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 12th ICdA H&S Committee

Risk management at the workplace: REACH compliance and monitoring

June 26th, 2014
9h30 – 16h00 at
DIAMANT - CONFERENCE & BUSINESS CENTER
Meeting room "Galilei/Huygens"
Boulevard A. Reyers 80
B-1030 BRUSSELS

1- Introduction

Welcome by Mik Gilles to the participants (cf. file 1 Attendance list); each participant is invited to sign a statement of compliance (Competition law).

The provisional agenda proposed by ICdA is adopted (cf. file 2 Provisional Agenda 12th ICdA HS ctee- 26 June 2014), with as main subject namely: 'Risk management at the workplace: REACH compliance and monitoring'.

2- Approval of the minutes of the 10th H&S committee (June 5th, 2013)

The minutes of the eleventh H&S committee (June 5th, 2013) are approved unanimously and the final minutes will be posted on the website.

3- REACH developments

Authorisation procedure: Cd, CdO and CdS (Christian Canoo – IZA) (cf. file 3 Presentation ICdA 12th H&S Committee)

Proposed by Sweden, Cd, CdO and CdS were candidate-listed in 2013; CdCl2 has been added recently to that list. Cd and CdO were prioritized using the new scoring system.

Position papers were prepared for Cd, CdO and CdS, with support of EPPA Consult, involved members and LR.

Updated files were submitted by the LR's, the co-registrants were contacted and advised to update their sections as well.

The results so far are that:

- Some Member States showed understanding for the low-moderate priority

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scoring of Cd (15 points) and CdO (15 points) for Authorization

- ECHA acknowledged information updates from all co-registrants and confirmed our scoring forecast
- ECHA did neither include (because of rather low score) Cd nor CdO, in their proposed 6th priority list
- The 6th list contains so far 21 substances, including several Pb-compounds

Regarding the status of other Cd compounds versus SVHC (substance of very high concern) candidate list, there is an expected public consultation on harmonised classification and labelling proposals for cadmium hydroxide, cadmium nitrate. But timing is not known yet.

Cadmium: threshold carcinogen (Noömi Lombaert – ICdA) (cf. file 3 Presentation ICdA 12th H&S Committee)

In the authorisation process starting from Annex XIV inclusion, ECHA distinguishes 2 ways of submitting a dossier: 1) the adequate control route and 2) the socio-economic assessment (SEA) route.
In the past there were several non-threshold CMR references for cadmium, namely in the Cadmium Risk Assessment (2007), the summary of the Risk Assessment (2008) and in the Risk Reduction Strategy (2008). But recently in 2010, SCOEL defined in their SUMDOC 136 Cadmium as a Category C carcinogen (genotoxic carcinogen for which a practical threshold is supported).
It has been demonstrated that Cd induces cancer by multiple mechanisms and the most important among them are aberrant gene expression, inhibition of DNA damage repair, induction of oxidative stress, and inhibition of apoptosis. The available evidence indicates that, perhaps, oxidative stress plays a central role in Cd carcinogenesis because of its involvement in Cd-induced aberrant gene expression, inhibition of DNA damage repair, and apoptosis. As opposed to direct DNA damage, interactions with proteins appear to be more relevant for Cadmium induced carcinogenicity.
Although SCOEL states that a threshold of 1000 µg/m³x years (or 25 µg/m³ during 40 years) has been reported for genotoxic effects in workers exposed to Cd by inhalation (based on Forni et al, 1990, 1992), no clear cut threshold confirmation seems currently agreed for cadmium in the regulatory world. Therefore the question is, if further research is needed on this threshold activity to justify the adequate control route in the authorization process. When the threshold route is not accepted, a SEA needs to be done in a minimum of time and the SEA route is a more expensive route than the adequate control route.
In 2009, Pary Consultants (UK), performed for the REACH Cadmium Consortium a review on the genotoxicity of cadmium and recommended a study to determine NOAEL for genotoxicity (chromosome and point mutations) and the influence of modification of DNA repair activity.
At that time no further actions were taken and in the meantime Prof Parry passed away. It is agreed that a second opinion will be asked to Prof David Kirkland who is a UK-consultant and experienced geno-toxicologist.

