

## BeST's comments on the Generic Risk Management Approach

### 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, in order to protect workers handling beryllium containing materials.

### Introduction

VVA consortium, mandated by the European Commission, has launched a survey on the impact of the extension of the Generic Risk Approach (GRA) in the frame of the ongoing review of REACH. The GRA 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.

### Comments

As a preliminary comment, BeST underlines that many of the questions included in the survey were poorly written, confusing, and biased. Consequently, responses were provided exclusively to questions of relevance where the text was clear and not subject to interpretation by the responder.

BeST raises the following several serious concerns:

- 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. Indeed, 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 risk-based approach should therefore be preferred, confirming that a substance proven to be safe should not fall in the scope of the GRA.
- The concept of derogation for minimal exposure, conditional on the demonstration of minimal/no exposure/emissions throughout the whole life cycle of the substance and on the demonstration of no available and acceptable alternatives – as described by VVA - is disproportionate and exceeds the declared regulatory objective of the GRA, notably protection of human health and of the environment during consumer use and during certain professional uses still to be determined. Considering this, any exposure assessment should be limited to the use phase and should consider the implemented risk management measures. The safe use concept adequately addresses both above requirements and should therefore be preferred. Additionally, where the use of a substance is proven safe, the availability of alternatives is irrelevant.
- It is concerning that new concepts with potentially generalised and substantial impact on EU strategic value chains are introduced, for the first time, in the frame of surveys launched by external consultants in absence of clear definitions and of prior socio-economic impact assessments.
- 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 stresses, once again, the need for a coherent and balanced approach. The regulatory actions stemming from the CSS should be developed in coordinated manner, coupled with proper impact assessments to determine benefits and drawbacks. To meet the green deal challenges, we will need to use hazardous chemicals. Simplistic and unscientific statements on phasing out hazardous chemicals will be counterproductive. A real risk-based approach is essential: Risk = Hazard x Exposure.