International Cadmium Association

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Minutes of the 11th ICdA H&S Committee
Risk control improvements & commitment

June 5th, 2013
9h30 – 16h00 at
DIAMANT - CONFERENCE & BUSINESS CENTER
Meeting room "Vesalius"
Boulevard A. Reyers 80
B-1030 BRUSSELS

1- Introduction

Welcome by Christian Canoo 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 11th ICdA HS ctee- 5 June 2013), with as main subject namely: 'Risk control improvements & commitment: guidance, targets and monitoring'.

2- Approval of the minutes of the 10th H&S committee (October 23rd, 2012)

The minutes of the tenth H&S committee (October 23rd, 2012) are approved unanimously.

3- Review of the comments submitted by ICdA, during the recent Public Consultation, regarding the Annexes XV (Cd & CdO) issued by Sweden as support for their proposal to include those substances in the SVHC-candidate list

(Christian Canoo - ICdA) (cf. file 3 ICdA 11th H&S Committee)

Last year Sweden notified through the Registry of Intentions (ROI), its willingness to propose CdO, Cd and CdS for inclusion in the SVHC (substance of very high concern) candidate list and to prepare accordingly Annex XV-dossiers. From then on, the REACH Cd Consortium, ICdA together with SAFT, RECHARGE, EPPA consult, contacted several MS to transfer information about our Cadmium Risk Management system and to convince that authorisation is not the good way since for the general population it has nothing to do with the uses of Cd but comes from Cd in fertilizers and this authorisation procedure will have no impact on Cd in the general population. Despite our collective efforts for avoiding Cd and CdO on the SVHC candidate list, Sweden confirmed on 4.02.2013 its proposal. Thereafter the following milestones happened:

- A public consultation (45 d) was opened from 4.03 till 18.04.2013

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- Comments were submitted to ICdA and others in due time
- Overview of all received comments was distributed early May to the MSC members (30 d consultation)
- Opinion of MSC is expected in the course of June (is scheduled for June 12th)
- "Candidate listing" will probably occur in July-August of this year

The MSC makes a proposal that must be endorsed by the MSCA. MSCA need to come to an unanimity on the Cd proposal by Sweden. If no unanimity is reached then it goes back to the Commission in comitology procedure. If there is full unanimity than Cd/CdO will come on the candidate list and ECHA will start looking into prioritization.

The 2 Swedish Annex XV-dossiers start with the proposal to identify both substances:

- As meeting the criteria of Article 57 (a) of the REACH regulation owing to its **classification as carcinogen 1B** and CMR
- As meeting the criteria of Article 57 (f) of REACH owing to the adverse effects on kidney and bone issue after repeated exposure and the **related classification STOT RE1** (for specific target organ toxicity after repeated exposure).

If only on basis of 57(a) inclusion on the SVHC list was justified, then we can emphasize on the route of threshold genotoxic carcinogen and hope for non-prioritization.
However with this extra 57(f) and the probably related non-threshold status, prioritization ranking may increase.

The Annex XV-dossiers articulate around:

- A first type of concern: general population exposed, and potentially at risk, through the Environment;
- A second type of concern: general population exposed and at risk due to Cd presence in manufactured articles.
- A third type of concern: occupational exposure of workers to cadmium

ICdA comments on the Swedish Annex XV dossiers:

- The comments were structured to (a) respond to each of the wrongly or not documented allegations and (b) provide elements that might be taken into account later in a prioritization phase. A short overview of the comments is presented and Christian Canoo mentioned if ICdA members are interested they can receive the complete files with comments as submitted to ECHA.
- This public consultation phase was now the only public window for giving our voice. ECHA has to take into account the arguments for prioritization and hopefully those comments will help in the submission of points in prioritization. In the prioritization phase there will be 2 public consultations again.

Other comments apart from ICdA on the Swedish Annex XV dossiers:

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A short overview is given on the other comments apparently also from aeronautics association and MS. All MS agreed on 57a. Regarding 57f : the Netherlands are not agreeing, UK says it should be discussed on a case by case basis, and not directly in favour of putting on the candidate list.

