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 13th ICdA H&S Committee

Risk control improvements & commitment

June 24th, 2015
9h30 – 16h00 at
DIAMANT - CONFERENCE & BUSINESS CENTER
Meeting room "Baekelandt"
Boulevard A. Reyers 80
B-1030 BRUSSELS

1- Introduction

Welcome by Mik Gilles to the participants (cf. Annex 1 Attendance list); each participant is asked to accept and comply with the statement of compliance as shown on the screen. (Competition law).

The provisional agenda proposed by ICdA is adopted (cf. Annex 2), with as main subject namely: 'Risk control improvements & commitment'

2- Approval of the minutes of the 12th H&S committee (June 26th, 2014)

The minutes of the twelfth H&S committee (June 26th, 2014) 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)

Proposed by Sweden, Cd, CdO and CdS were candidate-listed in 2013; $CdCl_2$, $CdSO_4$, CdF_2 have been added to that list in 2014. 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. CdS and CdCl2 are scheduled to be scored by ECHA in 2015.

For the 7th list recommendation, ECHA will score CdS and $CdCl_2$. We updated those files in February 2015, and for Cd and CdO as well. In principle, all co-registrants confirmed their individual updates with proper codes for Intermediate uses, with their tonnages and the final substance in which they are transformed and with indication of uses advised against professional & consumer uses.

Scoring of $CdCO_3$, $Cd(NO_3)_2$ and Cd(OH)2 will not be done before 2018-2019. These compounds have first to go through the time consuming process of harmonised classification (earliest 8/2016, see further) before they can be proposed for the candidate list (another 18 months). Once elected for the list, the scoring procedure can start.

The results so far are that:

- Informally we were informed that ECHA gave a score of 15 to Cd and 17 to CdO but we believe that the score for CdO will be reduced to 15, based on the most recent information that were filed in Reach. The score of 17 was based on older info and not the most recent update, notably on concerned volumes and uses.
- 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
- The 7th list (2015) will be published very soon.

Harmonized classification & labelling:$Cd(OH)_2$, $CdCO_3$, $Cd(NO_3)_2$ (Noömi Lombaert ICdA)
The public consultation on Annex XV (KEMI) during 45 days- ended 11/05. KEMI's Harmonized classification proposed for consideration by RAC focuses on mutagenicity, carcinogenicity and STOT RE. The proposed harmonized classification (as future entry in Annex VI, CLP regulation) is the result of the Annex VI group entry, i.e. Acute Tox. 4* (H302, H312, H332), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) and the harmonized classification proposed for consideration by RAC (muta, carc, STOT RE).
However, for this proposed harmonized classification the hazard classes coming from the group classification (acute tox!) are not re-assessed in this Annex XV dossier but taken over as such.
Kemi's classification proposal for consideration by RAC is different from the CLP joint submission (self-classification), notably "muta 1B" proposal for Cd(OH)2 and CdCO3 instead of "muta 2"
ICdA believes, that Sweden doesn't have a strong case. Therefore, comments on the muta proposal were submitted by ICdA and we are confident that our comments are solid and convincing to support the "muta 2" classification.

Restrictions (Christian Canoo – IZA)

The administrative restriction amendment (antifouling paints Taric 3208-3209): will probably be proposed to COM

The final outcome of the KEMI-proposal to restrict cadmium pigments in Artists paints is not supported and advised against by RAC/SEAC. We don't know yet how COM will react.

The proposal to enlarge the current restriction of Cd-compounds to more plastics than the 16 restricted resins is withdrawn and no longer on the agenda

Academic support (Noömi Lombaert– ICdA)

Contract with UCL (Prof Van Maele) is signed on 27/01 covering:

1) Cadmium and breast cancer in general population

- ✓ Systematic review + meta analysis → publication
- ✓ Timing: 6 weeks after signing of contract; first draft delivered end March
- ✓ Publication is submitted mid June to Peer Reviewed Journal and will be

presented at the 2nd Cadmium Symposium in Sassari end of June by Prof Van Maele

- ✓ Main conclusion: 'no statistically significant increased risk of breast cancer among postmenopausal women related to dietary Cd intake'

2) threshold/non-threshold carcinogen:

