Position Statement

Applying The Essential Uses Concept To Chemical Legislation

Background

The concept of essential use is being scrutinised by policy makers as a regulatory tool for banning or restricting the use of harmful chemicals in an application by evaluating the criticality/essentiality of their specific use(s) for society. It has also been suggested that this could be applied as a potential solution for addressing large groups of similar chemicals where there are human health and environmental concerns such as for persistent chemicals found in the environment. Under the concept chemicals that are harmful yet essential to society would be regulated for a specific use(s), whereas those deemed to be non-essential would either not be permitted for a use(s) or require further assessment to inform a decision on their use(s). Its implementation however is challenging, not only from the aspect of who decides whether a use is essential or even critical for society once the criteria for harmful chemicals has been defined but also whether there is a risk of unintentional impacts for society from a decision to not allow a use.

The essential use concept first appeared in 1992 where it was introduced to the Montreal Protocol for Ozone Depleting Substances to 'speed up' their phase out process because up until then, it was not possible to rapidly phase-out all uses [1]. Under the Montreal Protocol the use of a controlled substance (chemical) is deemed to be essential if it is "necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health".

Current Status

Policy makers are considering how the essential use concept might be implemented for managing large families of chemicals. In the UK, Defra held a stakeholder workshop in April 2021 to explore the concept and they also tasked their former Chemicals Stakeholder Forum to look at this but no consensus was reached with either. Defra continues to consider this as a potential regulatory tool.

Looking to the EU, the essential use concept was introduced in the European Commission's 2020 publication 'Chemicals Strategy for Sustainability Towards a Toxic Free Environment' (part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal) as a route to enabling action to ban "…*the most harmful chemicals in consumer products - allowing their use only where essential"* [2]. In 2021 the European Parliament subsequently tasked the European Commission to define the concept and criteria for essential use [3]. This resulted in publication on 26 April 2024 in the Official Journal of the European Union a Communication from the European Commission titled 'Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals' [4]. The Communication also linked the essentiality of a chemical in the same manner as the Montreal Protocol. However, there was one difference in that it also introduced the term "most harmful substances" (chemicals) and provided a list of hazard classes that this includes. A chemical with a hazard classification on the list is thereby defined a "most harmful substance" and its use can only be considered as essential provided that it is both (i) necessary for health or safety or functioning of society, and (ii) there are no acceptable alternatives.

Currently the European Chemicals Agency (ECHA) is considering how the EU could restrict under EU-REACH uses of a substantially large group of similar chemicals, where there are human health and environment concerns, known in general as Perfluoroalkyl and Polyfluoroalkyl substances (PFAS). Progress press releases from ECHA have indicated that the concept of essential use could be applied to a PFAS use based on persistence alone thereby deviating from the classification criteria in the European Commission's Communication of 26 April 2024 in the Official Journal of the EU [4]. The definition for a "most harmful substance" (chemical) in the 26 April 2024 European Commission's Communication does not include persistency on its own, instead it links this with additional hazards i.e. the EU hazard classes Persistent, Bioaccumulative and Toxic / very Persistent and very Bioaccumulative (PBT / vPvB); and

Persistent, Mobile and Toxic / very Persistent and very Mobile (PMT / vPvM). Persistence is not a formal standalone hazard class under both the EU's Classification, Labelling and Packaging (CLP) Regulation, and the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The EU hazard classes PBT/vPvB and PMT/vPvM, whilst recognised under EU CLP, are also not formally recognised under GHS (although work is underway to review whether they may be included in the future).

The essential use concept is also firmly linked with the EU's Safe and Sustainable by Design (SSbD) framework of voluntary guidance that aims to help researchers and innovators to (re)design a product [5]. SSbD is a key pillar of the European Commission's 2020 publication 'Chemicals Strategy for Sustainability Towards a Toxic Free Environment' with it aiding innovation of safer chemical alternatives, whilst the essential use concept potentially eliminating all but the most essential uses for society of the most harmful chemicals. An updated SSbD framework was issued in December 2025 by the European Commission's Joint Research Centre and it is expected that the European Commission will adopt this formally as its Recommendation. Under the safety assessment part of the framework, two risk approaches are presented: hazard-based (a generic approach for when data is available) and exposure-based. For substances (chemicals) with hazard data, three hazard-based SSbD criteria are used: the most harmful substances (chemicals), substances of concern, and other. The essential use concept is suggested as a potential tool for determining any derogated essential uses of the most harmful substances (includes those according to [2], and substances of very high concern (SVHC) under REACH [6]).

At the global level, the Organization for Economic Co-operation and Development (OECD) has also looked at the essential use concept.

