BeST
Beryllium Science & Technology Association

28-10-2016

Key Stakeholder Comments on the Issuance of the Draft

Beryllium and Inorganic Beryllium Compounds Recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL/REC/175) for Public Consultation

PUBLIC COMMENTS DUE BY 29 NOVEMBER 2016

The Scientific Committee on Occupational Exposure Limits (SCOEL) is seeking public comments on its recently issued draft recommendation for an occupational exposure limit (OEL) for beryllium. In the draft recommendation, SCOEL has proposed an OEL of 0.02 µg/m^3 as an 8-hour Time Weighted Average (TWA) for "Inhalable" beryllium-containing particulate. Comments are due to the SCOEL Secretariat by 29 November 2016. Comments should be sent by mail to SCOEL Secretariat, DG Employment, Social Affairs and Inclusion, Plateau du Kirchberg, L-2920 Luxembourg or by email to *empl-scoel@ec.europa.eu.*

BeST believes the scientific evidence coupled with the socio-economic analysis being conducted for the Commission by Risk Policy Analysts (RPA) is supportive of an OEL of 0.6 µg/m^3 (inhalable sampling method). Any value lower than 0.6 µg/m^3 is not supportable by the preponderance of scientific evidence nor would a value below 0.6 µg/m^3 be technically or economically feasible to the industries that rely on beryllium as a critical material.

The SCOEL recommendation is incorrectly based on beryllium immunological sensitisation and is not in accord with the SCOEL methodology. The methodology dictates that the critical health effect is chronic beryllium disease (CBD) and is clearly not beryllium sensitisation (BeS).

Unlike allergic chemical sensitizers, beryllium medical experts agree that beryllium immunological sensitisation is detectable only via a laboratory test as it involves no allergic response and no symptomology whatsoever. Medical experts also agree that BeS detected in the blood of a worker does not predict CBD in that worker and that the detection of BeS can turn on and off. BeS occurs in the general population that is not occupationally exposed to beryllium without any health consequences. Most importantly, as hypersensitivity to a substance has never been used by the SCOEL as the basis for setting an OEL, it is especially inappropriate for the SCOEL to attempt to do so with beryllium. Medical experts and government authorities have defined CBD is the critical health effect and therefore CBD is the only justifiable basis upon which to establish an OEL to protect beryllium workers.

The SCOEL incorrectly characterises all physical and chemical forms of beryllium as having equivalent health risks based simply on the presence of the beryllium ion.

Beryllium experts with field knowledge know that beryllium metal and soluble beryllium compounds have vastly different properties and are significantly different from a health risk perspective. Furthermore, no soluble beryllium compounds are commercially used by manufacturers anywhere in the EU. SCOEL should acknowledge and consider these chemical property and medical differences in its recommendation.

Any recommendation for an OEL for beryllium must include a conversion factor from the CFC sampling method to the inhalable sampling method to be scientifically valid.

The studies used by the SCOEL to support their recommendation for an inhalable OEL are based entirely on data collected in the U.S. using the closed faced filter cassette (CFC) sampling method. A beryllium exposure measurement study, conducted by the Fraunhofer ITEM, comparing the inhalable sampling method (used in the EU) and the CFC sampling method (used in the U.S.) shows that the inhalable sampler yields statistically valid exposure results approximately 3 times greater. The SCOEL document does not take this fact into account. This scientific fact was provided to the SCOEL and it is scientifically inappropriate for SCOEL to disregard this fact.

- The metal associated conversion factors found in numerous published studies (nickel, manganese, aluminum) align with that found for beryllium.
- Experts with detailed process knowledge, detailed knowledge of the epidemiology and a wealth of field exposure evaluation experience recognize the need to include a conversion factor to allow the OEL to be supportable from strictly a scientific and a health risk perspective.

The SCOEL recommendation is not in accord with EU regulation that dictates how substances are to be classified.

The draft document assigns a defacto classification as a respiratory sensitiser. Beryllium is not classified as a respiratory sensitiser under the CLP regulation nor does it have an associated category code or hazard statement code H334 for a respiratory sensitiser.

Beryllium does not meet the existing CLP criteria as a respiratory sensitiser and was not proposed to be classified as such when classification of beryllium was initially adopted in the EU. Therefore, the SCOEL cannot unilaterally ignore the legal classification of beryllium and designate beryllium as a respiratory sensitizer.

The SCOEL evaluation did not evaluate exposures associated with naturally occurring beryllium.

Exposures above the proposed OEL have been associated with exposure to naturally occurring beryllium in numerous industries including construction, agriculture, oil & gas, cement, steel production, electric utilities, and aluminium production.