- ✓ Monitoring survey: study of genotoxic effects in human lymphocytes (blood) of a well-defined cohort

Feasibility study on genotoxicity

- Start with literature study on genotoxicity of cadmium
- Make budget proposal based on quotes of competent genotoxicity labs.
- Study feasibility of the 2 different study design:
  A. dose response curve: genotoxicity study in different workers covering a broad range of 'doses' (low to mid doses) to determine a NOAEL (threshold)
  B. compare 2 exposure groups (no dose response curve):
     - study low dose exposed workers (<<10 µg/L) in comparison to controls
     - need for positive control to prove if no genotoxic effect seen, the test system is validated

For this exercise, we will need a test group with high CdU levels that is willing to deliver blood samples. Since in the general population, such people are difficult to find, we will approach our members that have such people in their workforce, and ask them if their workers are willing to participate in this study.
Timing: 6 weeks after the submission of the publication on Cadmium and breast cancer in general population
part 2 not started yet
Budget part 1 +2 : 25k€. .

4. Australian NICNAS: (Noömi Lombaert– ICdA)

Assessment draft report on Cd-pigments: Comments made by ICdA

- Public consultation on 'Human health Tier II assessment for pigments related to cadmium sulfide' ended 19/06
- Assessment (mainly based on read across from CdS) is not in line with our CSRs on cadmium pigment yellow, cadmium pigment red/orange:
  Proposed classifications: acute tox 4, STOT RE1, Muta cat2, Carc cat1B, repro cat2
  "However some or all of the classifications recommended may not be required if substantial evidence can demonstrate that the occupational risks can be mitigated through industrial surface treatment processes."

- Comments submitted by ICdA:
  - ✓ Explained our case for non-classification for any hazard as outlined in the REACH CSR: reference to CdTe (sparingly soluble) and very low bioaccessibility of Cd pigments
  - ✓ Reference to the Annex VI CLP EU group classification which covers 'cadmium and compounds' but excludes cadmium sulfoselenide and cadmium zinc sulphide → cadmium pigments not classed hazardous

- ✓ Emphasised cadmium sulphide is not used as a pigment and that all cadmium pigments covered by EU REACH registration are specifically treated to achieve extremely low levels of extractable cadmium

5. Chinese RoHS II: Comments made by ICdA: (Noömi Lombaert– ICdA)

The Ministry of Industry and Information Technology (MIIT) requested public comments to the recent published draft of a revised Decree No. 39, commonly referenced by industry as China RoHS II (Restriction of Hazardous Substances). ICdA was informed by Bergeson & Campbell about a potential issue with the revision of the Chinese RoHS regulation. Although it is said that compliance with Chinese RoHS II continues to be on a voluntary basis, concerns were raised by industries active in China that it would be better to express our concerns.

- Public consultation ended 17/06.
- RoHS II includes e.g. Cadmium and its compounds.
- Main comments posted by ICdA:
  - RoHS II does not include exemptions as in EU RoHS
  - 'its compounds': includes cadmium pigments which are not hazardous
  - Urged MIIT to consider the benefits of cadmium pigments' use, as well as the lack of suitable alternatives being less hazardous and equally socio-economically viable
  - Urged MIIT to allow greater consistency with similar RoHS implementations + consideration of exemptions to be specified

6- Lobbying actions and strategies *(Patrick de Metz, Saft group, chairman ICdA H&S com)*

Lobbying on scoring/prioritization was done for the first scoring exercise. The past experience taught us that there was little or no return for this specific action. Considering the cost of such advocacy, Patrick suggests not to enter in advocacy for the scoring and focus energy on checking that all registrants have entered the latest information in the Reach files Special attention should go to volumes and uses to avoid a too high score.
It is also important to prepare ourselves for "SEA-type" (SEA= socio-economic assessment) argumentation for a potential Public Consultation (Commission) that may be opened after an ECHA-recommendation of Cd and/or a Cd-compound for inclusion in Annex XIV; the question remains "what is the urgency of that proactive initiative"?
It is agreed that **ICdA will get first some info from experiences of other Consortia already involved in such SEA efforts. ICdA (volunteered by Howard Winbow and Patrick de Metz) will write up a one pager defining the scope of our SEA argumentation.**

7- OCdAIR: results, analysis, discussion *(Mik Gilles, ICdA)*

Objective:
Once we enter in the authorisation phase, which is expected to occur somewhere between 2018 and 2020, all plants will have to show compliance with the DNEL of 4µg Cd/m^3 (respirable) air. Therefore, it of highest importance that plants already focus on this upcoming limit, which is for most countries lower than what is asked today. Attention should be given on how to demonstrate compliance to this low value as well as the sampling procedure and statistical processing of the sampling results.

