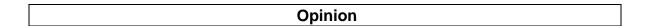


## The Advisory Committee on Safety and Health at Work



## Opinion on an EU Occupational Exposure Limit value for Cadmium and its inorganic compounds under Directive 2004/37/EC (CMD).

Doc. 663/17

Adopted on 31/05/2017

Cadmium and its inorganic compounds (as classified under CLP as Category 1A or 1B carcinogen):

The three interests groups discussed cadmium and its inorganic compounds during the October 2016 and the March 2017 meetings of the Working Party on Chemicals and agreed on the need for an EU

binding OEL for cadmium and its inorganic compounds.

In the meeting on 21<sup>st</sup> March 2017, the recently adopted SCOEL/ OPIN/336 (adopted 8<sup>th</sup> of February 2017) was discussed. SCOEL recommends the following occupational exposure limit values for

cadmium and its inorganic compounds:

8 h – TWA: 1 μg/m<sup>3</sup> (inhalable fraction)

15 min - STEL: None

BLV: 2 μg Cd/g creatinine in urine (sampling time not critical)

Additional categorization: SCOEL Carcinogen group C (genotoxic carcinogen for which a mode of

action-based threshold is supported and a health-based OEL is proposed)

**Notations: None** 

Two approaches were agreed by all three interest groups;

Approach one:

1 μg/m<sup>3</sup> (inhalable fraction, 8h TWA), with a transition period of 7 years (to end no later than 2027)

at 4 µg/m<sup>3</sup> (inhalable fraction, 8h TWA).

Approach two:

To combine an airborne OEL with the biological monitoring value proposed by SCOEL which could be used as a mean of demonstrating control of workers' exposure in those Member States where biomonitoring is carried out. This would be based on complying with both the SCOEL biomonitoring value of 2 μg Cd/g creatinine in urine and the 8 hour TWA of 4 μg/m<sup>3</sup> (respirable fraction) as

recommended by SCOEL/ OPIN/336 (page 10 paragraph 2, adopted 8<sup>th</sup> of February 2017).

The ACSH agrees that both approaches present adequate technical means of protecting workers' health. The ACSH requests the Commission to investigate whether the combined biomonitoring and TWA OEL approach could be included in the CMD as a directly related provision in accordance with

CMD Article 16.

The ACSH strongly recommends the Commission to adopt as soon as possible binding occupational

exposure limit value for this substance under Directive 2004/37/EC.

Specific comments of GIG: None

Specific comments from the Employers Interest Group:

(i) The EIG requests that it be also stated that: "approach TWO (2) of this opinion is the original

SCOEL/SUM 136 recommendation, the validity of which has been reconfirmed in SCOEL/OPIN/336

opinion of February 2017", and which industry has been implementing in a voluntary and proactive manner,

- (ii) The EIG is of the opinion that, should (the OEL-only based) approach ONE (1) be the only approach retained by the regulators, it will require:
  - a fundamental change to the risk management strategy implemented by the H&S Departments and Occupational Doctors of the Cd-using industry, along with the redesign and commissioning of more complex air cleaning systems,

whilst not providing the safety net that approach TWO (2) ensures thanks to the use of the urinary Cd BLV.

Indeed, urinary Cd, is first a comprehensive exposure bio-marker in the sense that it integrates all routes of uptake (ingestion and inhalation). It is also a well-demonstrated predictor of kidney tubular damage (Chaumont et al 2014). This is a strong benefit for a cumulative toxicant such as Cd in two very different situations:

In a systematic way: for plants where workplace air quality is well controlled, the involuntary ingestion route becomes the predominant uptake route over the inhalation route (it is worth noting that with the 2010 SCOEL recommendation of  $4\mu g/m3$  respirable, involuntary ingestion is a significant part of the uptake). Involuntary ingestion cannot be controlled by compliance with an OEL,

In accidental situations: when an air cleaning equipment malfunction goes undetected for some amount of time, the biomarker value acts as a safety net.

(iii) The EIG would like to highlight the fact that the authors of the Jarüp study (1988), which is key in developing the OEL proposal of 1  $\mu$ g Cd/m³ (inhalable fraction), state (p228) that data " (...) indeed suggests that the cumulative blood cadmium dose is a more sensitive predictor of renal damage than cadmium in air, particularly at low levels of air cadmium concentrations", hence giving clear preference of the use of an exposure biomarker over an OEL for the prevention of systemic adverse effects.

Specific comments from the Workers Interest Group:

- (i) About option two of this opinion, the WIG requests the Commission to also assess whether mandatory biomonitoring might infringe workers' rights to data protection, in particular with regard to Regulation (EU) 2016/679, article 9 thereof.
- (ii) The WIG is of the opinion that SCOEL's suggestion of the existence of a health-based OEL for cadmium and its inorganic compounds should not be followed. Instead, the WIG favours the approach taken by the German scientific committee which derived an exposure-risk-relationship (ERR) for these compounds .
- (iii) Based on the ERR derived in Germany, an 8-hour exposure concentration of 4  $\mu$ g/m³ Cd is associated with an additional cancer risk of 1:100. Should option 2 be implemented, the WIG believes that this BOEL should be reviewed in due time with a view to lowering it to a value of not higher than 1.6  $\mu$ g/m³ Cd (respirable) which is supposed to correspond to an additional cancer risk of 4:1,000.