With such an extremely low recommended OEL, the additional costs for addressing naturally occurring beryllium would increase by several orders of magnitude. Exposures to windblown soil have caused exposures above 0.01 $\mu g/m^3$.

Data from Member State Authorities shows that cases of CBD are very rare. This fact does not support the SCOEL recommended OEL of 0.02 $\mu g/m^3$(inhalable).

In 2014 and 2015, BeST conducted surveys of national authorities and accident insurance providers in all EU member states, Norway and Switzerland to assess the current extent of employee exposure to beryllium metal and the prevalence of respiratory disease that have been attributed to exposure to beryllium over the previous 10 years. In addition, BeST undertook customer surveys seeking similar information.

The data, as previously provided to SCOEL by BeST, illustrated that in member states having an OEL of 1.0 $\mu g/m^3$ (former eastern bloc), there was only a single CBD case recorded (Poland in 2009). That case was attributed to work conducted by an electrician who worked on central heating equipment that would not likely have components containing beryllium.

Setting an OEL below 0.6 µg/m^3 (Inhalable) would cause a severe disruption in the marketplace impacting the major industrial sectors within the EU and resulting in job losses, particularly in small and medium enterprises.

In recommending an OEL of 2.0 µg/m^3 (no sampling method defined), the IOM SheCan report to the Commission on amendments to the Carcinogen Directive calculated the total costs over the period 2010-2069 (Net Present Value) to be between €5 billion and €34 billion.

The IOM determined that for "those operations that would need to install ventilation, there is a significant cost to consider." They estimated the annualised operating cost per ventilation system varies from €4,000 to €25,000 with upfront capital costs in the range of €42,000 to €252,000 per ventilation system.

Based on the IOM report, it is reasonable to conclude that setting an OEL below 0.6 µg/m^3 (Inhalable) would cause a severe disruption in the marketplace that would likely impact the major industrial sectors within the EU. This is in agreement with the IOM which stated: "We consider that the costs of compliance with the OEL will disproportionately affect SMEs and it is possible that some could either close or cease to use beryllium-containing components.

BeST has provided data and technical insights to assist RPA, who is conducting the beryllium socio-economic analysis for the European Commission. Expert analysis by industry engineers finds that the engineering control technologies required to reduce exposures to 0.6 µg/m^3 coupled with the IOM cost analysis could be used by RPA to calculate an economic impact associated with an OEL of 0.6 µg/m^3 (equivalent to the U.S. proposed OEL of 0.2 µg/m^3) as an alternative OEL. BeST estimated the cost for typical ventilation controls alone to be *€24.6 billion - €147.9 billion for the 652,000 enterprises identified by IOM.* To achieve compliance with an OEL less than 0.6 µg/m^3 would require use of pharmaceutical type controls that would not be feasible in most metal processing operations as recognized by those with expert knowledge of metal operations and controls.

It is clear that evidenced based science dictates that the lower boundary of risk is no lower than 0.2 µg/m^3 (CFC method) which converts to a value of 0.6 µg/m^3 in the EU (inhalable).

Study	Date	Comments	OEL/DNEL
Kelleher	2001	Kelleher et al. (2001) cautioned against comparing their estimates of median LTW to occupational exposure limits (OELs) because OELs are based on the upper tail of the exposure distribution and not on the central tendency.	No recommendation on OEL advanced.
Schuler	2005	Sensitization and CBD were associated with an area in which beryllium air levels exceeded 0.2 µg/m^3 and not with areas where this level was rarely exceeded.	0.2 µg/m^3 CFC (Total)
Stanton	2006	No CBD or BeS was observed when 97% of exposure measurements were less than 0.2 µg/m^3. The highest exposures (95th percentile) at the service center handling bulk products was 0.26 µg/m^3 with no detected BeS or CBD.	0.2 µg/m^3 CFC (Total)
Madl	2007	Maintaining beryllium exposures below 0.2 µg/m^3 95% of the time may prevent beryllium sensitisation and CBD. Functionally, this would be equivalent to not allowing the daily 8-hr time weighted average concentration to exceed 0.2 µg/m^3	0.2 µg/m^3 CFC (Total)
Arjomandi	2010	These workers with BeS, characterized by a long duration of potential Be exposure and long latency, had a low prevalence of CBD.	0.2 µg/m^3 CFC (Total)
Schuler	2012	No BeS was observed when total mass exposures for average and highest job were < 0.09 and 0.12 µg/m^3. Highest exposure which no CBD was observed = 0.199 µg/m^3.	0.2 µg/m^3 CFC (Total)
Proctor [1]	2016	Defines NOAELs of 0.14 µg/m^3, and 0.41 µg/m^3 for total mass and inhalable Be, respectively. These values are consistent with SCOEL guidance.	0.065 µg/m^3 Respirable 0.14 µg/m^3 CFC (Total) 0.41 µg/m^3 Inhalable

[1] Dr Proctor presented her findings at the SCOEL meeting on 13 September 2016 in the Hague

The SCOEL draft recommendation relied heavily on a study by Kelleher (2001) even though the author cautioned against comparing their estimates of median LTW to (OELs) because OELs are based on the upper tail of the exposure distribution and not on the central tendency.

