



ASMoR considerations on the definition of “essential” in the WSP Essential Use Report

In the discussion on essential use and its reference in the WSP report, the term “essential” plays a central role. However, despite its importance, the report does not conclusively define “essential”. The term is rather explained indirectly by means of two other elements. These are “critical for the functioning of society” and “necessary for health/safety”. Both are equally undefined, instead discussed in a very broad manner and from different angles. This discussion does not always appear to be coherent, and it shows the complexity of the “essential use concept”, which is in ASMoR’s view one of the most important outputs of the report.

How to define “essential”?

In its Chemicals Strategy for Sustainability (CSS), the European Commission has committed to develop criteria for “essential uses” that are relevant for consumers and selected professional users. These criteria should “[...] ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health.”¹ The wording of the CSS on health and safety is relatively generic, however the report goes a step further and introduces a much more narrow frame by limiting this element to “severe health issues”².

On the one hand, the report highlights the relatively wide definition of “health” used by the World Health Organisation that describes health as “*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*”³. On the other hand, the report has difficulties to fully implement this globally agreed and harmonised definition. However, regarding severity it clearly states that it “*should be carefully interpreted to avoid subjectivity and ambiguity, and to ensure that only necessary (not only nice-to-have or beneficial) uses meet the criterion.*”². While this remark highlights the importance of objectivity, it is an interesting example of the complexity the definition “essential” bears. In the struggle to become more objective, the report makes use of two other terms, leaving once again considerable room for subjectivity, namely “nice-to have” and “beneficial”.

¹ Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM(2020) 667 final, p. 10.

² Supporting the Commission in developing an Essential Use Concept, Final Report, p. 48.

³ WHO, Basic Documents, 49th edition, p. 1 (Constitution of the World Health Organization).

In relation to the second criterion on the criticality to society, the report's opening chapter reflects on difficulties to assess this aspect in an objective manner. This was obviously underpinned by stakeholder feedback⁴ and is one of the major concerns of the Alliance for Sustainable Management of Chemical Risk. The stakeholder feedback provides an interesting glimpse into potential future discussions. While some stakeholders afforded high importance to societal elements like cultural heritage, some did not see a role for such aspects amongst the criteria⁵. Considering that there is already no consensus whether cultural heritage is essential or not, the discussion about a specific case for cultural heritage is doomed for deadlock from the beginning.

The aspect of cultural heritage becomes even more relevant in the context of the Lisbon Treaty, the fundamental basis of the European Union. The treaty highlights that “[i]t shall respect its rich cultural and linguistic diversity and shall ensure that Europe's cultural heritage is safeguarded and enhanced.”⁶ Based on this, one could argue that cultural heritage is indisputably essential, and this means that such a discussion within the context of chemicals legislation is out of place. Independently of how one may interpret this part of the Lisbon Treaty, in any case it clearly shows the significant political dimension of the discussion on “essential” going back to the very core of our societal contracts.

The complexity mentioned here is just one example of the difficult terms and discussions that the proposed definition of the essential use criteria will raise.

A closer look at the case studies

A very interesting part of the report is appendix B with its seven case studies. The authors analysed examples from the past and tried to apply the EUC to them. While, in principle, all examples are substances used in different applications, the conclusions are relatively diverse and underline the complexity of defining “essential” in practice. While the authors tried to apply the framework of a definition of the EUC to cases in a very systematic manner, ASMoR members are of the opinion that some answers are only a starting point for a more developed discussion around the term “essential”.

One of the examples addresses lead in alloys under the Restriction of Hazardous Substances (RoHS) Directive⁷. The substance clearly falls within the definition of most harmful chemicals (MHC), while at the same time is crucial for the safety of space craft. This is also the reason for a derogation under RoHS, which regulates waste management. In the EUC report, something interesting takes place in the assessment of the criticality for society and waste management. However, before we look at this, we must first return to another part of the study, namely the following:

“The essential use concept should not in this case assess whether society needs roller coasters (the product), but whether one of the most harmful chemicals provides a technical function that

⁴ Supporting the Commission in developing an Essential Use Concept, Final Report, p. 50.

⁵ Supporting the Commission in developing an Essential Use Concept, Final Report, p. 51.

⁶ Treaty of Lisbon, article 3 paragraph 2.

