

How to introduce the 'Essential Uses' Concept under REACH

According to the Chemicals Strategy for Sustainability, the Commission aims to limit the use of the “*most harmful chemicals*” to so called essential uses only.

Essential Use as a concept is not currently considered in the REACH legal text. The upcoming revision of REACH is an opportunity for the Commission to amend the various processes to work more efficiently and include the concept explicitly. The Commission and Member States have indicated their intention to move in this direction for gaining efficiencies in the REACH processes (restriction/authorisation) while controlling risks to human health and the environment.¹

Prior to including an assessment of Essential Use into the chemical regulation landscape², it is important to consider where this concept will be included, how the assessment will take place, and who will be responsible for ultimately deciding on this assessment.

As pointed out by the Commission in the documents shared with CARACAL, the main application of the Essential Use concept would be under REACH as this is the primary horizontal chemical legislation of the European Union.

Critical aspects to consider when introducing an Essential Use concept into REACH

When introducing an Essential Use concept into REACH, the following elements are critical for industry:

- It must facilitate decision-making on whether or not to continue to authorise / derogate a use of a substance subject to a ban or restriction, in line with the Chemicals Strategy for Sustainability.
- It should be strongly linked to scientific assessment and only implemented where an unacceptable risk is identified or where adequate control cannot be guaranteed.
- It has to be transparent, predictable and proportionate to the identified risk.
- It should be done on a case-by-case analysis of individual uses, without excluding entire industry sectors.
- Essential Use assessments must be
 - subject to challenge and review after a period of time to accommodate changing societal needs and priorities;
 - sensitive to different interpretations of 'Essential Use' in Member States and other regions e.g. as a function of geographical difference or socio-economic circumstances;
 - in line with international agreements, eg. WTO agreements.
- Decisions on Essential Use should be made by a politically accountable body that is empowered to take both decisions and responsibility for these decisions.
- Decision-making has to be transparent and should involve representatives from across the stakeholder community, including industry and civil society, to ensure legitimacy of the process.

¹ Whether the concept of essential use should only be applied to certain priority areas (eg. consumer products) is yet to be defined. At this stage it is assumed it would apply to all type of uses.

² How to incorporate the Essential Use concept from a legal perspective depends on how it finally will be rolled out. In any case a robust legal basis is indispensable.

Setting up an Essential Use Committee

As decisions taken around Essential Use could lead to significant impacts on society, it is important that the body empowered to assess and conclude on Essential Use has the authority and legitimacy to do so. Indications from the Commission, MEPs and other stakeholders are that decisions on Essential Use should be made under a political mandate, measured against specific defined essential use criteria, while taking into account the best scientific advice.

Unlike the ECHA Committees (Risk Assessment Committee and Socio-Economic Assessment Committees) that are primarily scientific and technical in nature and provide an opinion, the Essential Uses Committee needs political legitimacy³.

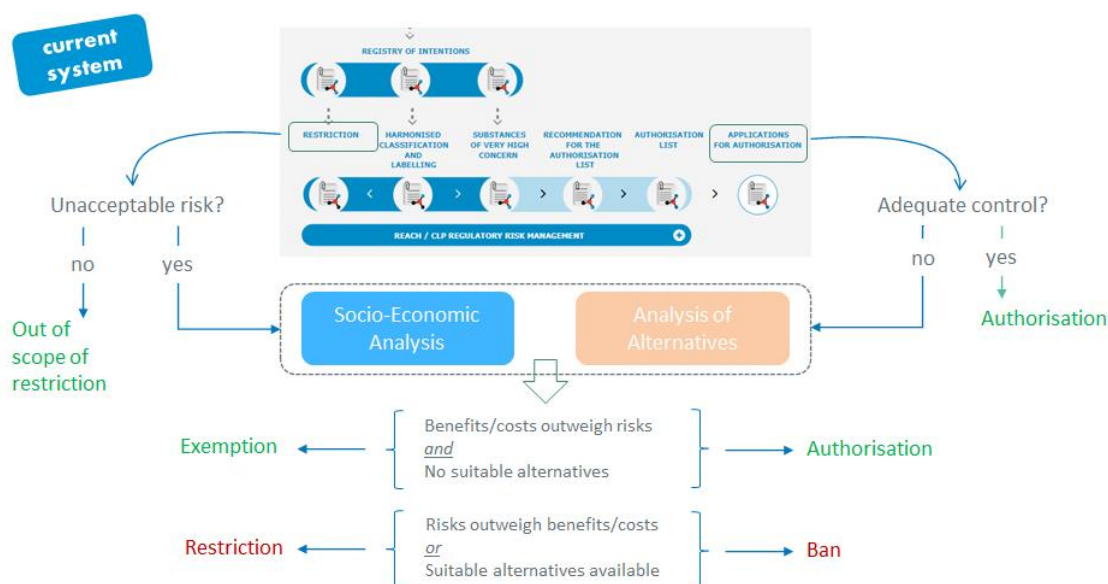
Therefore, we propose that a Committee be set up under the auspices of the Commission. This Essential Uses Committee (EUC) would be made up of representatives from the Commission, European Parliament, Member States, Civil Society and Industry experts. This body would be specifically empowered to assess essential use, and to provide feedback to MS Authorities and the EU Commission.

The Essential Use concept complementing Restriction and Authorisation processes

Restriction and authorisation are the two main regulatory processes for addressing the “*most harmful chemicals*”. As the Essential Use concept is linked to the management of such chemicals, inclusion of the Essential Use Concept complementing the existing Restriction and Authorisation processes could make sense.

