Beryllium Science & Technology Association

Brussels, 05 June 2023

Comments on the Essential Use Concept (EUC)
BeST feedback to the Report prepared by WSP

Key messages:

- *The report confirms that the essential use concept (EUC) is too complex, not fit for purpose and will not contribute to the achievement of the declared objectives of streamlining chemicals legislation and phasing out of most harmful chemicals. A reconsideration of the concept is therefore necessary.*

- *The criteria referenced to determine essentiality, namely essential for health, safety and critical for the functioning of the society, are vague, subjective, and subject to interpretation. The report confirms the overwhelming challenge in identifying clear, consistent, and agreeable essentiality criteria.*

- *The report places disproportionate burden on industry stakeholders to prove essentiality.*

- *The assessment of the safe use of a substance should always be the first step of the process. Where the use of a substance is proven to be safe, the essentiality assessment should be irrelevant.*

Conclusions:
The content of the report provided by the external consultant, the feedback and comments from industry stakeholders, and the experience from the Montreal Protocol, clearly underline that the concept of essential use is not well understood and controversial, and a reconsideration of the entire concept is needed.

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BeST has thoroughly assessed and analysed the report prepared by the consultant WSP entitled "Supporting the Commission in developing an essential use concept". The present position statement highlights BeST's main concerns and recommendations:

- ***The report confirms that the essential use concept (EUC) is too complex, not fit for purpose and will not contribute to the achievement of the declared objectives of streamlining chemicals legislation and phasing out of most harmful chemicals. A reconsideration of the concept is therefore necessary.***

The content of the report prepared by WSP, coupled with the lessons learnt from the Montreal Protocol and the feedback provided by stakeholders, clearly demonstrates that the concept is not fit for purpose and will not contribute to the declared objective of phasing out the use of the most harmful chemicals. On the contrary, the implementation of the concept will entail longer regulatory processes, complex bureaucracy, increased use of resources by competent authorities and industry, as well as negative unintended consequences on industry and societal well-being due mainly to regrettable substitution.

Indeed, in the report, the external consultant warns against the implementation of the EUC in a sweeping manner due to the high level of uncertainty this would cause. For this reason, a case-by-case assessment is proposed by the consultant. This confirms that the concept will not achieve the level of simplicity and streamlining desired. On the contrary, complexities and challenges associated with the implementation of the concept will negatively impact the content and length of regulatory procedures.

Moreover, the consultant highlights the need to review existing product and substance-specific EU legislation to implement the EUC as well as the need for additional legislation-specific guidance to address the uncertainty and confusion associated with the concept. This means that additional regulatory proposals will be necessary in clear contrast with the Better Regulation and the One in, One Out principles.

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The above are only a few of the numerous challenges and issues identified by the consultant in its report.

- ***The criteria referenced to determine essentiality, namely essential for health, safety and critical for the functioning of the society, are vague, subjective, and*** *subject to interpretation****. The report confirms the overwhelming challenge in identifying clear, consistent, and agreeable essentiality criteria.***

According to the Chemicals Strategy for Sustainability (CSS), 'essential' is intended as necessary for health, safety and/or critical for the functioning of society where no alternatives acceptable from the standpoint of environment and health exist. While the consultant has recommended that such criteria be retained, the difficulties in finding the right balance between granularity, flexibility and stringency were reiterated throughout the report. The consultant also stressed the importance of foreseeing a review clause for essentiality despite being unable to determine the best timeframe for the review exercise.

Indeed, the concept of essentiality is *subject to interpretation*, subjective, and prone to evolve over time. It is consequently impossible to know today what will be essential tomorrow. It will also be impossible to reverse the effects of the EUC once the use of a substance, initially considered as non-essential and later as essential, is phased out. This will inevitably render EU value chains vulnerable and dependent on third country producers of the products for which the use has been phased out.

It is also important to note that the use of the substance considered to be 'essential' is directly connected to the use of the substance not considered essential. Indeed, it is very unlikely that industry will be able to provide strategic and essential applications in a costly manner if non-essential uses are phased out. This will not be economically and technically feasible and will potentially result in the relocation of industry outside Europe and with an increased dependency of the EU on third countries.