Lobbying: Members States (MS) were visited:

- Great-Britain, Germany, France, Belgium, Poland, etc…were visited the last 2 months, with support of a local member, our Chairman and EPPA.
- P. De Metz explains the lobbying was tuff and not really successful since those visits were really political oriented and nobody wants to contest the Swedish Annex XV since in their view technically difficult dossiers and made by experts. It was felt that MS reason that once a day they come up with an Annex XV dossier they also want no contest from others.

***4*- Review and discussion of the biomonitoring-2012 exercise (OCdBIO-5)**

(Prof. A. Bernard) (cf. file 3 ICdA 11th H&S Committee)

Christian Canoo 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 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.
An overview of the solicited and responded EU sites is shown. It is remarked that Miasteczko (PL) did not respond because apparently not the company but the Unions follow the biomonitoring. A new reporting company is e.g Calyxo (DE), a thin film solar modules producer. They were informed on our OCdBio by First Solar (DE). Umicore-thin films in Hanau (DE) reported however after the deadline, so not included in the 2012 data. This company produces Cd-coatings for electrical contacts. Some of the solicited companies were not responding although they should have data, e.g. Boleslav (PL) is not a producer but have imports and exports.
The OCdBio 5 (data 2012) was proceeded to be able to include it in our ICdA comments on the Swedish Annex XV dossiers. Normally results are collected by July/August but now the data was collected by April.

Review of OCdBio 5 (data 2012), vs.1, 2, 3 and 4 (data 2008-2009-2010-2011) (cfr presentation)

Prof Bernard starts his presentation by commenting a tentative scale to evaluate risks of Cd-induced renal dysfunction according to urinary Cd in occupationally exposed subjects based on his publication Bernard (1996) establishing 4 zones, namely Cd-U (µg/g cr) : <2 :

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2-5; 5-10; >10; the red one (>10 µg Cd/g cr) being the zone we should avoid, considering that above this value there is a linear increase of the risk.

The distribution of Cd-U in EU-sites has been established using the data of
15 EU sites (2008), 15 EU sites (2009), 21 EU sites (2010), 21 EU sites (2011), 23 EU sites (2012).
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
15 EU sites (2008), 16 EU sites (2009), 18 EU sites (2010), 17 EU sites (2011) and 20 EU sites (2012)

The above mentioned data are based on various numbers of EU-sites included in the Cd biomonitoring. The data shown only with 15 EU-sites included in the Cd biomonitoring showed similar time trend, namely a general reduction in Cd-U and Cd-B.

Summary of the discussions (Trends analysis, comments and suggestions)

- In the graph of the time trend for all sites included, it can be seen that in 2012 9.7% has CdU>2µg Cd/g creatinin. This is close to the general population where about 5% has CdU>2µg Cd/g creatinin (notably women with low muscular body mass, smokers)
- Remark is made by Prof Bernard that we have no info about which lab methodology is used e.g. Atomic absorption spectroscopy (AAS) or Inductively coupled plasma mass spectrometry (ICP-MS). The same methodology started with, should be kept in the same plant. Prof Bernard also mentions the problem of molybdenum contamination. And therefore Cd-U corrections for molybdenum interference are advisable.
- The question was asked what about the comparison, if possible, on the biomonitoring trends before and after 2000.
  This is not yet explored so far.
- Prof Bernard emphasizes that CdB not only represents recent exposure but also a small part of accumulated Cd in the 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.

Associations of urinary cadmium with age and urinary proteins: further evidence of physiological variations unrelated to metal accumulation and toxicity- Chaumont et al 2013, Environmental Health Perspectives.

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Pr. Bernard presents in his second presentation some new scientific data (publication Chaumont et al 2013 in press in Environmental Health Perspectives), supported in the framework of the European PHIME project, related to low environmental exposure to Cd.
The aim of this publication was to assess if Cd-U is a good biomarker of cumulative exposure to Cd at low-environmental exposure as encountered by the general population? The objective of the publication was:

1. To study the lifetime trend of U-Cd as a function of diuresis, gender, smoking status and protein tubular reabsorption.
2. To analyze the associations between U-Cd and urinary proteins.

