Appropriate EU Occupational Exposure Limit (OEL) for Beryllium Metal and Alloys under the framework of the Carcinogens and Mutagens Directive

IN BRIEF:

In 2018, the European Parliament will shortly be asked to give an opinion on the proposal for amending the Carcinogens and Mutagens Directive, including a list of substances that have been identified for additional review. Beryllium is one of those substances, and the Beryllium Science and Technology Association (BeST) would like to have the opportunity to know your thoughts about the directive and also share with you the BeST's position on the matter.

These are the main points of our position:

- Beryllium metal and alloys have unique properties and are irreplaceable for specialized manufacturing and use in EU industries such as electronics, aerospace, automotive, defence and medical.
- The proposed EU Occupational Exposure Limit (OEL) should be based on the appropriate health effect point and consider all relevant science.
- The health risks are only in the work place, and then, only if not properly controlled.
- The proposed OEL should be feasible and not lead to disinvestment and job losses by small and medium enterprises.
- The solution is a technically and economically feasible OEL, as in force in other parts of the world, combined with a strong Voluntary Product Stewardship Programme.

Therefore, we ask agreement and support for the OEL accepted by the social partners of 600 nanograms per cubic meter (ng/m^3 – inhalable fraction – 8 hours Time Weight Average).

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BeST makes the following comments on the development of an European standard for an Occupational Exposure Limit (OEL) in the framework of an amendment to the Directive on Carcinogens and Mutagens (CMD).

FROM A SCIENTIFIC PERSPECTIVE:

SENSITIZATION WRONGLY CONSIDERED AS THE CRITICAL HEALTH EFFECT:

The Scientific Committee for Occupational Exposure Limit (SCOEL) identified sensitisation to beryllium as an adverse health effect and has subsequently recommended an extremely low OEL of 20 nanograms beryllium per cubic meter (ng/m3) which is overly restrictive and infeasible. However, sensitisation to beryllium should not be considered as an adverse health effect since it does not cause health consequences and occurs in approximately 1% of the general population without being occupationally exposed to beryllium, which represents 5 million people in the EU. The critical health effect to be controlled and for which an OEL should be based must be Chronic Beryllium Disease (CBD) or berylliosis, not sensitization.

NECESSITY OF CONVERSION FACTORS BETWEEN DIFFERENT SAMPLING METHODS:

It is important to keep in mind that the OEL values used in the US and in Europe do not correspond to the same particle sizes. The conversion factor between the OEL values used in the US (Thoracic or Total fraction, particles< 30 µm by the, Closed Face Cassette (CFC) sampling method) versus the values used in Europe (inhalable fraction, particles< 100 µm) is 3, according to a 2015 Fraunhofer Institut study. The studies used to support the SCOEL recommendation all utilized data collected in the US using the CFC method, but the SCOEL erroneously dismissed the need to utilize the conversion factor.

INFLUENCE OF PHYSICAL FORMS OF BERYLLIUM ON TOXICITY:

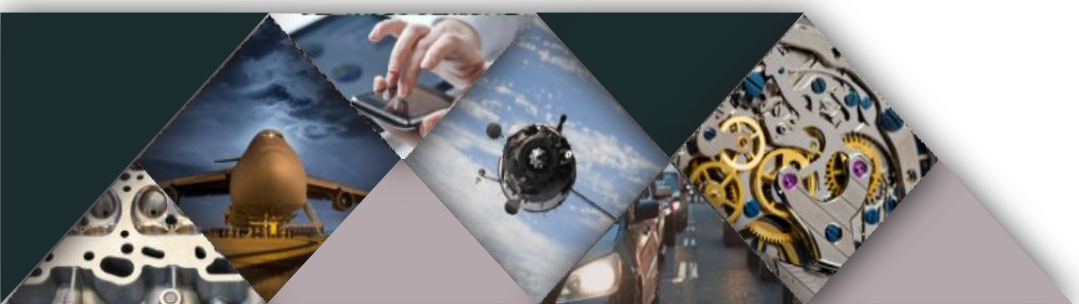
Both soluble and insoluble forms of beryllium are classified as having equivalent health risks. However, the form of beryllium used by industries in Europe is exclusively in insoluble metallic massive forms, mostly in copper alloys (maximum of 2%), and does not present the same risks as soluble forms of beryllium. In fact, recent studies (Boffetta 2014, 2016) demonstrate that the insoluble forms are not carcinogenic.

