

## ICdA position on the inclusion of cadmium biomonitoring at the workplace, and on the RAC recommendation for an OEL and BLV.

The members of ICdA have been implementing for more than a decade a strict set of measures to protect workers from exposure to cadmium. These measures are built on the SCOEL 2010 recommendation to implement both a BLV and OEL.

*“A biological limit value will mainly protect workers against systemic toxicity of Cd, mainly renal and bone effects. (...) Beside a BLV, an OEL is necessary to protect workers against long-term local effects.”<sup>1</sup>*

This combined approach was confirmed by SCOEL in 2017 and acknowledged by the Commission in Directive 2019/983/EU<sup>2</sup>, and the RAC was asked to assess this combined monitoring as an efficient way to protect against all adverse health effect.

The annual EU data collection (conducted since 2012) by ICdA on cadmium workplace monitoring (cadmium in air, in blood and in urine) demonstrates that implementing a combination of a BLV and OEL as recommended by SCOEL is an effective approach to ensure a steady decreases of cadmium body burden of exposed workers.

\*  
\* \*

**In its RAC recommendations for OEL and BLV values**, RAC did not respond to the Commission request<sup>3</sup> to:

*“[compare] the effectiveness of the health protection of the **combination** of an OEL and biomonitoring value as proposed in the SCOEL Opinion 336 (2017) compared to the OEL adapted in Directive 2019/983/EU”.*

Indeed, in its latest opinion<sup>4</sup>, the RAC recommended the setting of a BLV **without reassessing the OEL originally set** at 0.001 mg/m<sup>3</sup> (inhalable fraction), a value which was derived precisely under the assumption that no biomonitoring was conducted at the workplace and no BLV was set.

**ICdA supports workplace air monitoring** as an appropriate way to ensure no adverse health effects will occur in the respiratory tract (local effects). For this, an occupational exposure limit value (OEL) of 0,004 mg/m<sup>3</sup> (respirable fraction) has been considered appropriate by SCOEL (2017), a value which was not challenged by RAC.

**In addition, ICdA recognizes that air monitoring alone is not fully effective** to assure worker protection against systemic effects of cadmium exposure as it does not consider oral uptake of cadmium. ICdA therefore supports complimentary biomonitoring and the setting of a BLV for

<sup>1</sup> See SCOEL/SUM/136 dated February 2010

<sup>2</sup> See *inter alia* recital 18 of directive 2019/987/EU

<sup>3</sup> See page 1 of RAC opinion dated March 18<sup>th</sup>, 2021 at: <https://echa.europa.eu/documents/10162/20958724-bcdb-e18d-db23-48ded07496cf>

<sup>4</sup> See page 8 of RAC opinion dated March 18<sup>th</sup>, 2021 at: <https://echa.europa.eu/documents/10162/20958724-bcdb-e18d-db23-48ded07496cf>.

protecting workers against systemic adverse health effects, which are related to the total cadmium body burden, as a result of cadmium uptake by inhalation **and** ingestion.

**Furthermore, ICdA considers biomonitoring a valuable tool in workplace exposure management but does not agree with the RAC conclusion that adverse effects occur at 1 µg/g creatinine**, which contradicts a well-established conclusion that the LOAEL for workers is 5 µg/g creatinine and a protective BLV should therefore be set at 2 µg/g creatinine.

\*  
\* \*

## Background

The request of the COM was to assess if an OEL + BLV together could provide an equivalent solution to the existing OEL. The RAC recommendation refers to the current OEL of 1µg Cd/m<sup>3</sup>, inhalable fraction, set in the Directive to justify its conclusions. By doing so, RAC has not taken into consideration that this current OEL was set in absence of a BLV, which in that case justified the choice for the inhalable fraction and the reliance on modelled derivation from cadmium in air to urinary cadmium. With the addition of a BLV, this justification no longer applies.

ICdA supports **biomonitoring** as an effective way to follow up cumulative exposure and total cadmium body burden, which is a good indicator for setting thresholds **for systemic health effects**.

ICdA does not agree with the RAC conclusion that systemic health effects occur at Urinary cadmium (Cd-U) levels of 1µg Cd/g creatinine. Although there are many studies on the general population revealing statistically significant correlations between Cd-U and adverse health effect at or even below 1µg Cd/g creatinine, many experts have serious reservations about a potential causality. It is most uncertain that at levels around 1µg Cd/g creatinine, Cd-U still reflects the cadmium body burden.

Potential bias effects are insufficiently addressed, making it not possible to draw conclusions. Further, these correlations observed at low concentrations are not observed at higher concentrations (in occupational studies), which cast even more doubt on the validity of a causal relationship.

Furthermore, the recently concluded 5 years European HBM4EU project confirmed that in some Member States, a significant fraction of the population shows background levels of Cd-U >1µg Cd/g creatinine. In this context, setting a BLV at 1µg/g creatinine would create systemic discrimination against these populations. This EU-funded project published its overview on Cd and concluded that a value of 2µg Cd/g creatinine would be protective in the occupational setting.<sup>5</sup>

The scientific literature confirms kidney effects are still considered the critical effects of Cd exposure. Several studies confirm a LOAEL of 2µg Cd/g creatinine in the general population. In occupational settings the LOAEL has been identified at 5µg Cd/g creatinine. Those studies indicating effects in the general population at concentrations <2µg Cd/g creatinine should be interpreted cautiously, therefore **ICdA supports a workplace BLV of 2µg/g creatinine**.

---

<sup>5</sup> Lamkarkach F, Ougier E, Garnier R, Viau C, Kolossa-Gehring M, Lange R, Apel P. Human biomonitoring initiative (HBM4EU): Human biomonitoring guidance values (HBM-GVs) derived for cadmium and its compounds. Environ Int. 147:106337 (2021). <https://doi.org/10.1016/j.envint.2020.106337>

## Conclusion

ICdA continues to support, and indeed has implemented with demonstrable success with its Industry Members, the SCOEL recommendation of 2017 which concluded the protective nature of the combination of an OEL = 4µg Cd/m<sup>3</sup> (respirable fraction) along with a BLV = 2µg Cd/g creatinine.

Therefore, the proposal of ICdA is to amend the CM(R)D as follows:

### Annex III:

Name of agent	Limit values						Notation	Transitional measures
	8 hours			Short-term				
Cadmium and its inorganic compounds:	0,004 mg/m <sup>3</sup> (*)	-	-	-	-	-	-	-

(\*): respirable fraction

### Annex IIIa:

#### 2. Cadmium and its inorganic compounds

*2.1 Biological monitoring must include measuring the urinary cadmium level (CdU) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is: 2 µg Cd/g creatinine*