The overall message of his presentation (paper) is the explanation for the discordant patterns of Cd-U and K-Cd with age that can be found in two mechanisms governing the urinary excretion of Cd and whose respective contribution varies with the level of Cd exposure and the integrity of the renal function. First mechanism related to high Cd body burden, is the release or secretions of Cd accumulated in the kidney. Second mechanism is the glomerular filtration of Cd-MT and the excretion of Cd-MT unreabsorbed by the proximal tubule. In this mechanism, the urinary output of Cd is determined by the amount of circulating Cd- thus by the Cd intake- and by the capacity of the kidney to filter and reabsorb proteins. This second mechanism is predominant in determining Cd-U when the Cd body burden is very low.
The overall evidence suggests that a very low exposure levels, the associations between proteins and Cd-U might be non-causal and simply reflect the ability of the kidney to reabsorb proteins, including those transporting cadmium (MT). All this has important implications in the risk assessment of Cd which largely relies on the use of Cd-U as exposure indicator.

5- Review and discussion of the 2013-revised « ICdA guidance on risk-management of Cd" *(Christian Canoo – ICdA and Patrick de Metz- chairman ICdA H&S com)* (cf. file 3 ICdA 11th H&S Committee)

Patrick de Metz explained why the revision of the ICdA guidance was needed. First of all a revision was asked already by our former ICdA chairman Emil Josendal to make it more user friendly and to the point. The Pb industry has developed a similar guidance and revised it as well with the aim to reach that 95% of the workers has Pb blood below the DNEL(in blood). With this revision the occasion can be taken to make Cd-B system a bit more though (action levels lowering from 5 µg/L to 3 µg/L and from 8µg/L to 5 µg/L). It is commented that this lowering of Cd-B levels is already accepted in SAFT (SE).

The purpose of this revised ICdA Guidance is to supply guidance to occupational medical doctors and management of plants with the purpose of bringing Cd exposure of all employees as CdU<2µg Cd/g creatinin. The revised guidance rest on 3 pillars to be implemented together: 1) ensuring plant cleanliness 2) collective and individual hygiene procedures 3) medical surveillance.

Comments and proposals/agreements

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- It is noted by Howard Winbow that air monitoring is not discussed in this revised version, although some info was included in the version 2006. Notably, there is no practical guidance how to reach the 4µg/m3 respirable fraction (DNEL respirable: 4 µg/m3 in Cd REACH registration dossiers). There should be some reference to ambient air monitoring (EN norms)
  ACTION: H. Winbow will draft some text and this will be also practically revised by M. De Groof and Dirk Gielen (Nyrstar).
  M. De Groof explains that in Nyrstar the concept of 'Similar exposure levels grouping' (SEGs) is applied. A SEG can be defined as: 'a group of workers having the same general exposure profile for the agent being studied because of the similarity and frequency of the tasks performed, the materials and processes, with which they work, and the similarity of the way they perform tasks.'
- It is noted that more info is needed on Personal protective equipment (PPE): e.g air stream helmets, respiratory protection equipment (RPE),…
  ACTION: Rolf Rodermund will draft some text on PPE linked to the presentation/ survey he did for the 7th Ctee on 'Choosing and maintaining the right PPE'
- It is noted that nothing is currently in the guidance on distinguishing workers hired after 2000.
  ACTION: Patrick de Metz will include this. Something on this was already included the REACH CSR: 'The management system has been progressively implemented in the EU Cd industry over the last decades. Workers that may have been exposed to cadmium before its implementation have their situation reviewed by the supervising Medical doctor on a case by case basis. In all cases, when subclinical effect biomarkers approach or exceed the reference values (see last point above), workers are removed from exposure.'
- Important remarks to be included on creatinin correction of Cd-U at low exposure level: creatinin correction may introduce an error in the concentration of biomarkers studied, which is variable according to the age of the subjects. The difference between men and women is strongly attenuated when the concentration Cd-U is expressed as µg per liter and not as µg per creat. (cfr publication EHP Chaumont et al 2013)
- It is confirmed by H. Winbow that JMB could cope with the new action levels of 3µg/L and 5 µg/L for workers hired after 2000. It is noted that this tightening of Cd-B is needed since if CdB= 8, then it will never be possible to manage Cd-U<2.
- **ACTION**: the aim is and it is agreed on, to have the revised guidance ready before half of July for the next ICdA board meeting.

