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."*[1]

This combined approach was confirmed by SCOEL in 2017 and acknowledged by the Commission in Directive 2019/983/EU[2], 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.
See appendix '*ICdA Workplace Monitoring Observatory*', for more information on the ICdA (bio)monitoring practice in many member states for more than a decade.

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* *

In its RAC recommendations for OEL and BLV values, RAC did not respond to the Commission request[3] 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[4], the RAC recommended the setting of a BLV **without reassessing the OEL originally set** at 0.001 mg/m3 (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/m³ (respirable fraction) has been considered appropriate by SCOEL (2017), a value which was not challenged by RAC.

[1] See SCOEL/SUM/136 dated February 2010
[2] See *inter alia* recital 18 of directive 2019/987/EU
[3] See page 1 of RAC opinion dated March 18th, 2021 at: https://echa.europa.eu/documents/10162/20958724-bcdb-e18d-db23-48ded07496cf
[4] See page 8 of RAC opinion dated March 18th, 2021 at: https://echa.europa.eu/documents/10162/20958724-bcdb-e18d-db23-48ded07496cf.

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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 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/m³, 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.[5]

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

[5] 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: 10.1016/j.envint.2020.106337

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general population at concentrations <2µg Cd/g creatinine should be interpreted cautiously, therefore **ICdA supports a workplace BLV of 2µg/g creatinine.**

Conclusion

ICdA continues to support, and indeed has implement 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/m³ (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/m3(*)*	-	-	-	-	-	-	-

(*): 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*

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Appendix: ICdA Workplace Monitoring Observatory

For many years, the ICdA has been supporting its members in providing their workforce with a safe and healthy workplace.
As part of this assistance, a 'best practice' ICdA Guidance was developed and initially published in 1996. Following targeted Risk Assessments, SCOEL opinions and regular industry Health and Safety meetings this Guidance is now in its 4th version published in 2018. To monitor and measure progress, two major Monitoring Observatory programs were launched. In 2008, the ICdA began the collection of extensive occupational biomonitoring data on both cadmium in urine and cadmium in blood in Europe. In 2014, the collection of monitoring data of cadmium in workplace air was added.

Key facts:

- ***The ICdA Guidance on managing workplace exposure to cadmium has been in place since 1996. Annual exposure monitoring is conducted and collated to quantify progress.***
- ***The 14th annual data collection of cadmium bio-monitoring data from over 5000 exposed workers in 40 EU plants shows that urinary cadmium is now low and continues the steadily decreasing trend line over the last 15 years, providing practical evidence that today's cadmium exposure levels in industry are well managed.***
- ***This improved status is achieved by continued reduction of Cd levels in air at the workplace combined with more strict hygiene measures to minimize unintentional oral uptake of cadmium. It demonstrates that implementing a combination of a BLV of 2µg Cd/g creatinine and an OEL of 4 µg Cd/m3 respirable fraction (as recommended by SCOEL 2017) is an effective approach to ensure a steady decrease of cadmium body burden of exposed workers, ensuring that the risk of occurrence of chronic cadmium diseases by occupational exposure will be reduced to an insignificant level.***
- ***However, switching from Respirable to Inhalable fraction adds a further 5-10 fold reduction in the OEL value.***
- ***Furthermore, applying a statistical assessment for the air monitoring data, according to EN 689:2018, implicitly adds another safety factor of up to 10 to the cadmium chronic exposure risk. In practice therefore, EN 689:2018 has the effect of assessing exposure by comparing to 10% of the OEL.***
- ***The combination of workplace air monitoring and biomonitoring, following the SCOEL recommended values, has been very effective in monitoring exposure to cadmium and taking the appropriate steps to reduce such exposure where identified to enhance worker protection. These results could not have been reached by implementing only air monitoring or only biomonitoring.***

Bio-monitoring Observatory OCdBIO

In the Observatory of Cadmium Biomonitoring ("OCdBIO"), all participating companies' occupational doctors provide anonymized biomonitoring data to the ICdA in full compliance with RGDP. After collation, ICdA then publishes a yearly consolidation together with an updated time trend series across the whole EU industry.