Madl et al. (2007a) concluded that Kelleher (2001) underestimated historical exposures of beryllium-sensitized and CBD workers because contemporaneous data were not used to estimate historical exposures and a limited number of samples were collected for each job category. Madl's study corrected the findings in the Kelleher (2001) study and based her conclusion on 3831 personal label samples and 616 area samples where Kelleher's study was limited to only 100 samples.

The USA has proposed adopting an OEL of 0.2 µg/m3 (total).

The OEL science, economic and technical feasibility issues are similar between the EU and the USA. OSHA's proposed final beryllium standard is expected in 2016-2017 and establishes an OEL of 0.2 µg/m^3 (CFC method). OSHA's OEL is the same as that recommended to OSHA in 2012 by an industry/labor partnership that had conducted its own analysis. An unjustifiable ultra low OEL of 0.02 µg/m^3 can severely cripple the cooperative efforts needed between industry and labor to ensure workers are not theoretically protected but actually protected. BeST believes having the support and cooperation of trade unions, authorities and industry affiliations is not only critical, but is essential to protecting beryllium workers.

The SCOEL conclusion that analytical methods exist to measure exposures to determine the recommended levels with an appropriate level of precision and accuracy is not supported by experts who have a wealth of analytical experience in beryllium detection.

According to the industrial hygiene standards, an analytical method must be able to reach limits of quantification (LOQ) less than 10 % of the OEL. The LOQ for the most sensitive analytical method, which is not generally commercially available in the EU, is 0.005 µg/m^3 which would mean that the minimal measurable OEL for beryllium metal cannot be below 0.05 µg/m^3. The equipment required to detect this specified level is expensive and the increased cost of analysis would become problematic to companies and member states alike. To our knowledge, no commercially available analytical method is able to reach a LOQ of 0.002 µg/m^3 required by the proposed OEL of 0.02 µg/m^3.

Attachment 1

Engineering Control Assessment of Beryllium Operations

NA – No additional controls beyond normal operating controls
C – Controls Required including Engineering, Work Practice and Best Practices
C+ - Additional advanced pharmaceutical level control systems are necessary but are not likely to be economically feasible (Category 4) See: Pharmaceutical Control System for controls for categories 3 and 4
NF – Not Technically Feasible using engineering and work practice controls

Operations on Beryllium Alloys	Proposed Occupational Exposure Limit (Inhalable)			
	2 μg/m³	0.6 μg/m³	0.2 μg/m³	0.02 μg/m³
Abrasive Blasting	C	C+	NF	NF
Abrasive Processing	C	C+	NF	NF
Abrasive Sawing	C	C+	NF	NF
Adhesive Bonding	NA	NA	NA	NA
Age Hardening (<950ºF)	NA	NA	C	C
Annealing	NA	NA	C	C
Assembly	NA	NA	NA	NA
Bending	NA	NA	NA	NA
Blanking	NA	NA	C	C
Bonding	NA	NA	NA	NA
Boring	NA	NA	C	C
Brazing	NA	NA	C	C
Bright Cleaning	C	C	C+	NF
Broaching	NA	NA	C	C
Brushing	C	C	C+	NF
Buffing	C	C	C+	NF
Burnishing	C	C	C+	NF
Casting	C	C	NF	NF
Centerless Grinding	C	C+	NF	NF
Chemical Cleaning	C	C	C+	NF
Chemical Etching	C	C	C+	NF
Chemical Milling	C	C	C+	NF
CNC Machining	NA	NA	C	C+
Cold Forging	NA	C	C+	NF
Cold Heading	NA	NA	C	C+
Cold Pilger	NA	NA	C	C+
Cold Rolling	NA	NA	C	C
Coolant Management	NA	C	C	C+
Cutting	NA	NA	C	C+
Deburring (grinding)	C	C	C+	C+
Deburring (non-grinding)	NA	NA	C	C+
Deep Hole Drilling	NA	NA	C	C+
Destructive Testing	C	C	C	C+
Drawing	NA	NA	C	C+
Drilling	NA	NA	C	C+
Dross Handling	C	C	NF	NF
Dry Tumbling	NA	C	C+	NF

