



International Cadmium Association

168 Avenue de Tervueren/Box 4 • B-1150 Brussels, Belgium  
Tel. : +32(0)2-776 00 77 • Fax: +32(0)2-777 05 65  
Email : mgilles@cadmium.org

## Minutes of the 16<sup>th</sup> ICdA H&S Committee

**June 25th, 2018**

**10h00 – 16h30 at**

***BLUEPOINT - CONFERENCE & BUSINESS CENTER***

***Boulevard A. Reyers 80***

***B-1030 BRUSSELS***

### **1- Introduction**

Welcome by Mik Gilles to the participants (cfr. Annex 1 Attendance list).

The provisional agenda proposed by ICdA is adopted (cfr. Annex 2, slide 2).

Each participant is asked to accept and comply with the statement of compliance as shown on the screen (cf. Annex 2, slide 3).

### **2- Approval of the minutes of the 15th H&S committee (June 13th, 2017)**

The minutes of the fifteenth H&S committee (June 13th, 2017) are approved unanimously and the final minutes will be posted on the website.

### **3- REACH developments** (cfr. Annex II, slides 4-6)

Authorisation procedure: Cd, CdO and CdS (Noömi Lombaert– ICdA)

Each year, ECHA makes Recommendations of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation):

#### • 9<sup>th</sup> draft recommendation (June 2018):

- Cd(OH)<sub>2</sub>, CdCO<sub>3</sub> and Cd(NO<sub>3</sub>)<sub>2</sub> were added to the SVHC list and were also scored by ECHA and add to already listed Priority Substances Cd, CdO, CdS, CdCl<sub>2</sub>.
- However, ECHA picked up and grouped the Pb compounds this year. Considering that the workload for ECHA would have been too high when Cd compounds would be added, they were not picked up for Annex XIV.

#### • 10<sup>th</sup> draft recommendation (June 2019):

- With 3 cadmium compounds on position 1-2-3 of the list of Priority Substances, cadmium and cadmium compounds will almost certainly be grouped and proposed for the 10<sup>th</sup> draft recommendation next year.

#### **4. Academic support** (Noömi Lombaert– ICdA) (cfr. Annex II, slides 7-11)

##### **Threshold/non-threshold carcinogen:**

Noömi Lombaert gave an update on the genotox study. She recalled the aim of the study:

1. To analyse the shape of the dose-effect relationship for the genotoxic effects of Cd at low doses in occupational settings
2. To test the hypothesis of a threshold dose for the genotoxic effects of Cd
3. A secondary hypothesis is that the Cd-U threshold for genotoxic effects is  $>10 \mu\text{g/g}$  creatinine, i.e. higher than the current occupational exposure limit ( $2 \mu\text{g/g}$  creatinine)

The study is finalized and the university is preparing a paper. Conclusion of the study were:

- No increase of micronuclei, even not in the group of the highest exposed workers ( $>10 \mu\text{g/g}$  creatinine).
- Multiple regression analysis for the effect of confounding factors on MN showed:
  - No influence of smoking
  - No influence of Cd-B, Cd-U
  - Influence of gender (F>M)

Frank Van Assche made the remark that the radiated samples that were used as positive control could be challenged and advised to check for literature data on positive controls. Frank also advised to review the gender influence as presented by UCL.

##### **Conclusions of the study:**

1. Absence of genotoxic effects in lymphocytes of workers exposed to low levels of cadmium
2. The frequency of MN in lymphocytes of workers was related to internal Cd doses to test the hypothesis of a threshold for the genotoxic effects of Cd and showed the Cd-U threshold for genotoxic effects is  $>10 \mu\text{g/g}$  creatinine, i.e. higher than the current BLV ( $2 \mu\text{g/g}$  creatinine)

#### **5. Participation to ISES workshop** (Noömi Lombaert, ICdA) (cfr. Annex II, slides 12-14)

The International Society of Exposure Science Europe had its 1st European Exposure Science Strategy Workshop, June 19-20 at the Federal Institute for Occupational Safety and Health (BAuA), Dortmund. The mission of ISES is : "To integrate exposure science into European regulations and industry practice, and to anchor it in academic research and education, in order to foster innovation and to create a safe and sustainable future for humans and the environment"

Considering that the workshop took place at BAuA and knowing that BAuA was at the basis of rejecting biomonitoring from the CMD directive, ICdA presented 2 posters related to the ICdA risk management system and on the biomonitoring program OCdBio.