Question:
GAZ asked whether it was legally mandated by (REACH) law, that users of Cd or compounds for which the DNEL was set at 2µg/m3 (respirable fraction), had to comply with this DNEL.

ICdA is to ask Eurometaux if this question has received a clear answer.

The Chairman (PDM) expressed that this question, although interesting from a legal point of view, should not distract the industry from its goal of ensuring that compliance with this level of exposure (along with compliance with BLV CdU of 2µg/g) is obtained,

- Because these levels have been set by SCOEL as the very values which ensure risks to workers are under control,
- Because these levels have been retained by industry as the DNEL, and compliance with DNEL is what will be assessed when Authorization dossiers are filed and evaluated.

Results of OCdAir2
A significant increase in degree of participation was observed for this second year of monitoring. The quality of reporting improved but we see also room for improvement.

Air quality should be under control to assure < 4µg Cd/m³ **respirable** air, always and for all workers. Since it is not practical and economically not realistic to sample every worker permanently, standards give guidance on how to monitor to demonstrate compliance with an occupational exposure limit. In our case standard EN 689 on sampling is relevant. The method described in this standard is different from our recommendations in the OCdAir-2 exercise, leading to the following observations:

- Sampling and data treatment not yet in line with standards
- Amount of samples per SEG not yet in line with standards

Can we exceed this DNEL level in individual samples?

- Not according to EN 689
- Even more stringent with the upcoming revision of EN 689
  - All samples below 0,1 DNEL (minimum 3 samples) or
  - In a log-normal distribution (graph calculated from 9 samples), min. 95% of the workers should be below the DNEL.
  - From all reporting plants, only 2 demonstrated already full compliance with prEN 689 and DNEL of 4µg Cd/m³ respirable (=requirement for all in 3-4 years from now)

In 9 SEGs or 6,3% of monitored SEGs the average measured value was above 4µg/m². 67 workers or only 4,3% of monitored population are in SEG's which have an average exposure above 4µg Cd/m³ respirable.
First impression: not too bad, high degree of compliance, but the assessment method is more relaxed than the prescriptions in EN689 and the upcoming revision prEN689.

Guidance is given to improve the sampling and bring it in line with EN689 or prEN689.

1. Correct calculation of the value of a sample
   The average exposure over an 8h shift is the time average of periods of exposure and no exposure over an 8h shift. If there are non-sampled periods of zero exposure, these should be integrated in the time average mentioned and/or included in the value. Alternatively, sampling can be done over a period of 8h which avoid any extrapolations and calculations to derive the average exposure over the 8h shift. **ICdA will give further guidance on this in its next monitoring exercise OCdAir3.**

2. Integrate personal protection (P3 mask, airstream mask,…)
   Monitoring outside PPE (mask) is not representative for the exposure, but exposure conditions requiring PPE should become exceptional rather than standard practice.
   Since it is in most cases not possible to measure inside the PPE, some plants apply a correction factor. This seems to be standard practice in France. Although PPE manufacturers provide protection factors for the PPE, they are typically much higher then the practical protection factor. Ideally, plants should report uncorrected values and corrected values, together with info on the provided correction factor and type of PPE that is used. However, making a correct calculation of the average exposure will become difficult when the sampling period covers periods where the worker wears PPE and periods where he doesn't. **ICdA will adapt the reporting template to capture this information.**

3. Number of samples per SEG
   A SEG is a group of workers that are identified as experiencing the same exposure to Cd. Grouping workers in SEG's allows to reduce the number of samples to be taken while assuring adequate representation of the average exposure of each worker in that SEG.
   3 samples in each SEG is a minimum! And this is also what, at this moment, is recommend by ICdA. According to the revised standard, when all 3 samples are <0,4µg/m³ (<10% of DNEL), the SEG is compliant with the DNEL.
   When 1 sample is above 4µg/m³, the SEG is not compliant.
   When 1 sample within the original 3 samples is >0,4µg/m³ the new standard requires more samples to enable you to draw a log normal distribution and statistically determine the 95% compliance interval. In practice, the standard requires a total of 9 samples per SEG, taken at 3 different moments or shifts. Although this is not mandatary yet, the responsible manager should be aware of this and prepare (budgetary) for the future. ICdA expect this to become mandatory between 2018 and 2020, when we expect to enter the authorisation phase under REACH.