⁷ Supporting the Commission in developing an Essential Use Concept, Final Report, p. B36 ff.

would be needed for safety reasons in a component of the roller coaster, and therefore the use might be necessary for health/safety.”⁸

This approach – let’s call it the roller-coaster-approach or RCA – of restricting the assessment on the immediate function of the observed MHC and context, and not on the principal question on whether a product is needed or not, in matters of administrative efficiency, makes sense. However, in the lead case, the report seems to leave this stringent approach behind by recognising that *“[i]n making such a political judgment, the aims and objectives of circular economy would need to be considered, including the question under what conditions and with what quality requirements the recycling should be.”* For example, to understand the quality requirements of a recycled material, you first need to understand the supply chain and the role that the substance plays in products. Someone will have to decide what quality level is sufficient at each stage of the production/supply chain. In this regard, we do not see how one could consequently stick to the RCA in practice. Furthermore, the study highlights the need for political judgement, which will eventually need a more thorough assessment of the wider circumstances, and not only the immediate use or function of an MHC in a product.

The limitation of the RCA manifests also in another example on DEHP in medical devices⁹, when stating: *“For instance, the use of [an MHC] might not be considered ‘critical/necessary’ when they are used in shops but could be considered ‘critical/necessary’ when used in emergency units during hospital operations.”* Here it becomes evident that someone will need to decide, under which circumstances and while having the same use or function, how an MHC can be essential. Developing this thought, one can also question if certain types of operations are not essential, e.g., purely esthetic surgeries, surgeries on animals, or a voluntary cesarean.

Challenges in practice

Overall, the case studies give a fair overview of a variety of relevant elements and challenges in practice. The analysis of the derogation process under RoHS shows very well that the administration behind the assessments is significant, and due to the specific and/or technical nature data collection is not trivial. Worrying is the finding that such heavy processes are *“possibly discouraging SME engagement”,* what *“introduces some uncertainty about completeness and correctness of the information assessed and also contributes to the prolongation of the process”¹⁰.* ASMoR is concerned that this effect would push SMEs even further away from relevant decision-making processes, lower the acceptance of regulatory interventions, and make enforcement more burdensome.

The report suggests that clear criteria for EUC can encourage innovation in safe and sustainable chemicals to be used as alternatives to MHCs. This claim, at this stage, is not convincing. Respectively, it cannot be assessed due to the lack of a clear definition of “essential”. With the same legitimacy as considering EUC as an innovation driver, it can be also qualified as the

⁸ Supporting the Commission in developing an Essential Use Concept, Final Report, p. 36.

⁹ Supporting the Commission in developing an Essential Use Concept, Final Report, p. B51 ff.

¹⁰ Supporting the Commission in developing an Essential Use Concept, Final Report, p. B43.

opposite. Finally, the impact will depend on the concrete criteria and circumstances (e.g., company size, product, available alternatives, costs etc.).

For ASMoR, it is certainly too early to see the EUC as a potential driver for innovation. To be such a tool, it needs to be predictable and transparent. The criteria need to be understandable and not interwoven in a complex network of policy objectives like quality criteria for recycling, regulatory requirements like compliance with regulations for spacecrafts, or even more complex elements like cultural heritage or other ethical dimensions. As outlined in our recent paper¹¹ on the likelihood of regrettable substitution being promoted by the Essential Use Concept, we believe that research and innovation may be driven into inappropriate directions.

ASMoR shares the view of the report in relation to *“the effects of highly segmented exemptions leaving only few and very specialised uses available. When only niche uses are allowed, the production as a whole might become unattractive, leading to loss of production capacity in Europe for uses that are considered “essential””*¹². This effect would certainly be a critical blow to numerous SMEs, but also to larger competitors to the extent that niche applications would become economically irrational. This would come with the loss of EU competitiveness globally.

Conclusion

The report is an important contribution to the discussion on “essential”. It gives some orientation what could be relevant and what not for a more advanced discussion on the EUC. However, the report is still too theoretical to be used as a basis for regulatory intervention. While it could be clearly used as an instrument to define what is indisputably essential – e.g., something that is need for cancer treatment (= severe health criteria) or to keep water clean (=necessary for functioning of society) – it is very limited in the other sense, namely for a sound identification of non-essential. From an ASMoR perspective, it too easily dismisses uses that are beneficial. Therefore, ASMoR takes this opportunity to reiterate its position¹³ that the EUC can only be appropriately used when alongside the concept of exemptions for safe uses.

The report systematically approaches key elements around essentiality, but at the same time it lays bare several key questions. It does not offer a satisfactory answer to critical questions; for example, how to align the definition for “health” with the international definition of the WHO, or how to consider societal foundations like the Lisbon Treaty. Considering the potential that a poorly applied EUC could significantly harm the EU’s global competitiveness and innovation, ASMoR would appreciate a more thorough discussion process and refinement of the concepts included in the report.

¹¹ [ASMoR-Position-Paper-on-regrettable-substitution---March-2022-version-1646930044.pdf](#)

¹² Supporting the Commission in developing an Essential Use Concept, Final Report, p. B46.

¹³ [ASMoR Reaction-to-WSP-EUC-Study Appendix-C-1682599754.pdf](#)

ANNEX: List of Members of the ASMoR