## **6- OCdAIR: results, analysis, discussion** (Mik Gilles, ICdA) (cfr. Annex II, slides 17-24)

### Objective:

Once we enter in the authorisation phase, which is expected to occur somewhere between 2019 and 2021, all plants will have to show compliance with the occupational exposure limit value (OEL). On top of that, the OEL for cadmium, which is being discussed now in the revision of the Carcinogens and Mutagens Directive, will like enter into force mid 2020 and will become binding.

### Participation and quality of reporting

For 2017, the degree of participation raised by almost 50% with 30 plants and 2249 exposed workers reported.

The quality of the reporting improved:

- More samples per SEG
- More information given on the data (respirable/inhalable, use of PPE and protection factor)

Air quality should be under control to assure  $< 4\mu\text{g Cd/m}^3$  **respirable** air, always and for all workers. At the moment, we believe the 90 percentile will be more likely looked at. This is somewhere in between the geometric mean ICdA initially applied, and the 95% percentile with a 70% confidence interval described in EN689.

However, this limit value is challenged by the Commission. The Commission proposal for amendment of CMD only foresees air monitoring and therefor sets a much lower limit of  $1\mu\text{g/m}^3$  inhalable.

### Performance in 2017

With reference of an OEL at  $4\mu\text{g/m}^3$  respirable (ICdA guidance – SCOEL 2010)

- Geometric mean: 4 % non-compliant
- 90 percentile: 26 % non-compliant (20% of which are non-conclusive)

With reference of an OEL at  $1\mu\text{g/m}^3$  inhalable (= +/-  $0,25\mu\text{g/m}^3$  respirable): as proposed by the Commission

- Geometric mean: 47 % non-compliant
- 90 percentile: 81 % non-compliant

**Obviously, some further efforts are needed, even if we only have to comply by mid 2020 with the most optimistic OEL of  $4\mu\text{g/m}^3$  respirable.**

ICdA will push for implementing the 2010 SCOEL opinion at  $4\mu\text{g Cd/m}^3$  respirable (in combination with bio-monitoring) and not the 2017 alternative with air monitoring only that has a limit value set  $1\mu\text{g Cd/m}^3$  inhalable.

Conclusion:

- Exposure to Cd is under control in most workplaces.
- Over the past 10 years, our industry has consistently improved the workplace exposure of its workers...and these efforts should continue
- Plants should aim not to have workers with CdB > 3µg/L in order to have as little as possible workers with CdU > 2µg/g in 2020.