Our Opinions and Actions

- The Chemical Industries Association (CIA) supports transitioning uses away from chemicals that have been assessed to present an unacceptable risk, as well as those that have a high probability of presenting unacceptable risk that cannot be managed.
- CIA recognises the lengthy time that it has taken to arrive at some regulatory decisions under EU and UK REACH. We thereby appreciate the reasoning behind why authorities are considering whether the regulatory process can be made more efficient through possibly introducing the essential use concept.
- We note that some aspects of the essential use concept are already incorporated in the EU- and UK-REACH legislation. Its application can be seen with authorisations that are granted for the continued use of Substances of Very High Concern (SVHC) when viable alternatives are not available and where the socio-economic benefits of the use outweigh the risk from the use.
- The challenge in applying the concept lies with its definition in terms of criteria and importantly who decides whether a chemical use is essential. It may also not bring the expected benefits of simplification. Essential use assessments could differ widely in how they take account of personal, societal (there may also be geographical differences), regulatory, or governmental perspectives.
- Approaches on how the concept could be applied have been put forward not only within the European Commission's Communication of 26 April 2024 [4] but also by other stakeholders, and we hence call for careful evaluation of this concept. The European Commission's Communication on the essential use concept applies this to the "most harmful substances" (chemicals) defined according to their hazards, which will have been determined from (eco)toxicological scientific testing study results. Whilst it is important that this robust key scientific assessment approach remains in place to avoid the unjustified phase-out of chemicals which do not necessarily pose a risk, it is difficult to apply the essential use concept to large families of structurally similar chemicals where there are human health and environment concerns when not all their data is available and the number of uses is considerable.
- With large families of similar chemicals where there are human health and environment concerns, there is a conundrum since it is unfeasible to assess these individually and yet unscientific to assume their risk profile is the same (in the case of PFAS, this is tens of thousands of substances). Instead, CIA supports identifying sub-groups, based on structural similarities or evidence of similar persistence or hazards that would allow data gaps to be targeted and closed more quickly.
- Using a sub-group approach for applying a general ban to large families of similar chemicals human health and environment concerns may provide more flexibility since essential use assessments of the chemicals within sub-groups could allow certain chemicals to still be used / produced after scrutiny.

- An essential use decision-making panel should be created to prioritise and serve as a focal point for industry sectors to review the most harmful and SVHC chemicals that may need to be retained for critical functions/uses. There should also be flexibility where special unforeseen circumstances may exist or require further assessment and potential approval by the decision panel or via permit derogation.
- Caution is also needed when considering the concept since some uses of chemicals that are deemed to be non-essential today, may have a considerably higher priority in the future thereby running the risk of stifling innovation. A good example of this over recent decades is the advances society has made in technology – chemicals have and continue to make this possible. Furthermore, in times of an emergency, a chemical previously considered as being non-essential may become essential, so flexibility is therefore important.
- In whichever way the essential use concept is applied, it would require decisions to be made by an official body of some nature and inadvertently, its incorporation into the existing regulatory process could even lengthen the overall time it takes in reaching a regulatory decision due to the complexity of such an assessment.

Conclusion

As a stand-alone concept, essential use sounds promising as a potential regulatory tool for streamlining and making chemical legislation more efficient. Harmful chemicals essential to society would be regulated for a use(s), whereas those deemed to be non-essential would either not be permitted for a use(s) or require further assessment to inform a decision on their use(s). Whilst its application is ideally suited to the Montreal Protocol, the appropriateness of the concept for wider chemical legislation needs careful consideration in terms of identifying and assessing both direct and indirect implications for any option being explored by policymakers. Its implementation would be challenging…

- Who would decide whether a use of a chemical is essential or even critical for society?
- How can the risk of unintentional impacts for society from a decision to not allow a use of a chemical in an application be determined?
- Would decision(s) to ban non-essential uses make production economically unviable and if so, how would the UK maintain supply for UK critical/essential uses to society?
- What trade-offs might be needed?
- How would a decision on a most harmful chemical impact on UK future waste infrastructure needs (capacity, management e.g. are dedicated waste bags/containers needed and what is its chemical state since the risk of lack of control or exposure for a solid is a lot less than a gas/liquid)?
- How can imports be enforced?

CIA strongly encourages the UK authorities to fully engage with industry using existing platforms to facilitate this, as well as liaising with other stakeholders, to ensure that any policy proposal based around critical or essential use of a chemical is workable, non-discriminatory, scientifically justified and informed by risk-based evidence.

References

1. Montreal Protocol on Substances that Deplete the Ozone Layer, 1987 - https://ozone.unep.org/treaties/montreal-protocol
2. EU Chemicals Strategy for Sustainability Towards a Toxic Free Environment, September 2020 - https://echa.europa.eu/hot-topics/chemicals-strategy-for-sustainability
3. European Parliament Resolution on Chemicals Strategy for Sustainability, July 2020 - https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.html
4. Communication from the European Commission 'Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals' in EU Official Journal 26 April 2024 - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202402894
5. Safe and Sustainable by Design Chemicals and Materials – Revised Framework (2025) - https://publications.jrc.ec.europa.eu/repository/handle/JRC143022
6. EU-REACH - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410

For more information please contact:

Dr Roger Pullin

Head of Chemicals and Health Policy

Chemical Industries Association

Tel. 020 7963 6738; Mob. 07951 387317

Email: pullinr@cia.org.uk

About the CIA

The Chemical Industries Association (CIA) is the organisation that represents chemical and pharmaceutical businesses throughout the UK. Our activities are split between lobbying and provision of advice and services. Our policy agenda stretches across the economy and competitiveness; our products and the way we work; health, safety & environment and employment issues. We represent all sizes of chemical and pharmaceutical businesses, of which approximately 70% are overseas headquartered. This illustrates the increasingly international nature of the industry.

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