

**BeST comments to Consultation Questionnaire on the revised manual (draft)
methodology to identify and assess substances for possible restriction under the
RoHS Directive**

Introduction

BeST – The Beryllium Science and Technology Association – represents the suppliers of beryllium metal, beryllium-containing alloys and beryllium oxide ceramics in the EU market and has the objective of promoting sound policies, regulations, science and actions related to the use of beryllium as well as promoting good practices in the workplace, in order to protect workers handling beryllium-containing materials.

The comments below reflect BeST's answers to the Consultation Questionnaire and observation on the revised manual (draft) methodology to identify and assesses substances for possible restriction under the RoHS Directive within the frame of the Study for the review of the list of restricted substances and to assess a new exemption request under Directive 2011/65/EU (RoHS 2) – Pack 15.

BeST responses to the asked questions:**Questions:****1. Please specify additional lists of relevance for specifying substances identified or suspected of having hazardous properties (Section 1.1., pg. 24)**

BeST does not suggest any further lists than those already identified by Oeko Institut. However, we stress that a hierarchy of these lists should be considered. Relevance should be reserved to official and binding lists, such as the CLP, based sound scientific evidence and evaluation while other lists, such as NGO-lists, should be considered less relevant.

2. Please specify additional lists of relevance for specifying substances used or suspected of being used in EEE

BeST stresses that it is incorrect to refer to substances "used or suspected of being used" in EEE as this would imply the inclusion of any substance. On the contrary, reference should be limited to lists of substances actually "present" in EEE.

The statement *"even where clear evidence exists that a substance is not present in EEE it should not be excluded from the list but rather the information should be noted"* (ref. pg. 27 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive) confirms the irrationality of an identification procedure based on "suspected of being used" which is overreaching and over inclusive.

Notwithstanding the above, BeST stresses that the generation of several lists will result in loss of innovation of the EU industry, especially environmental-friendly technologies, loss of jobs and loss of high-tech know how, product safety and sustainability.

3. Please submit reference to legislation and/or to standards where thresholds are defined for the criteria mentioned, e.g. under what circumstances and measurement conditions would the volatility of substance potentially lead to emissions from an article in which it is contained (including non-intended use such as in case of breakage).

The above-mentioned question refers to the fulfillment of the conditions contained in Article 6 of the RoHS Directive, and in particular to condition b) *"could give rise, given its uses, to uncontrolled or diffuse release into*

the environment of the substances, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions”.

According to OEKO Institut, criterion b) is fulfilled when *“the substance/substance group is comparably easily releasable during use or during waste management due to the following reasons:*

- *The substance is used in or as a liquid (under ambient conditions) in EEE*
- *The substance is in particulate form in EEE*
- *The substance is highly volatile (under ambient conditions) when used in EEE” (ref. pg. 36 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive)*

In light of the above, BeST raises the following main observations:

- **The sole existence of emissions does not, per se, entail negative impacts**

In order to determine a potential restriction of a substance under RoHS, it should not be sufficient that the mentioned substance causes emissions. This is particularly true when the substance in question is a naturally occurring element. A risk assessment should be adopted in order to determine if the emissions imply a concrete risk for humans and/or for the environment. Only in this case, a potential restriction could be justified.

- **The potential restriction of a substance should not be determined on the basis of unintended use**

Substances should be restricted under RoHS only when they meet the necessary criteria contained in Article 6 of the RoHS Directive on the basis of their intended use. Industry cannot be considered responsible and reliable for unintended use of its materials.

- **Risk management measures to control emissions should exclude a restriction under RoHS**

Article 6 of the RoHS Directive refers to uncontrolled release of emissions. Over the years, industry has adopted effective risk management measures to effectively control emissions and protect workers, consumers and the environment, i.e. voluntary product stewardship programmes. These should be taken into account when assessing a particular substance as recognised by Oeko Institut (*ref. pg. 65 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive*).

Moreover, legislation specifically targeting emissions and/or exposures, i.e. the Carcinogens and Mutagens Directive and its Occupational Exposure Limits, are specific examples of controlled emissions/exposures, and therefore substances subject to these legislations do not comply with Article 6 criterion b). These ad hoc legislations are better equipped to address emissions/exposures than the RoHS Directive and therefore must be concretely taken into account in the methodology.