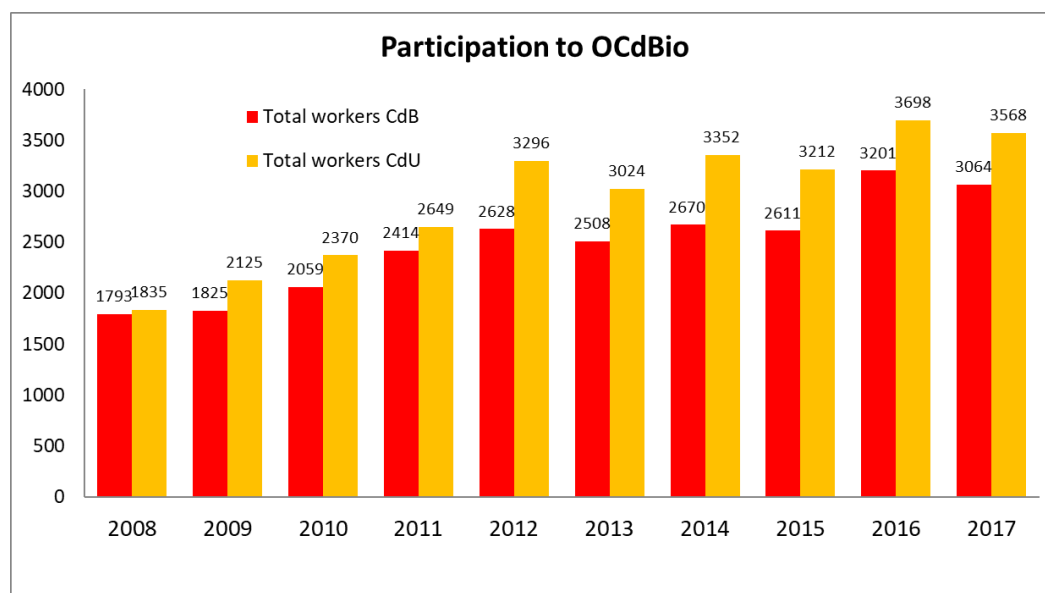
**7- OCdBIO-10: results, analysis, way forward** (Mik Gilles, ICdA) (cfr. Annex II, slides 26-41)

Mik Gilles gives a short introduction with reminding the aim of the OCdBio. The OCdBio, in which biomonitoring data is collected in the Cd industry, started up in 2008 in order to convince ourselves and authorities on the efficiency of our risk management program and the compliance of the current exposure levels with recommended BLVs. The selection of the 2 biomarkers of exposure for workplace bio-monitoring is explained. Cd-B (µg/l) is an indicator of recent (and older) exposure and Cd-U (µg/g creatinine) as biomarker of the amount of Cd stored in the kidney cortex where the first signs of Cd toxicity develop. A reference is made to the graph (cfr. 2013 ICdA guidance) on the use of “exposure biomarkers” to conduct adequate advanced medical surveillance.

The number of plants participating was the highest ever recorded since OCdBIO was launched in 2008.

- 36 EU sites participating (3737 workers)
- 36 sites reporting CdU (3568 workers)
- 28 sites reporting CdB (3064 workers)

Effort will continue to identify more plants and invite them to join.



Summary of the discussions (Trends analysis, comments)

The distribution of Cd-U and Cd-B in EU-sites has been established using the data of all EU reporting sites for the years 2008 up to 2017. The OCdBio data over this 10-year period include

neither the same individuals nor the same companies. New companies entered, other closed or did not report each year.

For CdB, the following observations were made:

- Good progress was made: Exposure of workers was again reduced in 2017
- But...
  - Still too many workers have too high level of exposure to keep (or bring) them below the target of 2µg Cd/g creatinine.
  - Comparison with CdU data shows that increased CdB values are most often not related to high historic burden => sign of too high recent exposure
- Future compliance with BLV of 2µg Cd/g creatinine?
  - We should keep all workers below 5 µg Cd/L in blood
  - We should strive not to have more than 1% workers above 3 µg Cd/L in blood (max.1% excused because of historic cadmium body burden)
- Continued efforts are required to reduce exposure and comply with the new upcoming exposures limits.

For CdU, the following observations were made:

**Forecast**

- The CdU values decreased further. When anticipating near future retirements, good workplace exposure and good personal hygiene, the most optimistic scenario indicates that in 2020, there will be 5% of all workers above the cut off value of 2µg Cd/g creatinine.
- Looking at the group of workers hired after 2000, the earlier trend of increasing CdU was reversed. If efforts are continued, 2% of these workers will remain above 2µg Cd/g creatinine by 2020.

