Beryllium Science & Technology Association

Brussels, 01 July 2022

BeST comments to the GRA final workshop

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 safe use of beryllium and to serve as an expert resource for the international community on the benefits and criticality of beryllium applications. It is also the objective of BeST to promote good practices in the workplace to protect workers handling beryllium containing materials.

Introduction

The extended application of the Generic Risk management Approach (GRA), announced in the Chemicals Strategy for Sustainability (CSS), would allow the European Commission to propose regulatory action targeting chemicals/substances on the sole basis of their intrinsic hazard properties, **independently from exposure and risk**. The declared objective of the GRA is to accelerate the substitution of the most harmful chemicals/substances according to their CLP classification.

Comments

Considering the discussions during the final stakeholder workshop held on 27 June 2022 and the background document disclosed to stakeholders on 24 June 2022, BeST submits the following key messages:

- **A risk-based approach constitutes a more efficient streamlining tool –** The extension of the GRA represents a departure from the current risk-based regulatory approach which will erase decades of risk management assessments and measures already implemented at EU level as well as result in duplication of efforts for both industry and authorities. **A real risk-based approach is essential: Risk = Hazard x Exposure.**

- **Safe use concept to be implemented in the GRA –** It is extremely concerning that stakeholders' views on the Safe Use Concept have been completely disregarded by policymakers as evidenced by the CARACAL paper Doc. CA/45/2022 of 22 June 2022. Over the years, industry has implemented effective and efficient risk management measures allowing the **safe use** of hazardous materials in strategic and commercial applications. **A substance proven to be safe should not fall in the scope of the GRA**.

- **Need for a scientific and transparent validation process –** The overall approach enshrined in the background document, full of assumptions and uncertainties, lacks the necessary detail to allow stakeholders to assess the approach implemented by the external consultant to assess the impact of the GRA.

- **Inclusion of clear definitions –** Clear and specific definitions for 'most harmful chemicals/materials', and 'consumer, industrial and professional uses' are necessary to allow the assessment of the impact of the extension of the GRA and guarantee legal and regulatory certainty.

- **Coordination with other regulatory policies -** A coordinated framework, streamlining resources and considering parallel regulatory actions, **specifically the Essential Use Concept and the Safe Use Concept,** is of pivotal importance. The European Commission's decision-making should be supported by RMOAs to determine the most appropriate risk management option for a given substance instead of a sweeping implementation of the GRA.

Conclusions

BeST raises concerns, once again, on the limited time given to stakeholders to participate in the consultation process. Stakeholders received the background document for the workshop **less than one working day** before the date of the workshop. Additionally, the deadline for feedback to the workshop was extremely short – **less than five working days**. It is impossible, in these conditions, for stakeholders to have a meaningful and constructive dialogue with policymakers which will result in overly simplistic regulatory proposals, detrimental to the competitiveness of EU industry and to the achievement of the EU Green Deal objectives.

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Annex I

Socio-economic costs and benefits

1. *Is the overall approach to estimating the scale of economic costs clear and logical, given the current uncertainties?*

The background document and the information shared at the workshop lack the necessary detail to allow stakeholders to efficiently assess the overall approach implemented by the external consultant. Additionally, the scientific basis of the study is questionable considering the number of uncertainties and assumptions put forward by the external consultant.

2. Do the anticipated effects e.g., number of substances and affected tonnages, appear realistic, based on any preparatory analysis you have undertaken?

The anticipated effects appear underestimated.

3. Have you identified – or are you able to identify – any key product functionalities that may be affected by the GRA? What would be the effects? Could examples be provided?

The sweeping application of the GRA does not consider whether there is actual exposure and risks. The GRA will ultimately result in a general ban of uses already established as safe with a ripple effect along the value chain, impacting all sectors.

4. What further information on potential implementation scenarios or substance prioritisation criteria, for example, would be helpful?

In terms of substance prioritisation, substances for which risk management measures have been implemented proving the safe use of the substance should not be targeted. Risk-based considerations (Risk = Hazard x Exposure) should be included in the priortisation exercise. Moreover, we caution against targeting strategically important substances, including critical raw materials, due to their high importance for the EU economy and societal wellbeing.

5. What advantages may occur as a result of the GRA? For example, greater clarity on regulatory decision making, stronger incentives for innovation, collaboration? Would this result in any business opportunities?

The declared objectives of the GRA, phasing out of the most harmful chemicals and streamlining of regulatory processes, will not be achieved. Regulatory tools already exist and are effective in addressing the risk associated with so-called most harmful substances. Moreover, the implementation of sweeping restrictions with derogations only for essential uses will lead to an extremely granular and burdensome assessment.

6. What about specific costs and benefits to Small and Medium Enterprises (SMEs)? Do they require specific support and/or mitigation measures?

Yes, SMEs require support and mitigation measures.

Human Health and Environmental Benefits

1. Is the overall approach to estimating the human health and environmental impacts suitable or an alternative method should have been used?

The background document and the information shared at the workshop lack the necessary detail to allow stakeholders to efficiently assess the overall approach implemented by the external consultant.

2. Are the population attributable fractions used for the comparison — 1%, 2.5% and 10% — reasonable? Should the central PAF be lower or higher? Are the lower and upper bounds adequate to capture uncertainty?

3. For the evaluation of the benefits of restricting EDs with human health effects, have the right health outcomes been selected? What other health outcomes should be considered?

4. For the hazard class STOT, what health outcomes should be considered for the evaluation?

Hazard class STOT should not be considered.

5. For respiratory sensitisers, the team is considering asthma as the most relevant health outcome? Should we consider any other health outcome?

No other health outcomes should be considered.