Current system

Looking at the current situation, a substance undergoes a review process⁴ to identify if there are grounds for further regulatory action. Where action is necessary, the substance can be prioritised for restriction or authorisation⁵. In this case a socio-economic analysis and analysis of alternatives is performed.



³ RAC and SEAC, while fulfilling critical roles under REACH in the assessment of substances, are technical committees, and do not currently have the relevant mandate/expertise to assess or decide on Essential Use. Already today, with the issue of microplastics in artificial turf, discussions on essential use are to some extent taking place. So far SEAC is unwilling to take a decision with political implications – this shows the need for a political body.

⁴ Called Integrated Regulatory Strategy.

⁵ Other regulatory action may include confirmation of the hazard properties through harmonised classification and labelling (CLH) or actions under other legislation (eg. setting EU-wide occupational exposure limits).

Including the essential use concept

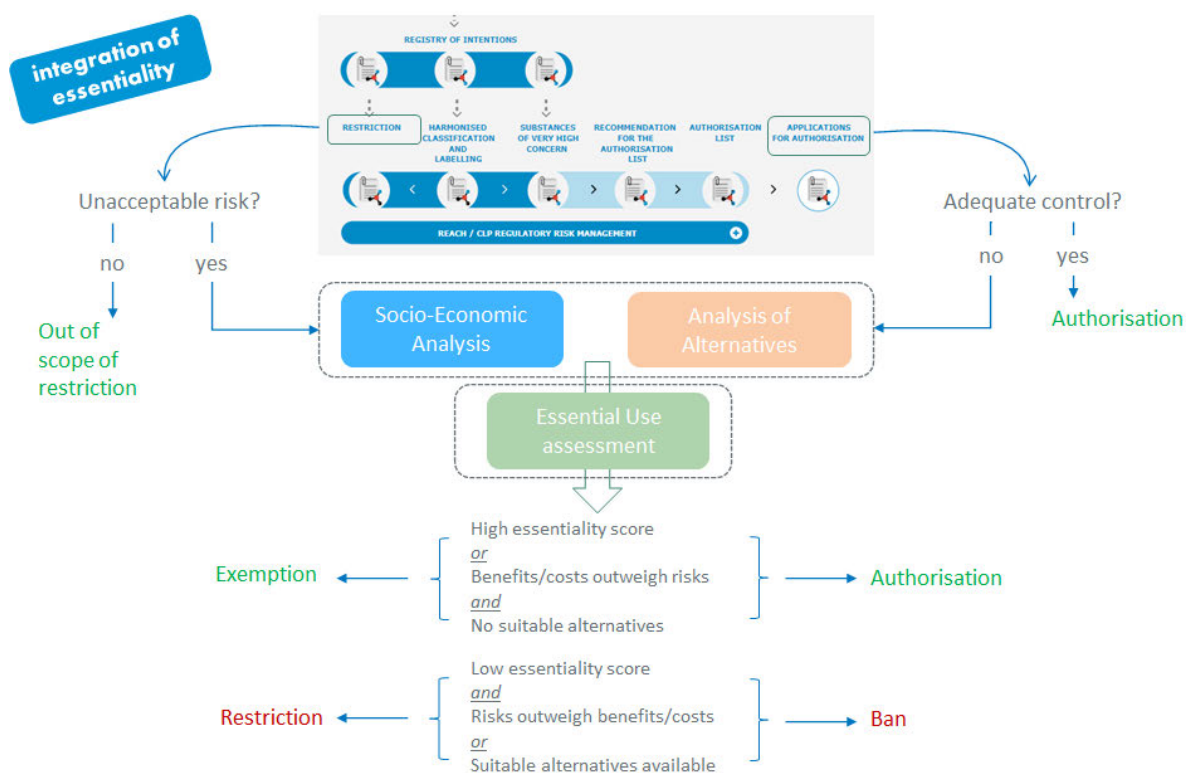
The current system as described above would be largely retained. Inclusion of the Essential Use concept into the Restriction or Authorisation process could add – on a case by case basis – an Essential Use assessment by the Essential Use Committee.

This assessment could complement the current socio-economic analysis and analysis of alternatives:

- Uses that are found to be essential would be derogated / exempted from a ban or restriction if no suitable alternatives exist. Risk management measures can be put in place to limit exposure during manufacturing, use and end-of-life treatment.
- Other uses where the identified risks outweigh the benefits would be restricted/banned, as well as non-essential uses where viable alternatives are available⁶.

How the actual essential use assessment could look is to be further determined.

This could be visualized as follows:



Conclusion

A smart integration of the Essential Use concept into existing REACH procedures can bring a supplementary element to the current system. Together with socioeconomic and availability of alternatives analyses, it can facilitate case specific discussions on whether to derogate a use of a substance subject to a ban or restriction.

This approach would help to promote innovation in those areas identified as key priorities by the Commission in the CSS (including but not limited to climate neutrality, sustainable by design, e-mobility, critical raw materials, EU recovery and resilience).

Cefic looks forward to engaging with the Commission and other stakeholders in working out the details of such an approach.

⁶ Where an 'essential use' assessment shows that a specific use is not essential, this use could still be allowed if the risk is sufficiently controlled or a clear socio-economic benefit is demonstrated.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.1 million jobs and account for 15% of world chemicals production.