**Positive elements:**

- Situation continued to improve in 2017
- Excellent progress: Number of workers above 2µg/g creatinine has dropped with 75% since 2008.
- Effect of reduced exposure as reflected by lower CdB values translates in a reduction of CdU values (but further efforts are needed at some places)
- The group with high cadmium burden (>5µg) is disappearing from the workplace (retirement, removed from exposure, lower exposure).
- Some plants should remind the medical doctor that removal from a workplace with increased cadmium exposure is recommended for workers with CdU > 5µg/g creat.
- Historic Cadmium burden of some workers is too high to bring them below 2µg Cd/g creat. by 2020, but this number is going down due to retirement.

## **8. Status of EU Commission proposal for amendment of the CMD which sets an OEL for cadmium at 1 µg Cd/m<sup>3</sup> inhalable** (Patrick de Metz, SAFT) (cfr. Annex II, slides 43-54)

### **History**

SCOEL recommendation of February 2010: combination of air and bio monitoring

- OEL (8h TWA): 0.004mg Cd/m<sup>3</sup> (respirable fraction)
- BLV: 2 µg Cd/g creatinine

ICdA has taken these values in the ICdA guidance 2013.

DG Employ program as of 10/01/2017: Develop amendment of the Carcinogens and mutagens Directive concerning cadmium (a.o.).

First step: ask the SCOEL what to do in case there is no bio-monitoring in place.

SCOEL released a new opinion on 8/2/2017 adding the following to its previous recommendation:

*“However, an isolated OEL of 4µg/m<sup>3</sup> (not linked bit a BLV) would not appear being equally protective against systemic nephrotoxicity of Cd.....Accordingly, an OEL(not connected with biological monitoring) for Cd and its inorganic compounds should be 1µg/m<sup>3</sup>.”*

Second step: Working Party on Chemicals (WPC)

Agreement on dual approach (OEL with a BLV) to the proposal. the new one with only an OEL (as suggested in the 2017 SCOEL opinion) as well as the original one with a combined BLV and OEL (from the 2010 recommendation).

Third step: Advisory Committee on Safety and Health at Work (ACHS)

The ACHS agreed on this dual approach (a 4µg/m<sup>3</sup> **respirable** OEL + BLV OR a 1µg/m<sup>3</sup> **inhalable** OEL).

The ACHS requests the Commission to investigate whether the combined biomonitoring and TWA OEL approach could be included in the CMD as a directly related provision with CMD Article 16.

Fourth step: Socio-Economic Assessment (SEA)

The Commission did a SEA on the effect of setting a binding BLV (subcontracted to UK consultant RPA). The Commission explicitly asked the consultant not to consider bio-monitoring.

Fifth step: Working Party on Chemicals (WPC)

The Commission representative rejected the option with bio-monitoring stating that it is legally challenging to introduce this in the CMD. The employers delegation did not agree with this position.

sixth step: The Commission (DG Employ) released a proposal for amendment on April 5, 2018. The proposal sets an OEL at 1µg/m<sup>3</sup> inhalable with a transition period of 7 years at 4µg/m<sup>3</sup> inhalable.

## Legal procedure

The proposal for amendment of the CMD is forwarded to the Council and the Parliament. The decision is by co-decision by Council and Parliament where both the Council and EP have to approve the amendment

- Further amendments are possible
- Council and EP must agree on all additional amendments
- Approval by qualified majority (2/3) in Council and EP. In the Council, a proposal can also be blocked by a number of countries that represent 1/3 of all EU people. So we can block with support of 3 large countries and 1 or 2 smaller ones. This is what we will aim for.
- Council is typically the stronger party in this process

ICdA has contracted consultant-lobbyist, Jose Lalloum, to assist in addressing Council and EP.

### What has been done already:

First position paper was issued in advance of the Council meeting of June 4<sup>th</sup>. We organized ourselves and appointed a country champion in each member state where we have presence. These champions organized contacts with national administration and communicated the ICdA industry position. All our members were asked to post comments on the dedicated Commission website. Meetings took place with French, UK, CZ and Finnish administration.