Restrictions (Christian Canoo – IZA) (cf. file 3 Presentation ICdA 12th H&S Committee)

(1) For Cd and Cd-compounds (targeting especially cadmium pigments), an Annex

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XV dossier was announced in preparation by ECHA on request of the COM. This proposal has been withdrawn (so far) for lack of evidenced risks

(2) For Cd pigments (in artists paints), an Annex XV dossier has been issued by the KEMI (Swedish agency)

(3) On request of the Commission, for administrative reasons and coherency of the existing Entry 23, Cd and Cd-compounds were proposed to be restricted to be marketed and used in paints.
- ✓ We submitted a "principle" comment regretting the precedent setting of arbitrary amending an existing restriction outside the legal frame of the REACH regulation

Regarding the above 2nd Restriction proposal – Cd based pigments in artist's paints, in view of the public consultation external support was asked from :
- Prof Bernard on CdU as indicator of adverse effects at low exposure levels
- Prof Van Maele on the cause-effect relationship of Cd and breast cancer
- Prof Smolders on soil Cd accumulation and bio-availability of Cd from pigments
- EFTEC-Consult on socio-economic evaluation of bone-fractures.

A first set of comments was submitted before May 28, before the RAC/SEAC meetings of June in Helsinki. For RAC : Prof Smolders (expert on soils-food transfer) attended the meeting and for SEAC : C. Canoo attended the meeting

The results so far are:
- RAC Rapporteur: impressed by the explanations of Prof Smolders related to the net decrease of Cd in agricultural soils in the EU, and the resulting decreasing exposure.
- SEAC Rapporteur: clearly proposed not to recommend a Restriction on the weak basis presented in the Annex XV. A report is expected in August

The way forward is:

- The Public Consultation is not yet finished
- We propose to work with Prof Smolders to prepare additional comments on EFSA report (a meeting with him is foreseen on 3 July);
  - The options for further testing Cd-pigments contained in article matrix will also be explored (paints, plastics)
- Suggestion Eurométaux : to develop a communication plan with some influential MS-CA
- Contact with CEPE (Janice Robinson) in the coming weeks

4- Lobbying actions and strategies

(Patrick de Metz, Saft group, chairman ICdA H&S com) (cf. file 3 Presentation ICdA 12th H&S Committee)

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Lobbying on scoring/prioritization; the plan
The Cd Consortium developed a tentative score for Cd and CdO using the new methodology. This was presented to ECHA and to some MS along with a regulatory efficiency analysis.

New scoring/prioritization methodology
The ECHA scoring methodology was revised last year and adopted during MSC-33 in December 2013, superseding the former May 2010 approach (document issued 10/2/2014)
The new scoring takes into account:

- ✓ Inherent properties
- ✓ Volume
- ✓ Wide dispersive use
- ✓ Additional considerations and refinements but no longer "regulatory effectiveness"

Annex XV – Regulatory Efficiency: Concerns expressed in the Swedish annex XV about general population and workers (slides 43-47)

Lobbying on scoring : outcome

MS position

- ➢ Against inclusion in Annex XIV : FR, BE, UK, IT, CZ
- ➢ Leaning against : DE, BG, RO, PL
- ➢ Neutral : NL

ECHA "draft scoring" released in MSC-35 (mid-April)

- ➢ Cd : 15 to 17 points
- ➢ CdO : 15 points

Cd/CdO listed in second half of a "list of 23 substances - excepted lead compounds - with a high score" presented at this MSC

Cd, CdO not listed on ECHA "6th draft ECHA recommendation of 21 substances for inclusion in Annex XV presented to MSC-36 (mid-June).

5- OCdBIO-6: results, analysis, way forward *(Patrick de Metz, Saft group, chairman ICdA H&S com and Mik Gilles, ICdA)* (cf. file 3 Presentation ICdA 12th H&S Committee)

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 the OELs. The selection of the 2 biomarkers of exposure for workplace biomonitoring is explained. Cd-B (µg/l) is an indicator of recent (and older) exposure and Cd-U (µg/g cr) 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.