HEALTH STATISTICS IN EUROPE:

Data from EU Member State authorities show that cases of CBD have been very rare over the past 10 years. This finding supports the premise that past use of an OEL of 1000 ng/m3 has protected workers.

INCONSISTENCY WITH THE OFFICIAL CLASSIFICATION OF BERYLLIUM:

The SCOEL recommendation is not in accord with the EU CLP (Classification, Labelling and Packaging) regulation since Beryllium is not a Respiratory Sensitizer (H334).



FROM A SOCIO-ECONOMIC AND TECHNICAL PERSPECTIVE:

TECHNICAL FEASIBILITY IN THE FIELD:

The SCOEL recommended OEL is neither technically nor economically feasible for the majority of beryllium operations in the European Union (EU). The Socio-Economic Impact Assessment (SEIA) completed for beryllium in 2016 for the European Commission (EC) should be considered by the European Parliament.

GOOD PRACTICES IMPLEMENTED ON THE WORKPLACE:

With the endorsement of the German Federal Institute of Safety and Health (BAuA) within the framework of the REACH Risk Management Option Analysis (RMOA) for beryllium, BeST has implemented a Product Stewardship Program (Be Responsible) based on a recommended exposure guidance of 600 ng/m3 inhalable which is technically feasible and protective for workers. (see www.berylliumsafety.eu)

Be Responsible
Beryllium Product Stewardship

SOCIO-ECONOMIC IMPACTS:

An OEL below 600 ng/m3 would have serious socio-economic consequences for small and medium enterprises (SMEs), which supply key components to large industries. SMEs that process beryllium-containing alloys should not be required to invest in costly controls that are overly restrictive, unnecessary and unachievable at the SCOEL recommended OEL.

CARBON FOOTPRINT OF INDUSTRY:

Since the addition of beryllium is indispensable in the production and recycling of magnesium (Mg) and aluminium magnesium (AlMg) alloys, an overly restrictive OEL creates a barrier on the use of beryllium. This would then lead to increased transport and duty expenses (Al alloys 6%) for users which will directly influence the global competitiveness of the EU automotive and aerospace industry. Furthermore, the greenhouse gasses (GHG) emissions and carbon footprint for export and re-import of recycled materials would greatly increase.

NO POSSIBLE SUBSTITUTION:

The 2017 European Commission report on critical raw materials determined that the unique properties of beryllium are not substitutable. Substitutions could be regrettable and cause unintended consequences, especially in transportation equipment, because of the loss of safety related reliability and performance.

CONSISTENCY WITH OTHER REGIONS:

The SCOEL OEL recommendation is 30 times lower than United States of America Occupational Safety and Health Authority (US OSHA) 2017 OEL (0.2 µg/m3 CFC = 200 ng/m3 CFC = 600 ng/m3 Inhalable), 50 times lower than the Japanese limit (1 000 ng/m3). The newly introduced US value was based on the technical feasibility of achieving its OEL. Inconsistent regulations among major trade partners contribute to economic trade imbalances that place the EU at a competitive disadvantage.

NATURAL PRESENCE OF BERYLLIUM:

The SCOEL did not take into account the natural occurrence of beryllium in common materials that the general population is exposed to such as concrete, soil, rock, steel, etc. Sampling data has demonstrated that the use and processing of these materials can result in exposures above the SCOEL recommended OEL.

LACK OF MEASURABILITY:

The analytical method necessary to achieve a detection limit of 2 ng/m3 to meet 10% of SCOEL recommended OEL, as is the standard procedure for sound industrial hygiene practice, has not been validated according to the European reference standards (EN 13890 and 482) and is not commercially available in Europe.