

Recommended Changes for Beryllium OEL Within the European Union

Review of Discussion and Inputs from BHSC/SAS and AWE Study Group

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What is SCOEL? What Is Their Methodology?

- **SCOEL = Scientific Committee on Occupational Exposure Limits**
- **Established in 1995 by European Commission**
- **Based on Council Directive 80/1107/EEC (1980) as amended by Council Directive 88/1107/EEC (1988)**
- **Focuses on health effects of chemicals**
- **Similar to process for ACGIH® TLV®**
 - Does not consider cost impacts or feasibility other than as specified on next slide
 - Does not consider ancillary provisions (e.g., medical surveillance, recordkeeping)
- **Study group reviewed a draft document, not a final recommendation (which was issued May 31, 2017)**



What SCOEL Considers

- **General procedure (clause 3.2 of SCOEL methodology document, version 7, 2013):**
 - Assemble relevant data
 - Determine whether the database is adequate for setting an OEL
 - Identify “crucial” adverse effects
 - Identify relevant studies
 - Establish mechanism (threshold or non-threshold toxicological model)
 - Assess dose/response data
 - Decide if a STEL is required
 - Decide if a biological limit value (BLV) might be established
 - Establish numerical values for OEL (8-hour TWA), STEL (if required), and BLV (if required)
 - Document the entire process so that rationale for OEL is clear.
 - “Assess the technical measurement feasibility of the air and biological values recommended”



What SCOEL Recommendation Does NOT Consider

- Does not appear to properly consider analytical feasibility – discussion to follow
- Worker protection requirements (apart from the limit values themselves)
- Medical surveillance requirements
 - Are COSHH guidelines sufficient? Is testing needed? If so, what?
- Exposure monitoring requirements
- Other ancillary provisions (e.g., housekeeping, training)
- No discussion regarding a potential EC OEL value, which may take one of two forms:
 - Indicative (IOELV) – member states required to set an OEL but not necessarily at or below the IOELV
 - Binding (BOELV) – member states required to set an OEL at or below the BOELV
 - *For BOELV, socio-economic and technical feasibility factors should be taken into account*



SCOEL Recommendation 175 (Beryllium and Inorganic Compounds) - Summary

- **At relevant concentrations, carcinogenicity, BeS, and CBD deemed “critical health effects” (but that term is not defined)**
- **Carcinogenicity – SCOEL *carcinogen group C* (genotoxic carcinogen for which a practical threshold may exist)**
- **Local non-cancer effects**
 - Acute Be disease at high single-exposure levels
 - BeS and CBD at repeated low levels
- **Systemic effects – likely those associated with reduced respiratory function**
- **Reproductive toxicity – No data**
- **OEL recommendation – 0.02 $\mu\text{g}/\text{m}^3$, inhalable fraction**
- **STEL recommendation – 0.2 $\mu\text{g}/\text{m}^3$, no fraction specified**
- **Sensitization – Notation recommended for both skin and respiratory tract**
- **Skin – discussion to follow**
- **Biological Guidance Value (BGV) – recommended: 0.04 μg Be per liter of urine**
 - Insufficient data to support a biological limit value (BLV); the BGV is intended to detect recent exposure to Be



Comment 1 (General)

The term “critical health effect” should be defined.

- Term used several times in recommendation
- Some effects might be precursors to a critical effect without themselves necessarily being critical
- A definition would allow for greater objectivity



Comment 2 (General)

The basis for defining BeS as a “critical health effect” is less definitive (than cancer and CBD).

- **Published SCOEL methodology document refers to “adverse effect”**
- **Clarification is needed as to whether SCOEL appraises BeS as an “adverse effect” and if so, at what level**
- **Is the proposed STEL aimed at guarding against BeS (and CBD), or just CBD?**



Comment 3 (General)

The recommendation does not appear to properly consider analytical feasibility.

- In some cases there may not be a suitable measurement technique.
- More discussion under Comment 8.



Comment 4 (Carcinogenicity)

Although the classification of beryllium as genotype Group C is appropriate, additional information is available that should be considered.