An overview of the solicited and responded EU sites is shown. Green boxes indicate sites

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that reported CdU and/or CdB. Red boxes indicate not reported sites. The number of reported workers in OCdBio, started up in 2008 (± 1700 for CdU) up to 2012 (± 3000 for CdU), indicates good participation although there are still some non reporting companies. Action proposal is to ask all REACH Cd members to report.

Review of OCdBio 6 (data 2013), vs.1, 2, 3, 4 and 5 (data 2008-2009-2010-2011-2012) (cfr presentation) (Patrick de Metz, Saft group, chairman ICdA H&S com)

The distribution of Cd-U in EU-sites has been established using the data of all EU sites for the years 2008 up to 2013
These OCdBio data over the several years include not the same individuals but the same companies.
We may guess that most of these people above 10 µg Cd/g cr, have nowadays been removed from exposed areas

The distribution of Cd-B in EU-sites has been established using the data of all EU sites for the years 2008 up to 2013

The above mentioned data are based on various numbers of EU-sites included in the Cd biomonitoring. The data set limited to the 15 EU-sites participating since 2008 in the Cd biomonitoring showed similar time trend, namely a general reduction in Cd-U and Cd-B, so no reason to present anymore these data of the initial 15 EU sites only.

Summary of the discussions (Trends analysis, comments)

- From the CdU-graph of the time trend for all sites included, it can be concluded there is a general reduction in Cd-U. Moreover, our initial target to have only 5% of employees with CdU >2 µg/g creatinin by 2017 is still feasible. (see below ICdA-2017/2020 initiative). From the absolute numbers an estimation can be made that the number of employees with CdU >2µg/g creatinine will decrease with about 50 per year. In order to reach by 2017 5% of the employees with CdU > 2µg/g creatinin, about 110 number of employees should disappear with CdU > 2µg/g creatinin during the next 4 years.
- The CdB time trend shows more variation. The time trend doesn't move so much, it is more or less flat. CdB does not only represents recent exposure but also a small part of accumulated Cd in the kidney. All Cd-B figures are coming from high Cd-U. In conclusion, Cd-B is not an indicator for short term exposure in case of long term exposed workers. It is only an indicator of recent exposure for new hired workers.
- Biomonitoring data was recently asked to our members on workers hired after 2000. The effort was made by our members and shows some decreasing trends in the collected data of the last 3 years.

ICdA- 2017/2020 initiative

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This ICdA initiative is not an individual but a collective commitment to achieve challenging targets in terms of biomonitoring results of the workers exposed to Cd. With the revision and further implementation of the ICdA guidance it is the aim to show the path followed in the past so far and having the goal of further reducing occupational exposure of the employees.

The goal in this initiative is to reach:

- **95% of European employees** subject to medical surveillance and bio-monitoring as required by their occupational medical doctor, below the urinary cadmium level of: **2 µg Cd/g creatinine by the end of 2017,**
- **98% of European employees** subject to medical surveillance and bio-monitoring as required by their occupational medical doctor, below the urinary cadmium level of: **2 µg Cd/g creatinine by the end of 2020**

6- OCdAIR: results, analysis, discussion (professional hygienist) *(Mik Gilles, ICdA* and dr Marc De Groof, Nyrstar) (cf. file 3 Presentation ICdA 12th H&S Committee)

In order to show compliance with the DNEL(respirable) of 4µg/m^3 and efficiency of our management system, we will have to be able to show results and improvements.
We are on good track with our database 'OCdBio' that we need to further refine according to best practice and we started in 2013 systematic measurements-campaign of Cd-air « Respirable fraction » vs total/inhalable fraction
Most of the measurements are specific for respirable fraction, but in a few cases, when 'inhalable' measurements indicate all values below the DNEL, those values are recorded (worst case) as 'respirable'
12 EU plants participated in OCdAir-1 and the results showed that 10% of workplace measurements are above 4µg Cd/m3 and 3,5% of workplace measurements are above 10µg/m^3 ! We need in any case better performance for our advocacy!