- **Metals and alloys should be addressed differently**

In addition, BeST highlights that in the case of metals, the alloying element is embedded in the metal matrix and therefore is not released in normal, intended and foreseeable use of the product.

4. Please indicate criteria for specifying when a potential for release is to be considered significant.

- **A risk-assessment approach should be adopted to determine “significant release”**

As stated above, the sole existence of emissions is not sufficient to classify these emissions as significant. A significant emission must be determined on the basis of the objective of RoHS which is to address the risk posed

to workers, users and to the environment by emissions of substances from EEE or from waste management of EEE.

Consequently, a risk assessment must be conducted in order to determine if there is a concrete risk to the health (i) of the workers or (ii) of the consumers of the final product or (iii) if there is a risk for the environment.

If such risk does not exist or if ad hoc legislation and risk management measures are already adopted to control the risk, the release must not be considered significant and therefore a restriction under RoHS is not necessary.

5. Evidence of elevated levels measured in the environment shall be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.). Do you support this specification – please explain your views and provide supporting data to explain them if relevant.

For many naturally occurring elements, such as metals and metal compounds, the levels in the environment could exceed the designated limit values or concentrations established. Therefore, background levels should be considered during this assessment and adjusted accordingly. If there is an OEL adopted at EU level this should be taken as a reference.

The use of these limit values (i.e. DMELs, PNEC, OELs) should be endorsed only when based on sound scientific and accepted evidence.

6. For the purpose of specifying an exhaustive list of socio-economic impacts to be considered, please specify categories that should be taken into consideration

The draft methodology correctly identifies the importance of conducting an impact assessment when assessing regulatory constraints for specific substances.

In addition to the categories identified by Oeko Institut, the following categories should be taken into account when conducting a socio-economic impact assessment:

- Impact on safety of the public
- Impact on sustainability
- Impacts on SMEs
- Impact on critical raw material (CRM) policies and initiatives
- Impact on life of the products
- Impact of restriction at global level, given that the impacts of the EU RoHS Directive are not limited to the EU and have a “spill over” effect on third countries
- Impact on trade, including international trade
- Impact on the quality of products
- Impact on innovation
- Impact on raw material utilization
- Impact on amount of waste generated
- Impact on the measurement of emissions on the basis of the properties of existing measurement techniques

Moreover, the classification of a substance must be based on the adequate EU framework, specifically the CLP Legislations. Other sources should not be taken into consideration as these are not equivalent nor aligned with the CLP and will amount to legal confusion and uncertainty.

As recognised by Oeko Institut, particular attention should be given to the evaluation of substitutes and their reliability in light of the particular characteristics of the substance they should be replacing and in relation to the properties it enables in EEE (*ref. pg. 47 and 61 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive*).

7. If you have any further comments, where relevant, please note the section/page to which they refer or quote the text of relevance from the manual to support understanding.

BeST submits the following concerns in relation to the Draft Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive:

General Comments – not substance related

- **Lack of justification of the identification of the seven substances identified for prioritization**

It remains unclear why seven substances, including Beryllium and its compounds, are already being assessed for restriction. Indeed, these substances are currently at Step P III (Detailed assessment of substances), even though Step P I and P II were not conducted.

It is illogical to proceed to the assessment of these substances without following the entire procedure identified in the draft methodology. This is a clear example of arbitrary prioritization that finds no legal or scientific justification, especially considering that some of these substances, if they had undergone the normal procedure as defined in the draft methodology, would likely not have been considered of high priority and therefore would not be currently subject to Step P III.

BeST urges not to proceed to the assessment of the identified substances and to allow them to follow the procedure to be adopted for ALL substances thus avoiding an evident case of lack of transparency and of discrimination.

Moreover, special attention should be reserved to critical raw materials - four of seven substances currently being assessed, including Beryllium - given their important applications, supply risk and difficult if not impossible substitution in their applications.

- **Risk-based approach that identifies actual risk and not potential risk must be implemented**

We endorse the recognition of a risk-based approach. However, the identified risk must be verifiable and not potential.

The language used in the draft methodology seems to convey an excessive power to the evaluating body with the risk of biased conclusions.

