



ASMoR considerations on exemptions and derogations in the context of the Essential Use Concept (EUC) development

To encourage innovation, a stable and predictive regulatory frame must be ensured. Exemptions would better support innovation, safety and the green transition compared with the by default application of derogations

EUC must not be linked to hazards and should only be applied in a targeted manner to ensure the achievement of the Green Deal objectives.

Exemptions and/or derogations must be put in place in the most relevant and efficient way. Clearly established mechanisms and standards must be set up.

ASMoR welcomes that the WSP Report “Supporting the Commission in developing an Essential Use Concept”, includes Appendix C “Stakeholder feedback on only applying the essential use concept for uses which are not ‘safe’”. However, we fear that the Appendix neither fully reflects facts nor contributions made by ASMoR and its Members during the consultation. As the debate on the Essential Use Concept (EUC) is advancing, and in addition to the position paper ASMoR has already published on the topic (available [here](#)), we would like to bring clarity on the difference between exemptions and derogations in the framework of the development of the EUC and highlight that we have concerns that introducing the EUC could adversely affect regulatory efficiency and negatively impact safe uses of articles and overall sustainability¹, and we encourage the Commission and Member States to carefully consider the need for the EUC.

Based on how the concepts of exemption and derogation have been used in the WSP report, we deem it crucial that the differences between the two are well understood, as derogation is not synonymous with exemptions, but they have often been misused to mean the same thing.

Exemptions are not derogations and could better support innovation, safety and the green transition

- Exemptions are part of an upfront process and result in the explicit and total exclusion from the scope of a specific rule or provision. Typically, exempted technologies or industrial processes are listed as a substantive element of the statutory act.
- Derogations are temporary waivers from general requirements or provisions, which are granted, under certain circumstances, according to an established regulatory or administrative framework. They are generally defined in the legal text and implemented only after the entry into application of a regulation. Applying for, assessing and granting derogations

¹ [ASMoR position paper on EUC Scope of Application](#)

require significant time and effort both from competent authorities and industry. Clearly established mechanisms and standards must be in place.

As such we would highlight that derogations **do not always grant a predictable regulatory environment as they do not provide the basis needed to foster and invest in innovation**. Derogation decisions are temporary and taken by the regulators. This significantly erodes property rights. Derogation timeframes are moreover often not in line with investment cycles. In addition, at present, derogation decisions at EU-level are taken without fully abiding by the principles of good regulation and administration. There is no full respect of uniform standards for excellence and impartiality in regulatory science, and there is partial understanding of the indirect impacts of risk management measures on the investment decisions by innovators and, more generally, on the value chains.

Overall, as suggested by ERIF in its report², the EUC concept could be a barrier to innovation. The concept is value-loaded and implies judgment for which is difficult to establish standards and scientific, objective bases. Accordingly, it increases the risk of administrative discretion while appeal mechanisms are currently insufficient. Companies would be forced to engage in disproportionate “Defensive R&D”, which diverts resources from investment in innovative, more sustainable and safer technologies.

The loss of technologies, along with loss of access to markets and regulatory uncertainty deriving from the discretion of the “essentiality” concept, will lead to the relocation of capital outside of the EU. Within this context, it must be noted also that derogations usually constitute a barrier for SMEs to ensure continuity on the market, as they do not have the resources needed to undertake the necessary steps to be granted one.

Due to the reasons outlined above, we believe that the extensive use of derogations, especially if associated with the non-fully mature and still evolving concept of essentiality, would conflict with the overall objectives to reduce the regulatory burden and improve the efficiency of the EU chemical legislative framework. From a policy perspective, benefits from banning hazardous substances are insufficiently investigated, and risk-risk trade-offs are underestimated. This undermines the achievement of the Green Deal objectives.

With regards to the use of the Essential Use Concept (EUC), we would therefore recommend **ensuring that the EUC is not automatically linked to hazard classification**, but only applied in a targeted manner, such that the burdensome essentiality assessment is only triggered where justified. This will reduce the workload for both authorities and industry and will enhance regulatory efficiency.

Thus, where derogations procedures are used, the criteria used for issuing them must be set out clearly, along with the legal basis for - and legal certainty provided by such decisions.

ASMoR members invite the Commission to keep in mind the difference between exemption and derogation and to ensure a predictable regulatory environment that incentivises innovation. The application of the EUC and its link to hazard will undermine the achievement of the Green Deal objectives.

² See ERIF dedicated webpage at www.eriforum.eu/NRPs