Finally, no indication is provided on the assessing authority. Indeed, the implementation of the EUC will require the identification of a competent authority at EU level who will be responsible for the assessment of essentiality. This will either increase the workload of an existing authority or will result in the creation of a new ad-hoc authority with consequent use of human and financial resources. Moreover, it will be important to guarantee that the competent authority operates in full transparency, is objective and has the necessary experience and expertise to conduct the assessments.

All the above confirm the difficulties in applying the EUC in a clear, transparent and consistent manner. There is a risk of arbitrary and subjective decisions with subsequent appeal actions. This will result in regulatory uncertainty, and dissatisfaction.

- ***The report places disproportionate burden on industry stakeholders to prove essentiality.***

According to the report, the burden of proof of essentiality would entirely fall upon industry. Despite the current lack of clarity in reference to the criteria for essentiality, the identification of the assessing authority and the documentation needed, the procedure already appears to be unnecessarily complex and burdensome for industry.

In addition to proving essentiality in the frame of health and safety, or criticality for society, industry will also need to assess alternatives (AoA) which is alone already a very complex, lengthy and costly process which requires a complete impact assessment. Moreover, the focus on non-comparable hazards also impedes the AoA. A less hazardous substance (with respect to hazard class, etc.) could still pose a higher risk due to a higher exposure (risk = hazard x exposure). As an example, a substance may be classified hazardous under the CLP by inhalation but feature low exposure and very limited risk that is efficiently and effectively addressed via risk management measures. Consequently, quantitative comparison is only possible by considering risk. Additional criteria such as loss of performance, contribution to the EU's green deal objectives, economic and technical feasibility, should be included. In the specific case of loss of performance, it is important to clearly identify the level of loss of performance that would be acceptable, and this is inevitably connected to the use of the substance and its contribution to the performance of the end application.

Moreover, industry will need to prove minimisation of the essential use, decrease in exposure, emissions and risks, as well as proof of appropriate effort to substitute the essential use.

The above demonstrates the clearly disproportionate burden on industry which will be detrimental to EU industry, severely curtailing its competitiveness.

- ***The assessment of the safe use of a substance should always be the first step of the process. Where the use of a substance is proven to be safe, the essentiality assessment should be irrelevant.***

The concept, as currently described, represents a departure from the current risk-based regulatory approach and will erase decades of risk management assessments and measures already implemented at EU level. For this reason, the EUC should be coupled with the safe use concept.

The safe use concept, as introduced by the EC in the CARACAL Document CA/03/2022 on REACH Authorisation and Restriction reform, should constitute the initial step of the stepwise approach proposed by the consultant, were the EUC be developed and implemented.

Indeed, the EU chemicals legislation has already assessed many substances and concluded that the use of these substances is safe for consumers and professionals.

Considering this, derogations for safe use should be considered as the initial step. In the case of a safe use of a substance, the question of essentiality should become irrelevant.

This would also be in line with EU regulatory principles which state that restrictive requirements must not go further than the necessary measures to achieve their objective.

Conclusions

The content of the report provided by the external consultant, the feedback and comments from industry stakeholders, and the experience from the Montreal Protocol, clearly underline that the concept of essential use is not well understood and controversial, and a reconsideration of the entire concept is needed.

The EUC, as currently theorised, will require many different capabilities, will result in increased burden on authorities and industry, and will be a long and complex procedure with limited to no added value.

The objective of simplifying regulatory procedures, i.e. REACH, will not be achieved unless an overly simplistic system is put in place that will drive industry and innovation outside the EU, increase the dependency of the EU supply chains on third countries, favour regrettable substitution and jeopardise the EU's Green Deal objectives.

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About BeST

The Beryllium Science and Technology Association (BeST) represents the manufacturers, suppliers and users of beryllium metal, beryllium containing alloys and beryllium oxide ceramics in the EU market. BeST has the objective of promoting sound policies, regulations, science and actions related to the use of beryllium and to serve as an expert resource for the international community on the benefits and criticality of beryllium applications.