Indeed, according to Oeko Institut, *“looking at RoHS Article 6(1) criteria suggests that it suffices for a substance to have a potential for risk during use and/or during waste management in order to justify its restriction under RoHS. In this sense, if a substance is classified with a hazard potentially resulting in risk in these phases, a restriction would be justified regardless of actual occurrence and risk management options”*. (ref. pg. 15 and 16 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive)

This interpretation is overreaching and will inevitably translate in general restrictions unjustified in terms of scientific evidence, socio-economic impact assessments and actual risk. It includes all possible substances and creates general uncertainty for industry with consequent negative effects on EU economy, consumers and the environment.

- **RoHS Directive must not be an example of overregulation**

According to OEKO Institut, *“If a substance is listed in Annex XVII under REACH and the restriction covers applications in EEE or if such a restriction has been proposed, the substance shall be prioritized for assessment”* (ref. pg. 37 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive).

Indeed, the statement is in contradiction with TABLE I “*The relation between REACH and RoHS in respect of the restriction or authorization of substances*” contained at page 14 and 15 of the draft methodology, which states that “*when a restriction under REACH Annex XVII exists and applies to EEE, a restriction under RoHS is to be considered redundant*”.

This contradiction, combined with the general language used in the draft methodology, confirms the attempt to regulate any given substance independently from the fulfillment of the criteria established under RoHS and contributes to the general lack of coherence of EU legislation and to the overregulation of substances.

This has even worse impacts when the substance in question is a critical raw material, deemed strategic and important for EU Industry by DG GROW but subject to restrictions and limitations by the other DGs, i.e. DG ENVI and DG EMPL.

Coordination and coherence among the various DGs of the European Commission and among the various EU frameworks are absolutely necessary in order to allow and foster growth and development at EU level.

- **High-quality data must be considered in order to avoid biased conclusions**

The data sources used need to be robust and the quality of the data needs to be verified and evaluated to ensure that high quality scientific data is used and that the conclusions of the assessment are based on sound science.

The primary source of information should be the REACH registration dossiers while additional sources of information should be peer-reviewed European risk assessments, scientific data and expert knowledge of the producers of the substances and of the EEE.

- **In case of grouping of substances, the most hazardous group member must not be considered as the benchmark for prioritization**

The statement “*It is important that, following the precautionary principle, the most hazardous group member will be taken into consideration for the prioritization of substances*” (ref. pg. 37 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive) is illogical and has no scientific justification.

In order to be effective, the decision on a specific substance must be based on the actual presence of that substance in EEE and not on the worse case material in a substance group. Examples demonstrating such illogicality are assessing powder aluminum to restrict all aluminium compounds or radioactive cobalt 60 to restrict all cobalt compounds.

- **Substances already assessed should not be assessed in the future unless compelling new evidence emerges**

This will allow the regulated community to continue to provide their customers some degree of certainty and predictability regarding future use of substances.

- **Member State restriction proposals must follow the draft methodology**

Any proposal to restrict substances under RoHS must follow the draft methodology developed independently if submitted by the European Commission or a Member State.

Beryllium specific comments:

- **Grouping of Beryllium and its compounds is unjustified**

Only beryllium metal – used in massive form mainly as an alloying element with copper at 2% - and beryllium oxide ceramics are present in EEE and are commercialized in the EU. Therefore, any assessment should be limited to these two forms of beryllium.

Moreover, the grouping of beryllium metal and beryllium oxide with other beryllium compounds is not justified according to any of the criteria proposed in the Appendix of the draft methodology at page 74.

In particular, grouping cannot occur due to fundamental difference in inherent toxicology. As an example, only soluble beryllium compounds have an environmental classification Aqua Chronic 2 and therefore fall within the Hazard Group II. However, these are not present in EEE and are not commercialized in the EU.

It is therefore illogical to group beryllium metal and beryllium oxide ceramics with other compounds that are not present in EEE, are not commercialized in the EU and have substantial different toxicological characteristics and different modes of action.

- **Beryllium metal and Beryllium Oxide Ceramics must not be assessed as a priority substance**

It is unclear why this assessment addresses the grouping “beryllium and its compounds” while previous assessments were conducted correctly on beryllium metal and beryllium oxide ceramics, the only two forms of beryllium present in EEE. If the draft methodology had been applied to correct two forms of beryllium present in EEE, these would not have been identified as priority substances as they do not fulfill the criteria identified in Article 6.

