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Conducting an Essential Use Assessment

This document outlines Cefic's proposals for running an Essential Use Assessment under REACH

Principles

The essential use assessment is intended to support decision making on whether to grant a derogation to aa generic ban or restriction when an unacceptable risk is identified. It should complement existing processes by looking at the broader consequences of banning the use of a certain chemical or groups of chemicals. In other words, exploring the implications for society if certain uses for certain substances cease and certain products or applications are no longer available. An essential use dossier would be expected to answer these questions, defining the impact of the withdrawal of a substance from a specific use, and the impact this would have on society.

The essential use assessment has to be **transparent, predictable and proportionate** to the identified risk. Industry requires certainty in order to make investment decisions. The assessment should also be done on a **case-by-case analysis** of individual uses, without excluding entire industry sectors.

The current thought starter puts forward a first set of ideas on the data needed to conduct an essential use assessment, who should provide these data, how to integrate the data into the current processes, etc.

In line with Cefic's concept paper outlining how the essential use concept could be introduced under REACH, the essential use assessment should be reviewed by a politically empowered Essential Use Committee to decide on essentiality complementing the restriction and authorisation processes to address the "most harmful chemicals".

Data to be used for running an Essential Use Assessment

Industry (from manufacturers through to formulators and end-users) is best placed to provide the data required for an essential use assessment, though it will require much greater involvement of downstream actors including further communication up and down the supply chain. The assessment report for the Essential Use Committee should be generated according to specific guidance provided by authorities.

In Cefic's approach, a multistakeholder Essential Use Committee with political legitimacy would be empowered to assess essentiality of (a) use(s) against specific criteria and to deliver an opinion to the European Commission. It is important to note that the Essential Use Committee will play a complementary role to the SEAC and RAC, with each providing opinions and being responsible for their own areas of expertise.

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Some information will be complementary – for example, an analysis of alternatives is an important component of a socio-economic analysis in an application for authorisation, and the conclusions from this review will inform the discussion of essentiality. Where opportunities for substitution are limited, the essentiality of a certain substance in a certain use is likely to be higher.

To run an essential use assessment the following data will be required to prepare an essential use assessment before involvement of the Essential Use Committee:

- Use related
    - Overview of the use / application looking at as much of the value chain as necessary to show essentiality.
    - Functionality of the chemical in a specific use / application, including performance: why is the chemical used for a certain application?
- Alternatives: Consider conclusions of the Analysis of Alternatives from SEAC opinion (including alternative technologies):
    - Are there any substances / technologies available that would provide a similar function / performance in technical and economic, environmental and safety terms and meeting product market requirements or technical standards?
    - Assessment of the direct / indirect consequences of not being able to use anymore a certain chemical or when shifting to alternatives (e.g., impact on the availability of certain products, reduced performance of certain applications).
- Long / short term impact on society
    - Assessment of the broader consequences, including impact on the EU open strategic autonomy (see below) of absence of certain uses (apart from negative consequences on the business of the applicant) / applications to facilitate the assessment by the essential use committee. This could include the impact of reduced production of substances impacting other product lines.

The data provided would be limited to the scope of the regulatory action – firstly the substance under review, and secondly the uses this substance goes into (which may also be limited by the regulatory action – e.g. substances in consumer products). The Essential Use assessment should therefore come at the end of a regulatory procedure (i.e. after review by RAC and SEAC, to ensure that only those cases necessary are actually reviewed, and the complete information is available.

Criteria to Consider Conducting an Essential Use Assessment

When starting from the essential use criteria put forward in the Montreal Protocol, an essential use assessment needs to answer the following:

1. *Is the use of the substance in the specific product necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects)?*

Furthermore, the Montreal Protocol takes into account the availability of alternatives and the risk assessment:

2. Are there no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment health and safety?
3. Have all economically feasible steps been taken to minimise the essential use and any associated emission/exposure of the controlled substance?

The essential use assessment according to the Cefic concept should support answering only the first question above. The two other questions are addressed in other regulatory stages of the authorisation/restriction process (risk assessment and analysis of alternatives).

In order to answer this first question, 'what-if-the-use-ceases' elements should be considered. Questions to support an assessment and answer "What if the use ceases" should be developed to consider the different areas below. These assessment areas would be integrated in guidance for companies and authorities in order to allow flexibility for periodic amendment and review.

