Beryllium Science & Technology Association

Brussels, 11 March 2022

Comments on the Essential Use Concept (EUC)
BeST feedback to the workshop and to the background document

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.

Key messages

- *A holistic assessment of the EUC in line with the overall reform of the EU chemicals framework, including the extension of the generic risk approach, the REACH review, and the review of sectoral legislation, is necessary. This assessment must be coupled with a proper impact assessment of the policy options evaluated, both individually and jointly.*

- *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.*

- *The criteria referenced to determine essentiality, namely essential for health, safety and critical for the functioning of the society, are vague, subjective and dynamic by nature. Clear and consistent definitions that allow for certainty as well as flexibility would therefore be needed for the EUC to be implemented in a feasible manner. It will prove difficult, however, to identify and ultimately agree on these criteria, as demonstrated by past experiences (The Montreal Protocol).*

- *Decoupling the substance use from its contribution to the performance of the end product, article or service would translate in an overly simplistic assessment resulting in phasing out of strategic and critical substances, unintended consequences and regrettable substitution, with negative impact on the achievement of the EU's Green Deal objectives as well as on the general wellbeing of society.*

- *Where the use of a substance is proven to be safe, the essentiality assessment should be irrelevant*.

- *The potential review clause should be applied to both essential and non-essential uses. Additionally, an appeal process should be envisaged.*

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

Comments on the structural elements of the Essential Use Concept

- ***A holistic assessment of the EUC in line with the overall reform of the EU chemicals framework is necessary. This assessment must be coupled with a proper impact assessment of the policy options evaluated, both individually and jointly.***

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The EUC and other policy measures stemming from the CSS are currently at a very initial stage of discussion characterised by general uncertainty in reference to the elements of the policy measures considered, i.e. definitions, criteria, scope of application, and to their combined implementation, i.e. the coordination and combined impact of the EUS, the GRA, REACH review, etc.

It is extremely difficult for stakeholders to maintain an overview of the different ongoing processes and provide feedback on how to integrate these parallel debates in the frame of EU's chemicals legislation, especially in the extremely short deadlines provided.

- ***The EUC represents a departure from the current risk-based and will result in tabula rasa of decades of risk management measures implemented at EU level.***

By implementing the concept as described in the CSS, the EC will deviate from the current risk-based approach. The mere presence of a hazardous substance in a process or product should not automatically be associated with the default occurrence of a risk threatening human health or the environment.

The EUC, as currently envisaged, does not constitute a proportionate approach and will substantially undo all the work and assessments of substances already conducted by EU and Member State authorities to address exposure via the implementation of risk management measures that have proven to be efficient and effective.

- ***The experience gained from the Montreal Protocol has already clearly demonstrated the complexity and difficulties associated with the implementation of the EUS.***

The EUC, as theorised in the CSS, derives from the similar concept developed in the frame of the Montreal Protocol, implemented to a limited extent due its complexity and lengthy process. Moreover, the limited examples of EUC in existing legislation shows that it was used on an ad hoc basis where there was a concrete exposure-based concern and was not, therefore, driven by hazard alone.

- ***The criteria referenced to determine essentiality, namely essential for health, safety and critical for the functioning of the society, are vague. subjective and dynamic by nature. Clear and consistent definitions that allow for certainty as well as flexibility would therefore be needed for the EUC to be implemented in a feasible manner. It will prove difficult, however, to identify and ultimately agree on these criteria.***

The concept of essentiality is by nature dynamic, 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.

Similarly, health, safety and criticality for the functioning of the society, are broad, vague and subjective concepts that vary over time and often differ across Member States.

Considering the above, it is very difficult to define key aspects of the EUC that would ensure certainty, consistency and transparency as well as the needed flexibility to respond to new and emerging societal needs.

- ***Decoupling the substance use from its contribution to the performance of the end product, article or service would translate in an overly simplistic assessment resulting in phasing out of strategic and***

critical substances, unintended consequences and regrettable substitution with negative impact on the achievement of the EU's Green Deal objectives as well as on the general wellbeing of society.

According to the background document and to the statements made in the workshop, the EUC will be based on the technical function of a substance decoupled from the end application. Technical function is described as the role the substance fulfils when it is used, i.e. what it actually does as such in a process or what it actually does in an article.

It is unclear how this will be applied in practice. The use of a substance in a specific product is generally connected to the intrinsic properties of the substance and their contribution to the performance of the end product. By limiting the assessment of essentiality to the use of the substance, regardless of the application, the EUC would encourage the phasing out and regrettable substitution of the use of a substance that plays a pivotal role in the performance of the end product.

- ***The assessment of alternatives (AoA) from the standpoint of the environment and health would result in generic and incomplete assessments welcoming regrettable substitution. Additional criteria such as loss of performance, contribution to the EU's Green Deal objectives, economic and technical feasibility, etc. should also be included.***

An AoA is a complex, lengthy and costly process which requires a complete impact assessment. Moreover, an AoA from the sole standpoint of the environment and health is insufficient and would result in generic and incomplete assessments. 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.

Finally, 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 efficiently and effectively addressed via risk management measures. Consequently, quantitative comparison is only possible by considering risk.

<u>Comments on the stepwise approach described by the external consultant</u>

- ***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 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.

- ***The inclusion of a review clause to address technical progress or wider societal needs could be used as an instrument to support flexibility. However, the review should be applied to both essential and non-essential uses and developed in such a way to support certainty in the industrial sector and encourage investments. An appeal process should also be envisaged.***

As mentioned above, 'essentiality' is by nature dynamic and the review clause could allow for flexibility. The clause, however, should be applied to both essential and non-essential uses. Indeed, emerging societal needs could justify the need to review a non-essential use similarly to an essential use.

Moreover, the clause should be developed in a way that guarantees certainty, i.e. by avoiding periodic reviews in short time-frames, and avoids hampering investment and innovation.

Finally, an appeal process should be envisaged to challenge the essentiality assessment.

Additional comments

- ***Thorough socio-economic impact assessments should always be implemented as one of the initial steps of any policy proposal impacting the use of a substance.***

The potential implementation of the EUC according to the process – Safe Use, Essentiality/Criticality assessment and AoA – should always be coupled with the development of a socio-economic impact assessment considering the impact of phasing out the use of a substance.

It is 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 result in the relocation of industry outside Europe and with an increased dependency of the EU on third countries.

- ***It will be necessary to identify a competent authority at EU level tasked with implementing the EUC.***

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.

Additionally, 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.

- **The comments in the chat and clear indication of the criteria used to select participants for the breakout groups should be included in the workshop report.**

In conjunction with other stakeholders, BeST encourages Wood to:

- Include the overwhelming number of comments provided in the chat in the official report of the workshop (in anonymous form), given the extensive and substantial impact the concept will

potentially have on the sector, the relevant content of the parallel discussions occurring in the chat and that many participants were not invited to the breakout sessions.

- Disclose the criteria used to select participants to attend the breakout sessions in compliance with transparency standards as well as the list of selected stakeholders to allow participants to assess that their sectors were adequately represented at the breakout sessions.

Conclusions

The description of the concept by the external consultant, the comments from participants, 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 current understanding of the concept is insufficient and needs further reflection, consultation and clarification to ensure transparency and allow a better evaluation of the potential benefits and/or drawbacks of the EUC and its implementation, along with the other policy measures enshrined in the CSS.

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/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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