This is also confirmed by previous assessment conducted by Oeko Institut in 2010 and 2013 which concluded that beryllium metal and beryllium oxide ceramics, the only two forms of beryllium used in EEE and commercialized in the EU, “*did not constitute significant health and environmental risks when used in electrical and electronic equipment*” and therefore are not to be proposed as candidate or phase out substances. Nothing has changed in terms of application, use of beryllium or scientific development to alter such conclusions.

REACH studies concluded that beryllium is not orally toxic, not a skin or eye irritant, not a skin sensitizer and not carcinogenic to humans. The lack of observed carcinogenicity has been recently supported by scientific experts in toxicology and in cancer (Boffetta 2016).

This is furthermore confirmed by the Risk Management Option Analysis (RMOA) on Beryllium conducted by Germany’s Federal Institute for Occupational Safety and Health (BAuA – Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) in 2016 in the frame of REACH where it was concluded that “*Although a general or even a partial ban will undoubtedly reduce risks, the societal impacts would be disproportionate. Beryllium is used in many high-technology processes and articles, and in most cases it is unclear, whether suitable alternatives currently exists. This makes it questionable, whether a meaningful case for a restriction could be created*”. The current setting of a Binding Occupational Exposure Limit for the EU is the most suitable regulatory action with a “*high potential for risk reduction capacity and equivalent health benefits for workers*”.

- **The soon to be adopted Binding Occupational exposure limit for Beryllium will adequately protect all workers occupationally exposed to the critical raw material**

As already clearly demonstrated in previous assessments and confirmed in various scientific studies, beryllium in massive form poses no threat to the consumer of beryllium containing products nor to the environment.

The OEKO Institut identifies beryllium as an example of substances present in EEE potentially causing risks for human health and the environment and which may require special emission control and treatment measured

during WEEE management. In particular, BeST strongly objects to including Beryllium in the statement: “emissions of particle bound substances (e.g. ... metals such as Be, As or Ni)” (ref. pg. 29 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive). Such statement is presumptive and prejudicial and will cause irreparable harm to the supplier and producers of beryllium. The statement is unwarranted and factually incorrect, considering previous reviews by the OEKO Institut and the results of studies conducted at recycling facilities that clearly demonstrated worker exposure to be well below established regulatory levels. Our position is well documented at <http://beryllium.eu/health-environment-legislation/recycling/>.

In addition to the above, beryllium will soon be subject to a binding occupational exposure limit (BOEL) under the Carcinogens and Mutagens Directive (CMD). This effort aims at harmonizing the already existing OELs applied at national level and will be applied in all sectors, including recycling, therefore adequately controlling the risk associated to exposure to beryllium. RoHS should not interfere with the specific workplace legislations which is better equipped to adequately protect workers, also at the recycling stage.

Moreover, the beryllium industry has promoted the **Be Responsible** Voluntary Product Stewardship Program, supported by EU-OSHA, in order to adequately inform employers and employees on how to safely manage and process beryllium through the implementation of specific risk-management measures throughout the supply chain, including recycling.

In light of this, a restriction under RoHS would not have additional effect in terms of protection of workers, already adequately protected under the CMD, and will only result in loss of innovation of the EU industry, especially environmental-friendly technologies, loss of jobs and loss of high-tech know how and product safety.

Conclusions:

In light of the above comments, BeST cannot fully support this draft methodology developed by Oeko Institut. In particular, the draft methodology (i) identifies substances mainly on the basis of their use or potential use in EEE and (ii) the seven substances identified for prioritization have been arbitrarily selected to undergo full assessment (Part III of the draft methodology) without having the possibility of following the normal procedure and therefore obtaining a lower priority classification.

Overall, the drafted methodology appears, in some instances, illogical and contradicting. There are several flaws in the text, for example “no” instead of “yes” in the workflow (ref. pg. 21 of Draft Manual Methodology for the Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive), indicating the insufficient attention reserved to such an important draft methodology. BeST calls for a thorough, adequate and attentive analysis given the impact that a restriction would have on industry, society and environment.

We remain at your disposal to discuss the above-points and for any further assistance.



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