A remark is made that it would be interesting to know if in a certain SEG a mask is worn or not.

Marc De Groof, company doctor in Nyrstar was invited to give a presentation on respirable air sampling at the workplace.
As an introduction the definition of the several air fractions: inhalable, thoracic and respirable was clarified. Currently the ISO/ACGIH/CEN sampling conventions defines the 50%cut of for respirable and thoracic dust samplers at 4 and 10 µm respectively.
In the next part the 'behaviour' (deposition and clearance) of aerosols in the airways was situated. There are 5 mechanisms for the deposition of particles in the airways, namely 1) inertial impactation (for the bigger particles >5µm, in the upper region: nasopharynx), 2) sedimentation (for the medium particles 1-5 µm in the small airways: bronchi), 3) diffusion (for the small particles <0.1 µm in the alveoli), 4) electrostatic precipitation and 5) interception. Clearance is depending on the solubility of the particles for which different clearance mechanisms exist.
The next part of the presentation was focused on the procedures in measuring the respirable fraction. An overview on 1) the equipment (sampler pump , filter (sampler) head and filters ,

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calibrator and maintenance), 2) preparation of the measurements namely creating Similar Exposure Group (SEGs) and deciding how many measures per SEG, 3) Lab Analysis and 4) the interpretation of the results was given.

7- IAR (Inventory of Air releases) *(Mik Gilles, ICdA)* (cf. file 3 Presentation ICdA 12th H&S Committee)

Emissions of cadmium to air showed some small fluctuations over the past years and are around 100kg Cd/year for all cadmium producing and further processing plants. Data were reported by 20 plants. Fluctuations are often attributed to additional monitoring points and the detection limit. For emissions below the detection limit some plants took the detection limit for calculating the annual emission.
The reported emission values demonstrate that the annual emission of our industry is only a fraction of the Cd emission to air in Europe.

8*- Other business (Mik Gilles, ICdA, Frank Van Assche, IZA)* (cf. file 3 Presentation ICdA 12th H&S Committee)

-UNEP (Mik Gilles, ICdA)

ICdA made comments during the public consultation on UNEP Decision 27/12 Chemicals and Waste Management; Section II on Lead and Cadmium , Paragraph 4:

- Information on techniques for emissions abatement and on the possibility of replacing cadmium with alternate substances was submitted.
- Many references were made to the CADMIUM 2011 Kunming conference papers

-ICdA Code of Conduct (slide 80) (Mik Gilles, ICdA)

The code will be submitted for official approval to the general assembly in October 2014 in London.

-Water framework directive (WFD): update (Frank Van Assche, IZA)

The Water framework directive (WFD) aims at enhancing protection and improvement of the aquatic environment in Europe and with the goal of achieving zero emissions of priority hazardous substances (e.g: Cd) by 2020.
The WFD requires from the EC (European Commission) to establish EQS (Environmental quality standards) for Priority substances and Priority Hazardous Substances (PHS). These EQS are safe concentration levels which should not be exceeded in order to protect human health and the environment. Currently 33 substances (including Cd and its compounds) are on this list of Priority substances (pollutants presenting a significant risk to or via water), with the most hazardous of these, classified as Priority Hazardous Substances (PHS) and 'Cd and its compounds' are considered as PHS.

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The Cd EQS are very low and give problems for the MS to comply with. Currently there is a mandate from the Commission to WCA consultant (UK) to check on bioavailability correction to relax those Cd EQS.
In the frame of the development of BLM for Cd a literature study is now finalised by WCA and University of Gent. WCA has now an experimental work proposal presented for the second phase.
This research on those Cd-EQS is very important since it has also direct relationship in the description of 'safe use' under REACH.

9- Settings for the 12th H&S committee and longer term planning

The date for the 12th H&S committee - theme to be determined later- was proposed for June 2015.
A remark was made how to still improve attendance to this kind of meetings.

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