- **Surface particle count (McCawley et al., 2001) may also be a contributing factor.**
- **Conclusions from *Managing Beryllium* (NRC, 2008) support holistic physiological burden measurement (i.e., evaluate and control exposure from routes other than just inhalation).**



Comment 5 (OEL)

The recommendation relies on the same studies that ACGIH® used for its TLV®, but reached a different conclusion.

- **ACGIH® adopted 0.05 $\mu\text{g}/\text{m}^3$ instead of 0.02, after originally (in 2005) proposing 0.02.**
- **SCOEL conclusion seems to be based mainly on this statement from Kelleher et al. (2001): “None of the 22 workers with LTW exposure $<0.02 \mu\text{g}/\text{m}^3$ had BeS or CBD.”**
- **ACGIH® noted that statement and the following from the same study:
“Comparison of our data with occupational exposure limits, however, must be made with caution because occupational exposure limits are based on the upper tail of the exposure distribution rather than on measures of central tendency.”**



Comment 6 (OEL)

Lifetime weighted average data should not be used as a basis for an 8-hour TWA.

- Madl et al. (2007): LTWs can mask variation in daily samples, and do not account for duration of exposure or peak concentration.
- LTWs involve combining averaged data that are averaged more than one time.
- Madl (2011) suggested that maintaining Be exposures below $0.2 \mu\text{g}/\text{m}^3$ 95% of the time may prevent BeS and CBD.



Comment 7 (OEL)

Sampling issues associated with the designation of the OEL as an inhalable fraction have not been adequately considered.

- **The two commercially available inhalable particulate samplers are based on work at IOM (Edinburgh), and were originally designed for gravimetric analysis.**
- **Major limitations of these samplers:**
 - Sampling flow rate (fixed at 2 L/min)
 - Risk of cross contamination (since they are not disposable)
 - Lack of laboratory capacity (to handle the number of samplers that would be required, especially for cleaning between uses)



Comment 8 (OEL)

Measurement issues associated with the proposed OEL have not been adequately considered.

- **Method sensitivity is a function of amount of air drawn through a filter and the sensitivity of the analytical method.**
- **ISO 20581 requires that detection limit should be at most 10% of the OEL.**

SCOEL stated that NIOSH 7102 (GF-AAS) was the most sensitive method.

- **The LOD is 0.005 µg/sample.**
- **That would not be sufficiently sensitive for samples less than 0.25 m³ under the SCOEL draft recommendation.**
- **Fluorescence, at 0.0001 µg/sample, is the most sensitive.**



Comment 9 (STEL)

There appears to be a lack of basis for the STEL recommendation.

- SCOEL appeared to be concerned with potential for acute effects, which studies indicate would require 50+ $\mu\text{g}/\text{m}^3$ of exposure.
- SCOEL appears to have relied on Madl et al. (2007), but the studies it cited do not provide any basis.
- At an OEL of 0.02 $\mu\text{g}/\text{m}^3$ over eight hours, if the entire exposure occurred in 15 minutes, it would be only 0.64 $\mu\text{g}/\text{m}^3$, less than the proposed STEL.



Comment 10 (Skin)

Comments provided by AWE:

- Implementation of stringently low airborne limits alone may not prevent BeS.
- Dermal exposure should be quantified or alternatively workplace surface contamination evaluated and mapped systematically to data.
- ATSDR (2002) notes: *“Two types of dermal effects have been observed in beryllium exposed workers: an inflammatory reaction and an immune reaction.”*



Comment 11 (BGV Proposal)

There is a lack of data to support correlation of beryllium levels in urine with adverse health effects.

- Urinary beryllium levels represent recent and accumulated exposure.
- Half-life of Be in urine: 450 days (IPCS, 1990)
- Measurable amounts of Be in urine do not imply an adverse health effect.
- Rocky Flats experience (unpublished) did not identify correlation between urinary levels of Be and results of BeLPTs.
- Summary of December 2014 feasibility study (AWE and U.K. HSL):

	AWE Results	Background levels (Established)
	166 samples	295 background levels
Median urinary	24.9 ng/L	5.4 ng/L
95th percentile urinary	37.2 ng/L	-11.6ng/L
Range	10.4-59.4ng/l	<LOD-50.8 ng/L
Corresponding air sample range (8hr TWA)	2-17ng/m3	UK limit 2 µg/m3 TWA
Corresponding surface sample range	1.2-46.2µg/m2	UK n/a

- No correlation shown between Be levels in air and urine, but slight statistical indication that surface data may be linked – more research required.