Starting in 2008 with 1800 workers in 15 plants, the OCdBIO observatory is today widely accepted and implemented to cover annual reporting data on **more than 5000 workers** from **40 plants**, in **12 countries** (see table below):

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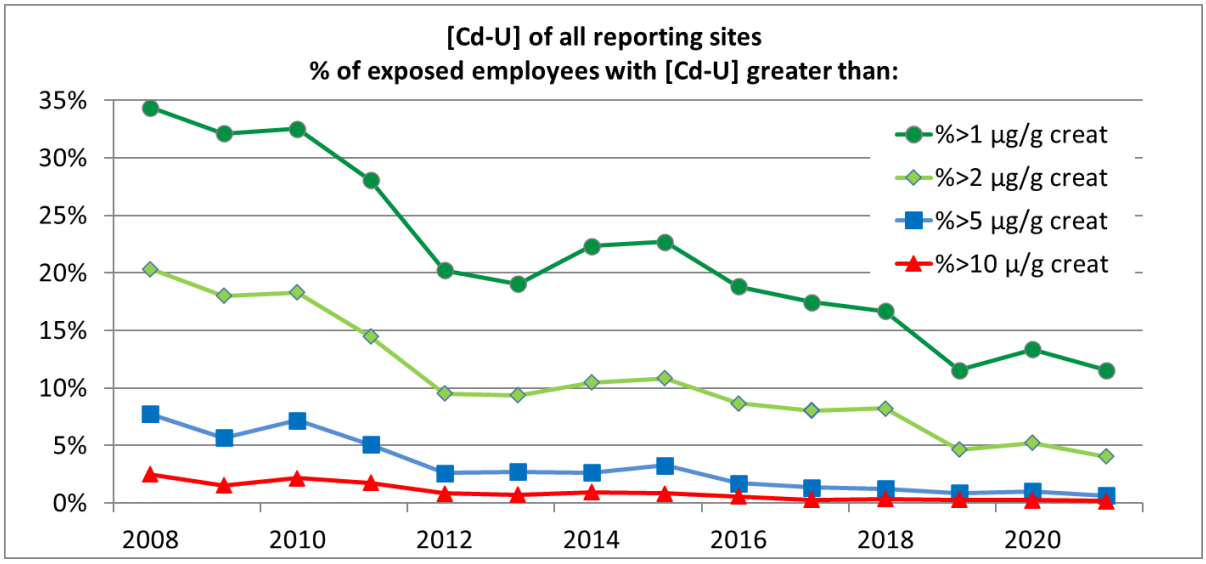
Country	Number of participating plants	Country	Number of participating plants
Belgium	8	Italy	1
Bulgaria	1	Netherlands	1
Czech Republic	3	Norway	1
Germany	9	Spain	2
Finland	1	Sweden	1
France	9	UK	3

Bio-monitoring results: urinary cadmium

The figure below shows an overview of reported urinary cadmium levels from 2008 until 2021, illustrating the steady and significant decrease of urinary cadmium in occupationally exposed people. The share of workers with urinary cadmium >2µg/g creatinine has dropped from 20% in 2008 to only 4% in 2021.



It should be noted that clearing of historic accumulated cadmium from the human body is a very slow process. The decrease of urinary cadmium, even after a complete stop of Cd exposure in this population, does not happen over a period of a few months but rather many years. Cadmium half-life in urine is estimated to be 20 years

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The ICdA Guidance (revision 4, 2018)[6] details best practice for plant and worker management. Nonetheless, should Cd levels increase, the Guidance recommends a series of actions to be taken if it exceeds 2µg Cd/g creatinine. This includes;

- An enhanced medical surveillance including regular measures of urinary cadmium to ensure workers protection.
- A detailed analysis of the related workplace environment along with an assessment of individual hygiene procedures implementation, including coaching by the occupational doctor.
- With occupational doctor consultation, removal from exposure if the CdU level of a worker exceeds 5µg Cd/g creatinine.

Conclusion on biomonitoring

The widespread implementation and monitoring of best practice across ICdA members over many years has allowed a demonstrable steady reduction of exposure as witnessed by evolution of urinary cadmium levels, which integrate exposure from both inhalation and ingestion.

Workplace Cadmium in air monitoring observatory OCdAIR

Data reporting to ICdA and fraction measured

In 2014, the ICdA started the Observatory of Cadmium Air Exposure ("OCdAIR"), in which all participating companies report their workplace air exposure information following a very strict protocol. Note that the reported exposure concentrations are corrected for the use of personal respiratory protection.

In accordance with the SCOEL conclusions of 2010 and 2017, the fraction reported to ICdA is the respirable fraction, as defined by EN 481. Appropriate equipment to capture the respirable fraction is selected by participating companies. For a few companies which report only data on the inhalable fraction, these are considered to encompass the respirable fraction and included as such in the OCdAIR database as conservative respirable data. From plants reporting both fractions, we see that **inhalable and respirable fractions are in a ratio of 5 to 10.**

Switching to Inhalable rather than Respirable fraction adds a 5-10 fold reduction to the SCOEL value.

Similar exposure groups (SEGs) and SEG distribution

All participating plants are required to use the concept of Similar Exposure Groups (SEGs) which bring together workers with a similar exposure profile.

