

Any ban of a use would need to be closely linked to a substance for which a clear unacceptable risk which needs to be addressed on a Community-wide basis has been identified taking into consideration intended use and exposure potential. Then, on the basis of clear essentiality criteria, which allow for objective and predictable assessment by all stakeholders, a transparently designated body should be responsible for an essentiality determination following a clearly defined process. We believe that SEAC expert's competences would be best placed for this and their judgment should be established in accordance with Better Regulation principles and allow for transparent and structured consultation with all relevant stakeholder groups.

⁵ https://ec.europa.eu/commission/presscorner/detail/en/MEMO_18_1363

Potential Challenges to Consider with concept of essential use

Adaptable to future requirements: an essential use concept should allow for the dynamic adaptation of its scope and assessment criteria as a function of changing societal need and future innovation. Pre-emptive decisions on what may be essential to society in the future is not in line with the Commission's principle of technology neutrality and might prevent the EU from benefiting from technological developments of the future. Any presumptive decisions on what might be essential in the future are likely to seriously hinder Europe as an R&D location and parts of its manufacturing base, which once lost will be difficult to re-establish.

Finished Products vs components: Many complex products of high societal value are enabled by fluoropolymers (e.g., medical devices, airplanes, smart phones, computers, automobiles), as such a narrow approach to essential use focusing on chemical substances is not practical. Even if consensus could be reached with respect to the classification of a finished product, each one is made up of hundreds of individual component products.

Acceptance of differences: Recognition should be given to regional and cultural differences in what is seen as essential e.g. in cold-wet northern regions certain performance textiles may be essential while not necessarily so in southern Europe.

Trade and diverging global standards: What European authorities determine as being essential may not be assessed as being so in other regions of the world, and vice-versa. Resulting differences in interpretation could lead to dispute and risk the essential use concept being considered as a technical barrier to trade. Given the nature of the global economy, to mitigate against the risk of regional difference in interpretation, the concept of essential use should be discussed at international level.

Enabling innovation in the EU: Chemicals enable technologies that are essential to delivering the Green Deal objectives and helping to achieve the European Union's overall goal of carbon net neutrality by 2050. In this context, the impact on innovation and the role innovation plays to achieve overall strategic goals of the EU must be considered. Innovations such as cars, computers and cell phones were not immediately recognized as essential. Essential use is a static way to look at the future. If Europe wants to lead by innovation, it needs to adapt its regulatory frameworks to incentivize it, including by minimizing the regulatory uncertainty for innovations and investments that go with it.

Conclusion

Following the presentation of the Commission's paper at the CARACAL in November 2020, a period of reflection until early 2021 was given in order for stakeholders to share their views on the essential use concept. We welcome and support that the Commission indicates that "*[O]nly once the potential advantages and disadvantages of variations of the essential use concept have been sufficiently debated, challenged and assessed, it will be meaningful to investigate in what way a consensus form of the concept can be best deployed (self-regulation, legislation, guidance, standards, etc.).*"

Whilst discussion on applicability of the essential use concept and feasibility to use it under REACH is still in its early stages, five EU Member States are progressing in preparing a grouping restriction proposal aimed to restrict all PFAS in non-essential uses. We believe using an essential use concept in this complex restriction dossier would be premature and not in accordance with the REACH regulation. Without in-depth discussion and agreement at EU-level this restriction may set a precedent that will have unintended consequences beyond this restriction.

Only once a criteria of essentiality are well-defined and agreed, could it be integrated on a case-by-case basis under existing procedures related to socio-economic considerations dealt with by the experts in the SEAC.

Finally, many issues still need to be clarified and questions answered. The introduction of policy and regulatory change deserves extensive debate and review with all stakeholders. Along with this, the Commission should provide a clearer explanation on the gaps they see in the current regulatory framework and why they conclude an essential use concept would help fill this gap. Likewise, a proper impact assessment of the (in)direct benefits and consequences of the essential use concept and of its legal basis would be needed.

Annex

Some thoughts on criteria for determining essentiality

- Whether or not the safety of users of a product as well as workers who are at the production site of a product, can be ensured without the substance;
- Whether or not the product contributes to safety and health of human being (i.e. used in the medical applications, such as devices and pharmaceuticals, but also other sectors); that are e.g. critical infrastructure related or of systemic relevance;
- Whether or not a whole production asset is essential as not only certain uses can be essential, but that the production assets on which they are produced need to have sufficient capacity to meet increased demand during medical and/or environmental crises (i.e. surge capacity)?
- Whether or not material efficiency would be achieved without the substance;
- Whether or not energy efficiency would be achieved without the substance;
- Whether or not there are available alternatives and/or are alternative technologies to produce a product without the substance;
- Whether or not a product is performing according to applicable standards which are defining specifications and procedures to ensure the reliability of a product;
- Whether or not durable and sustainable products can be produced and placed on the market without the substance;
- Whether or not a product produced without the substance is accessible by general public (with reasonable cost and efforts);
- Whether or not a substance is needed in critical industries researching and developing innovations pivotal for the European Green Deal and an economy focusing on sustainability;
- Whether the substance is vital for innovation & development of future technologies;
- Whether the substance is needed to achieve broader policy goals including but not restricted to the European Green Deal;
- Whether the substance is essential to prevent or control a serious danger to human health, animal health or the environment.

About Us

The Fluoropolymers Product Group (FPG) represents Europe's leading fluoropolymer producers and experts. With a unique set of properties unobtainable by other polymers, fluoropolymers are non-replaceable across many key sectors and applications. Fluoropolymers ensure safety, reliability, durability and performance in numerous technologies, industrial processes and everyday products that are critical for human health, safety and the environment.

We are committed to promoting innovation, safe use of our products, sustainable manufacturing and stewardship across the industry for all our products. As the voice of the industry across Europe, the Fluoropolymers Product Group advocates for a balanced regulatory environment based on scientific facts to ensure that European industries remain competitive and sustainable.

Part of PlasticsEurope, the group's members are 3M, AGC, Arkema, Chemours, Daikin Chemicals, DuPont, W. L. Gore & Associates, Gujarat, Honeywell, and Solvay.