At the June 4<sup>th</sup> meeting, we did get good support from UK, France and Finland and many countries mentioned that the values were low and that they would have to revert with national industry before taking a position. France informed us that they will need more countries to support our position in the next meeting (July 6<sup>th</sup>?). If not, they say it will make no sense to continue opposition and our case will be lost.

ICdA worked out an alternative proposal for amendment and drafted a second position paper. The position paper was presented to the rapporteur of the parliamentary Commission. This is the person that chairs the technical working group in the parliament on this amendment. The ICdA proposal was well appreciated and will be proposed at the meeting. ICdA will approach key representatives of other political fractions (=shadow rapporteurs) participating in this technical working group.

### Next steps

Council:

Meetings are planned with Italian and Spanish administration.

The text and argumentation of the ICdA proposal for amendment will be shared with the Council members via our appointed country Champions.

Austria, who will take over presidency in the Council as of July 1 has been contacted by Jose Lalloum and informed about our proposal for amendment. Austria will likely delay the July 6<sup>th</sup> meeting and push it to the next week to have more time to prepare.

Parliament:

ICdA will approach key representatives of other political fractions (=shadow rapporteurs) participating in this technical working group of the EP. We need to convince them to support the proposal of the rapporteur.

We need support from the Unions. CZ unions have given support, but weight is too low. We will now try to get national support from Swedish Unions. According to Jose Lalloum, strong opposition from Unions could block our amendment. So, it is extremely important to get some Unions on our side.

## **9. Review of the ICdA Guidance document** (Patrick de Metz, SAFT) (cfr. Annex II, slides 55-59)

To show active involvement in improving workplace conditions, it is important that we regularly update the guidance document, sharing positive experience gained in the group.

The text was discussed and following proposal were made:

- Switch position of section 3.1 and 3.2
- Add something on fit test for masks (not applicable to air stream masks)
- Suggestion to explicitly refer in 4.2 also to actions already defined in 4.1
- Soften the requirement for effect biomarkers at the lowest CdU values.
- In section 5.4, the decision diagram is changed. The action levels for Cd in blood will shift from 3 to 2 and from 5 to 4.
- In section 6, add that all other external factors should be considered when making an individual assessment (e.g. smoking habits, diet, health condition...)

The text will be edited with inclusion of these remarks, and an updated draft will be circulated. Considering the urgency of having an approved updated version, we will ask to send in comments within the next two weeks.

## **10- Other business)**

No other business was proposed, and the meeting was convened at 16:20h.



**Attendance list**

<i>Meeting</i>	<b>ICdA_16<sup>th</sup> H&amp;S Committee</b>
<i>Date</i>	<b>26 June 2018, from 10h am to 16h30 pm</b>
<i>Place</i>	<b>Blue Point Meeting Center</b>

<b>Names</b>	<b>Company</b>	<b>Names</b>	<b>Company</b>
WINBOW Howard	JAMES M BROWN	LOMBAERT Noömi	ICdA
DE METZ Patrick	SAFT	GILLES Mik	ICdA
VANMOL Thierry	FLAUREA	CANOO Christian	Cadmium REACH Consortium
VOS Ann	NYRSTAR	VAN ASSCHE Frank	IZA
JONGEN Richard	NYRSTAR	BRUYNINCKX Bruno	LAMIFIL
VAN DE MIEROP Hild	METALLO	CHARPENTIER Leah	FIRST SOLAR
KOLISNYK Paul	TECK	HEINECKE Mario	GLENCORE/NORDENHAMER
JANOTA Matous	NIMETAL	MARQUEYROL Muriel	SOFRADIR
<b>By conference call:</b>			
MATTSSON Sven-Erik	SAFT	WADE Andres	FIRSTSOLAR
VASLIN J-C	SAFT	BOOTH Mark	VENATOR
LADIETTE Martine	AMPHENOL-SOCAPEX	BOROWSKI Kamil	SILESIA



## **ANNEX 2**

Slides presented at the ICdA 16<sup>th</sup> H&S Committee