In 2021, as shown below, **33 plants,** representing **211 different SEGs** and **3607 workers**, reported their workplace monitoring data on cadmium in air to the ICdA.

	2013	2014	2015	2016	2017	2018	2019	2020	2021
# Plants	12	22	20	16	30	25	31	33	33
# SEGs	67	142	131	124	162	165	204	216	211
# Workers	994	1548	1369	1278	2249	1857	3499	3662	3607

[6] ICdA – Eurometaux Guidance on the Management of the Risks related to Chronic Occupational Exposure to Cadmium and its Compounds (2018). https://www.cadmium.org/wp-content/uploads/2022/01/2018-icda-guidance-document.pdf

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Testing for compliance: geometric mean

Compliance testing is conducted using 1) the geometric mean or 2) standard EN 689:2018 (70% confidence interval of the 90 percentile), of measured values for each SEG. Those values are calculated and compared with the 4 µg Cd/m3 respirable fraction which is to be considered in combination with the 2 µg Cd/g creatinine exposure biomarker.

If we consider the geometric mean as assessment criteria, excellent progress has been made so that by 2021 there were only 3 Similar Exposure Groups (SEGs) representing 24 workers, where the exposure limit of 4µg Cd/m³ respirable was exceeded.

Geomean	number of workers in this range				
Range [µg/m³] respirable	**2017**	**2018**	**2019**	**2020**	**2021**
<4 µg Cd/m³ respirable	**2169**	**1711**	**3241**	**3510**	**3437**
non-conclusive	**28**	**126**	**99**	**101**	**146**
4 <=> 7	48	20	21	36	15
7 <=> 10					
> 10	4		18	15	
other non-compliant					9
total	**2249**	**1857**	**3379**	**3662**	**3607**

Testing for compliance: workplace air monitoring standard EN 689

Although the geometric mean value is a more representative indicator for the exposure and long-term accumulation of cadmium by workers, the revised monitoring standard EU EN689:2018 has now defined a different statistical indicator for general application in workplace exposure assessment, which is based on the 70% confidence interval of the 95th percentile. Since toxicity levels for cadmium in air have been derived based on a cumulative 40-year occupational exposure the EN689:2018 approach is more conservative by a factor of 10. In practical exposure assessment, the statistical analysis does not consider previous sampling results. Therefore, the simplified statistical approach considers compliance is met when all samples are below 10% of the OEL. This means that in practice, exposure assessment following EN 689:2018 is more than 10 times more conservative than a geometric mean value.

Assessment of occupational exposure by EN 689:2018 introduces an additional safety factor of 10.

When applying the more stringent statistical monitoring standard EN 689:2018, which most member states implement, the limit value of 4µg Cd/m³ (respirable fraction) is exceeded for 253 workers representing 7% of the exposed workers. The ICdA, via an annual Health and Safety meeting and regular review of its Guidance, assists the Members in statistical interpretation and provide valuable support on continuous improvement to further reduce occupational exposure.

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EN689	number of workers in this range				
Range [µg/m³] respirable	**2017**	**2018**	**2019**	**2020**	**2021**
<4 µg Cd/m³ respirable	**1441**	**852**	**2393**	**2476**	**2493**
non-conclusive	**517**	**521**	**553**	**698**	**861**
4 <=> 7	158	147	124	65	34
7 <=> 10	41	99	67	29	35
> 10	92	166	184	311	146
other non-compliant*		72	58	83	38
total	**2249**	**1857**	**3379**	**3662**	**3607**

*for workers in these workplaces, there are insufficient number of samples for the EN 689:2018 statistical assessment.

Reducing the workplace limit from 4µg Cd/m³ respirable fraction to 1µg Cd/m³ inhalable fraction, means in practice that the SCOEL exposure limit value reduces by a factor 20 to 40. This adds to the implicit safety factor of 10 from EN 689:2018.

If a workplace limit would be set at 1µg Cd/m³ inhalable fraction, using the stringent statistical approach of EN 689:2018, only 27% of all exposed workers would be in a compliant workplace. Clearly that would be a dramatic scenario and full compliance would be unattainable in practice.

Conclusion on air monitoring

The data presented above demonstrate that industry has been successful in increasing the number of workers for which workplace air is regularly monitored. By implementing this voluntary programme aligned to the SCOEL conclusions the number of workers who belong to SEGs which comply with the OEL of 4 µg Cd/m3 (respirable fraction, geomean value) has increased to over 87%. Conversely, the number of reported workers for which the geometric mean value exceeds 4µg Cd/m³ respirable fraction, has dropped to 24, now representing only 0.66% of all workers.

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