

ESSENTIAL USE CONCEPT

A.I.S.E. comments following CARACAL
45 discussion, 6 July 2022

15 July 2022

A.I.S.E. thanks the European Commission for the comprehensive discussion on the reform of authorisation and restriction under REACH in CARACAL. A.I.S.E. welcomes mechanisms to enable derogations - especially from purely hazard-based generic restrictions, to avoid unintended negative consequences. A.I.S.E. wishes to reaffirm our position that a derogation system based on safe use is more suitable to achieve the goals of the Green Transition while protecting the safety of society and the environment.

The concept of essential use remains vague, undefined and at times conflicting. The general principle “necessary for health, safety or critical for the functioning of society” was established under the Montreal Protocol specifically for ozone-depleting substances and this was used as a starting point. Nonetheless even the definition mentions cultural and intellectual aspects in assessing criticality for the functioning of society, reflecting the importance of a holistic view. The Commission has acknowledged that the definition requires much more detailed elaboration under REACH, as noted in CA/45/2022.

The Chemicals Strategy for Sustainability states that “*criteria for essential uses [...] will in particular take into consideration the needs for achieving the green and digital transition*”. These will include climate, circularity and environmental impacts, but also innovation, competitiveness, a healthy internal market and strategic autonomy, to name just a few.

The Commission has stated on numerous occasions that essentiality will be decided based on the essential role the substance plays within the final product, which suggests a scientific judgment. However, arbitrarily deciding whether a substance is critical for health, safety or functioning of society is a political decision. We fear that a narrow definition of “political” essentiality for an otherwise scientifically essential substance could result in a loss of product performance and unintended negative compensating behaviours from consumers.

An inclusive view of both concepts is necessary, as reflected in the Commission’s Better Regulation toolbox and defined by the World Health Organisation as “*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*”

Basing derogation decisions on essential use implies a shift away from a science-based approach to safe use to a political judgment, which will not speed up nor simplify decision-making. It will remove safe-effective products from the market without acknowledging the differences between sectors.

A.I.S.E. thanks the Commission for taking these remarks into consideration and looks forward to further discussion of its planned criteria.