Operations on Beryllium Alloys	Proposed Occupational Exposure Limit (Inhalable)			
	2 µg/m^3	0.6 µg/m^3	0.2 µg/m^3	0.02 µg/m^3
Electrical Chemical Machining (ECM)	C	C	C+	NF
Electrical Discharge Machining (EDM)	C	C	C+	NF
Electroless Plating	NA	NA	C	C+
Electron Beam Welding (EBW)	C	C	C+	C+
Electroplating	NA	NA	C	C+
Extrusion	NA	NA	C+	C+
Filing by Hand	NA	NA	C	C
Forging	NA	C	C+	NF
Grinding	C	C+	NF	NF
Gun Drilling	NA	NA	C	C+
Hand Solvent Cleaning	NA	NA	NA	NA
Handling	NA	NA	NA	NA
Heading	NA	NA	C	C+
Heat Treating (inert atmosphere)	NA	NA	C	C
Heat Treating (in air)	C	C	C	C+
High Speed Machining (>10,000 rpm)	C	C	C+	NF
Honing	NA	C	C+	NF
Hot Forging	NA	C	C+	NF
Hot Rolling	NA	C	C+	NF
Inspection	NA	NA	NA	NA
Investment Casting	C	C	NF	NF
Lapping	C	C	C+	NF
Laser Cutting	C	C	C+	NF
Laser Machining	C	C	C+	NF
Laser Scribing	C	C	C+	NF
Laser Marking	C	C	C+	NF
Laser Welding	C	C	C+	NF
Machining	NA	NA	C	C+
Melting	C	C	NF	NF
Metallography	NA	NA	C	C
Milling	NA	NA	C	C+
Packaging	NA	NA	NA	NA
Painting	NA	NA	NA	NA
Physical Testing	NA	NA	C	C+
Photo-Etching	C	C	C+	NF
Pickling	C	C	C+	NF
Piercing	NA	NA	C	C+
Pilger	NA	NA	C	C
Plating	NA	NA	C	C+
Point and Chamfer	C	C	C+	NF
Polishing	C	C	C+	NF
Pressing	NA	NA	C	C
Process Ventilation Maintenance	C	C+	NF	NF

Operations on Beryllium Alloys	Proposed Occupational Exposure Limit (Inhalable)			
	2 µg/m³	0.6 µg/m³	0.2 µg/m³	0.02 µg/m³
Radiography/X-ray	NA	NA	NA	NA
Reaming	NA	NA	C	C+
Resistance Welding	C	C	C+	NF
Ring Forging	NA	C	C+	NF
Ring Rolling	NA	C	C+	NF
Roll Bonding	NA	NA	C	C
Roller Burnishing	C	C	C+	NF
Rotary forging	NA	C	C+	NF
Sand Blasting	C	C+	NF	NF
Sand Casting	C	C+	NF	NF
Sanding	C	C+	NF	NF
Sawing (tooth blade)	NA	NA	C	C+
Scrap Management (Clean)	C	C	C+	NF
Sectioning	NA	NA	C	C+
Shearing	NA	NA	C	C+
Shipping	NA	NA	NA	NA
Sizing	NA	NA	C	C
Skiving	NA	NA	C	C+
Slab Milling	NA	NA	C	NF
Slitting	NA	NA	C	C+
Soldering	NA	NA	NA	NA
Solution Management	NA	NA	C	C+
Spot Welding	C	C	C+	NF
Sputtering	NA	NA	C	C+
Stamping	NA	NA	C	C+
Straightening	NA	NA	C	C
Stretch Bend Leveling	NA	NA	C	C
Stretcher Leveling	NA	NA	C	C
Swaging	NA	NA	C+	NF
Tapping	NA	NA	C	C
Tensile Testing	NA	NA	C	C
Thread Rolling	NA	NA	C	C
Torch cutting (i.e., oxy-acetylene)	C	C+	C+	NF
Trepanning	NA	NA	C	C+
Tumbling	NA	C	C+	NF
Turning	NA	NA	C	C+
Ultrasonic Cleaning	NA	NA	NA	NA
Ultrasonic Testing	NA	NA	NA	NA
Upsetting	NA	C	C+	NF
Water-jet Cutting	C	C	C+	NF
Welding (ARC, TIG, MIG, etc.)	C	C	C+	NF
Wire Electrical Discharge Machining (WEDM)	C	C	C+	NF