AWE Workplace Monitoring Data

Data from AWE machining facility over 57 months (January 2012 – September 2016):

8 hour TWA ($\mu\text{g}/\text{m}^3$)	number of samples	percentage
less than or equal to 0.02	24360	99
≤ 0.1	293	1
≤ 0.5	3	0
≤ 1.0	0	0
≤ 2.0	0	0
> 2.0	1	0



Subsequent Activities (March 2017 to present)

- **SCOEL Recommendation 175 was finalized largely as originally proposed**
 - Officially adopted February 8, 2017
 - 8-Hour TWA of 20 ng/m³, inhalable fraction
 - 15-Minute STEL of 200 ng/m³, inhalable fraction
 - Biological Limit Value: none recommended
 - Biological Guidance Value: 0.04 µg/L (sampling time not critical)
 - Carcinogenicity: Group C
 - Notation: Sensitization (dermal and respiratory) but no skin notation
- **Advisory Committee on Health and Safety at Work (ACSH)**
 - Tripartite body established by European Commission in 2003:
 - *Employers Interest Group*
 - *Governmental Interest Group*
 - *Workers Interest Group*
 - A standing Working Party on Chemicals (WPC) discussed beryllium at meetings in June 2016, October 2016, and March 2017



ACSH Final Recommendation (adopted May 31, 2017)

As agreed by all three interest groups:

- **8-Hour TWA of 600 ng/m³ (inhalable fraction) for a five-year transitional period, and 200 ng/m³ after that**
 - Compared to SCOEL 8-Hour TWA of 20 ng/m³, inhalable fraction
- **No STEL was recommended**
 - Compared to SCOEL 15-Minute STEL of 200 ng/m³, inhalable fraction
- **Biological Guidance Value: 0.04 µg/L (same as SCOEL)**
 - With footnote to emphasize importance of biomonitoring for beryllium exposure risk management ... *not routinely done in U.S.*
- **Notation: Sensitization (dermal and respiratory) as recommended by SCOEL**
- **ACSH “strongly” recommended adoption of binding OEL values as soon as possible**
- **Comments from interest groups:**
 - Employers: 200 ng/m³ (inhalable) will be technically challenging, noting the OSHA PEL (same value but using CFC sampling)
 - Governmental: No comment
 - Workers: Want a review in the future with a view to lowering to original SCOEL proposal of 20 ng/m³



Biological Monitoring – U.K. Health and Safety Executive (2016)

- Beryllium in urine can now be measured at very low levels (<1 ng/L)
- Unexposed persons have levels <12 ng/L
- Workers show higher levels, which may increase over the work week
- Smokers may have higher levels than non-smokers
- **AWE pilot study in 2014 – 18 workers – summary:**
 - All but one sample were above 95th percentile for unexposed persons (11.6 ng/L)
 - However, 98% were below German biological reference value of 50 ng/L
 - No correlation with air samples but did not compare with wipe samples
- **U.K. HSE:**
 - Believes that biological monitoring will help to control current exposures
 - May propose a Biological Monitoring Guidance Value based on 90th percentile of data from workplaces with good control

(Source: Dr. Jackie Morton, U.K. Health and Safety Laboratory presentation “Biological Monitoring for Beryllium”, 2016 – provided by Joanne Gill, AWE)



How Will “BREXIT” Play Into the Impact to the U.K.?

- **Brexit will not be complete until March 2019.**
- **Action may be taken on this proposal before then.**
- **The U.K. may not want to be seen as “less protective” than its European neighbors in any event.**



Conclusions

- Although ACSH OEL recommendation is more in line with OSHA PEL than original SCOEL recommendation, it is still seen as technically challenging for industry
- OEL is based on lifetime weighted average data – not a recommended approach.
- STEL as proposed by SCOEL did not seem to have a firm basis and in fact was not agreed by ACSH.
- SCOEL and ACSH seem to place high value on biological monitoring, but there is still no clear correlation between urine and air concentrations.