The precise list of questions should be built within a multi-stakeholder group, including authorities, industry (up & down the value chain), NGOs, Commission, Parliament, etc.

Preliminary & non-comprehensive list of impact areas to be assessed (in no specific order), as being essential for health, safety or critical functioning of society:

- Sustainable development: Link to Sustainable Development Goals and Circular Economy
- Climate neutrality/ CO_2 emission reduction
- Energy supply
- Circularity
- Biodiversity and pollution prevention and control
- EU digitalization agenda
- Food and drinking water security, safety and supply
- Transport and mobility
- Innovation and research & development
- Social practices and representation of minority groups
- Education & culture
- Art & aesthetic
- Law & fundamental rights
- Environmental protection & safety
- Health and disease control
- Quality of Life / Safe use (i.e.: effects in cleaning)

Actual criteria and questions should be defined in the preparation of the relevant guidance, with the involvement of stakeholders. An essential use assessment would be expected to respond to these questions, defining the impact of the withdrawal of a substance from a specific use, and the impact this would have on society. A thought starter for an example of a potential assessment matrix is included in Annex 1 to this document.

Outcome of an essential use assessment by the Essential Use Committee

The multi-stakeholder Essential Use Committee would report the outcome of the assessment to the Commission (e.g. in the form of an opinion) including a timeline if/when a reassessment should be done.

As discussed in the Cefic proposal, an Essential Use decision should be:

- **Subject to challenge and review** – after which period of time is a review planned to accommodate changing societal needs and priorities (given the often long timeline for product development and capital investments)?

- **Sensitive to different interpretations of 'Essential Use'** – how will the different evaluations by Member States and regions be ranked, e.g., as a function of geographical differences or socio-economic circumstances?
- **In line with international agreements –** how will the Commission ensure compliance with, for example, WTO agreements?

Conclusion

The advantages of running an assessment as outlined above are as follows:

- The assessment documents are prepared by industry, allowing industry to demonstrate the importance of chemicals to society;
- The application is assessed by an independent multi-stakeholder Essential Use Committee rather than the existing ECHA committees;
- The outcome of this assessment can feed into the authorisation or restriction processes, leading to an improved restriction or authorisation of substances deemed essential.

Annex 1 – Example of matrix for essential use assessment

Essential Use Matrix	Yes/No or score?	Comment
Does the substance have a suitable alternative in this use (considering performance in technical and economic terms, product market requirements, availability of volumes or technical standards)?	Y/N	• If yes, assessment can be stopped for this use (substance in this use could still be authorised under SEA) • If cost of regulatory measure is high, longer derogation due to essential use could be justified.
Possible Industry Sectors where Essential Use could be justified: (Note – responding yes to any single category below is sufficient to justify an Essential Use Assessment)		
Sustainable development: Link to Sustainable Development Goals and Circular Economy	Y/N	If yes - document how
i.e. Would removal of this substance from this use impact the achievement of the UN SDG or circular economy?		
Climate neutrality goals and environmental protection	Y/N	If yes - document how
i.e. Would removal of this substance from this use impact achievement of climate neutrality goals, or negatively impact on environmental protection or conservation?		
Objectives of Sustainable Finance Taxonomy	Y/N	If yes - document how
i.e. Climate change mitigation, climate change adaptation, the sustainable use and protection of water and marine resources, the transition to a circular economy, pollution prevention and control, the protection and restoration of biodiversity and ecosystems		
Energy supply	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact energy supply or security in the EU?		
EU digitalization agenda	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact digitalization in the EU?		
Food and drinking water security and supply	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact on food or potable water supply?		

Transport and mobility	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact transport of people or goods within the EU?		
Health and Disease Control	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact health outcomes, disease treatments, or disease control?		
Innovation, research and development	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact research and innovation activities in the EU?		
Social practices, culture and representation, art and aesthetics	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact cultural practices of EU citizens or minorities, inhibit traditional social practices or negatively impact the production or art and/or culture?		
Law & fundamental rights	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact on the legal or fundamental rights of citizens or minorities of the EU?		
Defence and National Security	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact national security, operational readiness or public safety in the EU?		
European sovereignty		
i.e. Would removal of this use negatively impact the autonomy of Europe and increase its dependence to non-EU countries ?		