4. Compliance according to the sampling standard
   - Actual standard (EN 689): often no conclusion
     - 1 sample <0,1 DNEL: **compliant**
     - 3 samples from 3 shifts, all < 0,25 DNEL: **compliant**
     - 3 samples from 3 shifts < DNEL and geometric average < 0,5 DNEL: **compliant**
     - 1 sample > DNEL: **non- compliant**
     - All other cases: **no conclusion**
   - Future standard (prEN 689): always a conclusion
     - 3 samples and all samples <0,1DNEL **compliant**
     - If one sample if greater than 0.1 DNEL, take 6 more samples for a total of 9:
       - One sample > DNEL: **non-compliant**
       - All samples < DNEL : assume log-normal distribution
         - Download excel tool for statistical assessment and check
         - http://ohshub.com/ihstat-statistical-analysis-of-health-safety-data/
           ⇒ At least 95% < 4µg/m³ **compliant**
           ⇒ More than 5% > 4µg/m³ **non-compliant**

The statistical treatment of the data can easily been done with the ihstat tool, which is an easy to use Excel document. A short practical explanation was given on how to use this tool. **The tool will be added to the mailing for the next OCdAir exercise**.

8- OCdBIO-7: results, analysis, way forward *(Mik Gilles, ICdA)*

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 bio-monitoring 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.
A remark was made that not all national legislations give companies access to the blood and urine analysis of their workers. Notably in Germany, it is impossible to access these data if the worker does not give his explicit approval. When blood or urine levels are too high, German law does not impose the companies the obligation to give another function with no exposure. A worker that would inform his employer about too high Cd burden therefore risks to lose his job when no no/low exposure job is available. Functions with potential cadmium exposure are often better paid than functions with no exposure. This is another reason why workers are reluctant to reveal their CdU and CdB values. Companies facing such lack of transparency cannot comply with the guidance document engagement that workers with too high cadmium burden are removed to a function with low/no exposure to cadmium.

ICdA- 2017/2020 initiative
This ICdA initiative is not an individual but a collective commitment to achieve challenging targets in terms of bio-monitoring 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**

Summary of the discussions (Trends analysis, comments)
The distribution of Cd-U in EU-sites has been established using the data of all EU sites for the years 2008 up to 2014. The OCdBio data over the several years include not the same individuals nor the same companies. New companies entered, other closed or did not report each year.
We also asked companies to report on workers removed for high Cd burden. 60% of workers with CdU >5 µg/g creatinine were reported to be removed from their workplace. A remark was made that not all workers are removed from their workplace. Some olders workers have historic cadmium burden and do not need to be removed when exposure values of workers in the same SEG do not show signs of high cadmium exposure.
For this year, the selection of the initial 15 plants is not shown anymore for two reasons: not all 15 plants continued to report and the trend for this selection of plants was similar to the trend for the whole group of reporting plants.

For CdB, the following observations were made:

- The trend of decreasing CdB values continues for the group “all workers” reported in OCdBIO, but has stopped and even increased for the group of workers hired after 2000. Continued attention is required!
- Workers hired after 2000 have much lower CdB values than the total population. The percentage of workers with high CdB values is only half of the percentage seen for the total population. This is partly related to the fact that these group has no high historic cadmium burden. Workers with high historic cadmium burden and no recent exposure will have typically higher CdB values as well since there seems to be a balance between cadmium accumulated in the renal cortex and Cd in blood.
- Decreasing CdB levels are clear indicators that exposure to Cd at the workplace is reduced year by year.
  - From the new hired evolution, we see that there was on average no further improvement achieved in the last year. Therefore, it can be questioned if the actual level of CdB is sufficient to reach the CdU target of 98% <2µg Cd/g creatinine. We will come back to this item when discussing the CdU values.