6- 'Organization of a collective commitment to achieve challenging targets in terms of bio-monitoring results of the EU-workforce potentially exposed to cadmium" *(Christian Canoo – ICdA and Patrick de Metz- chairman ICdA H&S com)* (cf. file 3 ICdA 11th H&S Committee)

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

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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.

After collective discussions and looking back into the OCdBio data (all reporting sites), in which already in 2012 90.5% of the workers has Cd-U<2µg/g creatinin and seeing a gain of 5% in 1 year from 2011-2012: 85.6%-90.5%, we agreed on the following commitment:

- **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**

Christian Canoo proposes this ICdA 2017 format to be linked with the OCdBio questionnaire.

7- Organization of practical measurements and systematic reporting of Cd-in air on the workplace (expressed in "respirable µg Cd/m^3") in order to proof the general compliance, on the field, with the REACH-chosen DNEL (4 µg/m^3, respirable fraction) *(Christian Canoo – ICdA and Patrick de Metz- chairman ICdA H&S com)* (cf. file 3 ICdA 11th H&S Committee)

The question arises, and related to the definition of adequate control according to ECHA (95% below DNEL), how we can demonstrate this with the current biomonitoring data.

How to demonstrate adequate control for Cadmium exposed workers related to this 95th percentile?
Some facts:

- DNEL respirable: 4 µg/m3 , so strictu sensu we should demonstrate adequate control for 95% of the workers (air measurement values <DNEL of 4µg/m3)
- Today most data are inhalable air measurements

It is agreed that industry starts collecting air values (respirable fraction vs total/inhalable fraction) currently in place in our industry. A spread sheet (**OCdAir**) will be prepared by ICdA and sent to the involved industry parties. The aim is to develop a distribution graph indicating number of workers per level of exposure.

Goal: to collect the first data (OCdAir-respirable vs total/inhalable) by Q3 (October) 2013 in order to include it in the OCdBio reporting campaign of 2014. OCdBio 6 (data 2013) questionnaires have to be sent back by March 15th 2014

Facts:

- It is recommended for workplace air monitoring to perform personal sampling. Static sampling is only useful to detect leaks or sources of emissions.

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- UK JMB Workplace air monitoring: every worker is measured twice a year via personal sampling; 40 static measurement are done and the goal is to be compliant against 30µg/m3 respirable (OEL UK). It is explained that in the REACH dossier on Cd pigments the DNEL of 4µg/m3 is binding for the manufacturing sites (imput of CdO, Cd salts) of pigments. For DU this 4µg/m3 is more an advice and risk management is recommended.
- Nyrstar works with SEGs
- La Floridienne and SAFT confirmed they work with individual monitoring

Trend results (CdU) today are showing we are on the way of adequate control of the workers but we cannot yet 100% prove it. We hypothesize that the workers with CdU >5µg/g cr are related to the older workers and will retire in the near future.

***8-* Other business** *(Christian Canoo – ICdA)* (cf. file 3 ICdA 11th H&S Committee)

The 10th H&S committee was on the Water framework directive (WFD) which 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. To try to achieve this, companies can start with development of no emission process (evaporation solutions, closed circuits (cfr SNAM presentation 10th H&S com).
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.
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 in the order of 12500-18000 euro (by WCA and University Gent) will be proposed to the ICdA board for the budget of 2014. 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 early 2014

Prof Bernard indicates that a proposal for a next topic could be a discussion on which lab methodologies are used in.the OCdBio Observatory.

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