Fluoropolymers Product Group
Updated Views on Essential Use

Brussels, June 2022

Introducing an Essential Use Concept (EUC) in the EU regulatory framework should not be presented as a mere technical modification of the current process. Such a major change warrants a **full impact assessment** before presenting a proposal for an EU EUC.

After months of discussion about what is essential and what is not, **the concept remains subjective**. Until agreed and deemed necessary at EU-level, an essential use concept should not be used to regulate chemical substances, including the broad and chemically diverse PFAS group.

What European authorities will determine as being essential today may not be assessed as being so in other regions of the world, or 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 risk of variability of the concept can be seen as a risk for future investment by the industry.**

To enable the sustained advancement of the EU economy and ensure its citizens continue to benefit from access to the wide variety of products needed to meet European society's evolving needs, an **essential use concept should only be applied where there is a clearly identified unacceptable residual risk**, taking into consideration intended use, control measures, hazard classes and exposure potential.

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

Essentiality should not be viewed in isolation

Introducing a concept of essential use in the EU regulatory framework warrants a full impact assessment being made before a proposal on a EUC is put forward. A concept should also not be considered in isolation from other EU legislation without analysing how all the different elements of the EU regulatory system link together.

Discussion about what is or is not essential is by definition idiosyncratic and introducing subjective criterium in a regulation (e.g., REACH, but also other types of technical regulation) is not correct from our point of view. Defining whether a substance in an application is essential for society should not be a political choice and whilst what might constitute an essential (or non-essential) use may be perceived as increasing regulatory efficiency when scrutinizing a REACH restriction dossier, from an economic and social perspective, essentiality should not be looked at in isolation when regulating substances.

To establish essentiality of the most harmful substances both essentiality of a substance within a specific article or mixture (for instance to achieve a desired level of performance) as well as the essentiality of the technical function of the product in its end use should be considered.

As such, essential use has to be made on a case-by-case assessment. 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.

Assessment of Unacceptable Risk

The essential use concept should only be applied where there is a clearly identified unacceptable residual risk, taking into consideration intended use, control measures hazard classes and exposure potential.

The implementation of an essential use concept for the most harmful chemicals, would also require an assessment of its necessity for health/safety, the criticality for the functioning of society and the availability of non-regrettable alternatives. Initial screening for necessity/criticality of products could be used to provide initial insight but seems an over-simplification of decision-making. Essentiality assessment should be performed on a case-by-case basis and as mentioned previously should combine the essentiality of a substance in a product as well as essentiality of the product specific application. Essentiality should especially consider products contributing to safety and health of human beings (for example products used in the medical applications (medical devices and pharmaceuticals) and PPE) ~~and~~, products supporting critical infrastructure and sectors that are of systemic relevance (digital, automotive, aerospace, renewable energy, industrial) and wider EU policy objectives (e.g. EU supply chain autonomy like The European Chips Act).

Screening should not undermine that principle and could lead to flawed conclusions and present an over-simplistic picture. A simplified screening for alternatives is not advisable and could lead to cases of regrettable substitution. There must be a robust analysis to justify why an alternative is a suitable substitute. Such a decision should only be taken once all R&D, testing, regulatory and standard approvals for use of the substance in the article, high-quality hazard data has been assessed, a thorough analysis to the whole life-cycle of the alternative is made, it's availability is guaranteed and its economic feasibility is known.

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 in 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. In order to be inclusive (and allow for the manufacturing of products for export) cultural aspects should be viewed from an inclusivity point of view. If the cultural heritage will be taken into consideration would Member States have a veto/exemption on an essential use decision? If no other country asks the same exemption, would a manufacturer continue to produce the original product just for one country and reformulate for the others?

Production viability: Essentiality should also consider production viability and the manufacturers ability to respond to surge in demand for essential product applications (e.g. the manufacturer needs to have sufficient capacity to meet increased demand during medical and/or environmental crises by de-prioritizing less essential products to enable to meet the surge demand).

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, for example, 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. 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. There would be increasing hesitancy from industry to opt for chemicals that would be included on any list of harmful chemicals, even if they are considered essential. This would have a negative impact on innovation and the speed of commercialization of competitive solutions in Europe.

Conclusion

Whilst discussion on applicability of the essential use concept and feasibility to use it under REACH is in the last 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 criteria of essentiality are well-defined and agreed, could it be integrated on a case-by-case basis under existing REACH procedures related to socio-economic considerations.

Finally, many issues still need to be clarified and questions answered by the Commission and its consultant, Wood. Even in May 2022 after nearly 2 years of stakeholder discussion, much confusion around an EU EUC remains. Likewise, a proper impact assessment of the (in)direct benefits and consequences of the essential use concept and of its legal basis is still to be delivered.

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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.