For CdU, the following observations were made:

- The trend of decreasing CdU values has stopped and even increased. This trend is even more pronounced for workers hired after 2000.
- Decrease of the intermediate exposed workers (2-5 µg/g) has stopped and increased. In 2014 there were 246 workers in this group. By 2020, this number should decrease to 33 workers. **ICdA will check retirement forecast in this group during the OCdBio8 exercise!!!**
- Fast decrease of the highest exposed workers (>5µg/g). From the 67 workers in 2014, 35 will retire by 2020. 32 will stay which represent 1% of the total reported workforce.
- ➢ The battle of the evolution of highly exposed workers (CdU >5µg/g) has been won but now we need to work on the intermediate levels of exposure (5µg/g > CdU > 2µg/g) where we have had almost no gain since the inception of OCdBIO. The 2020 Target to have 98% of the workers < 2µgCd/g creatinine will be very difficult to achieve as we know already 1% will be populated by workers with CdU > 5µg/g. It will therefore requires that there are less than 35 workers (1%) at levels 5µg/g > Cd-U > 2 µg/g creatinine by 2020, (when we currently have 246 workers in this range, which is over 7.5% of reported workforce).

Conclusion

Continued efforts are needed to reach or at least approach the targets that we have set ourselves. A lot of improvement of the values comes from retirement of people. To achieve the targets, it is very important that the exposure of new hired is sufficiently controlled to keep them in the groups of lowest Cd burden and to bring those that are a little bit too high (2-3 µg/g) back below the 2µg Cd/g creatinine threshold.
In further communication, we will emphasize the nice progress without stressing too much the ambitious targets.

9- IAR (Inventory of Air releases) *(Mik Gilles, ICdA)*

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.

10- Other business) *(Mik Gilles, ICdA)*

The next international cadmium conference will be organized end of October - early November 2016 (next year). Since there was no support for organizing the conference in China, South-, Central- or North-America, we will bring it to Europe and have selected Lisbon, Portugal, as a location with good international airline connections and nice conference settings.

International Cadmium Association

ANNEX 1

Attendance list

Meeting	**ICdA_13th H&S Committee**
Date	***24 June 2015, from 9h30 am to 16h pm***
Place	***Diamant Meeting Center*** ***Room "Baekeland"***

Names	Companies
CANOO Christian	IZA
DEGROOF Marc	NYRSTAR
DE METZ Patrick	SAFT BATTERIES
GIELEN Dirk	NYRSTAR
GILLES Mik	ICdA
HENNIG Katja	GLENCORE
HUDSON Bob	UK ENERSYS
ILIE Michaela	5NPLUS
KELLEY Barry	UK ENERSYS
KREHER Philippe-René	ARTS-ENERGY
LOMBAERT Nöomi	IZA
OPATRNY Zdenek	SAFT FERAK
SEIDEL Joerg	GAZ-GmbH
SCHUURMANS Erik	NYRSTAR
VAN ASSCHE Frank	IZA
VANDAMME Anne-Lise	FLAUREA CHEMICALS
WINBOW Howard	JAMES M BROWN

By conference call:	
WADE Andreas	FIRSTSOLAR
Apologies from:	
DE FOURNOUX Benoit	SAFT BATTERIES
HENKE Dieter	HOPPECKE
ROWLEY Phil	JAMES M BROWN
THIRLAWAY Colin	BLACKDECKER
MATTSSON Sven-Erik	SAFT-BATTERIES
GEIJKE-HAESERT Anna	BOLIDEN
MARK BOOTH	HUNTSMAN

International Cadmium Association

ANNEX 2

Agenda

- Approval of the Minutes of the 12th H&S committee (June 26th, 2014)
- REACH developments
    - Follow-up of the authorization process
    - Status of restriction proposals
    - Prepare for authorisation dossier

Lunch (12h45-14h00)

- Lobbying actions and strategies
- Monitoring Cd exposure of workers
    - OCdAIR-2: results, analysis, discussion
    - OCdBIO-7: results, analysis, discussion
    - Conclusions and way forward
- Inventory of Air releases (IAR)
- Other business: