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 17th ICdA H&S Committee

April 4th, 2019
10h00 – 15h00 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 16th H&S committee (June 25th, 2018)

The minutes of the sixteenth H&S committee (June 25th, 2018) are approved unanimously and the final minutes will be posted on the website.

3 REACH developments (cfr.Annex 2, slides 4-15)

3.1 Authorisation procedure: Cd, CdO and $Cd(OH)_2$ (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):

- 10th draft recommendation (to be presented at MSC-67 on 9-13 December 2019):
  - With 3 cadmium compounds, highly ranked on the list of Priority Substances, cadmium and cadmium compounds will likely be grouped and proposed for the 10th draft recommendation this year. The entrance of 4 new PBT and endocrine disruptors on the priority list could push cadmium compounds to a later list.
  - ECHA also communicated that from now on, new recommendations will only be issued every 18 months. The 10th list will be presented at the 67th Member States Committee (MSC) of ECHA in December 2019. ECHA will no longer release info on chemicals on the list before the MSC meeting where they will be presented.

- Authorisation: If selected in the 10th list, the expected timing is :
  - Public consultations: Feb-April 2020 for 3 months, one with ECHA and another one with the Commission.

- MSC voting and submission to the Commission: October 2020
- Commission decision: fall 2022??? The delay is an estimate based on previous rounds and depends on the different comments received in the consultations.
- From that moment you have 18 months (until the Latest Application Date - LAD) to submit an Application for Authorization (AfA) .
- If no AfA submitted, the application will have to stop after 3 years (2025) at the sunset date.

A second workshop aiming at preparing the Applications for Authorization (AfAs) was organised on June 22nd 2018, with the participation of manufacturers of substances but also with a broad participation of downstream users. Main conclusions were:

- The Consortium will not be in charge of submissions of AfAs
- Interested companies in the supply-chain will have to organize themselves and choose for the best structure for preparing the several AfAs
- The Consortium could look for potential consultants specialized in AfAs, if requested
- The Consortium could, in cooperation with a specialized consultant prepare the 2 dose-response curves for renal and cancer effects

A third workshop for manufacturers and also downstream users was scheduled for July 3rd,but it is postponed until after MSC 67 due the recent news of delay on the 10th draft recommendation list. In case cadmium will not be on the 10th list, the workshop will be further delayed by 18 months.

Points for discussion:

- Outcome of the 10th recommendation list
- Preparation of the 2 Public consultations
- preparation of the Applications for Authorization (AfAs)

3.2 Academic support (Noömi Lombaert– ICdA) (cfr. Annex 2, slides 9-15)

3.2.1 Initiative with German experts on workplace limit values:

Why with Germany? In the Council, Germany opposed very much to the ICdA proposal of having air monitoring combined with biomonitoring in the CMD amendment text. We see it as an opportunity to revise at German level the occupational exposure limits. The scientific opinion of the SCOEL was also to large extend copied from the German assessment of the AGS.

Discussions with Wirtschafts Vereinigung Metalle (Martin Wieske) has lead to appoint by the REACH Cadmium consortium consultant Dr Fritz Kalberlah (ex-FoBiG). Dr Kalberlah was consultant for the recent Commission impact assessment on CMD revision for cadmium and is the author of the current AGS document 2014, in which the Occupational exposure limit analogue value (non-carcinogenic effect) = 1 µg cadmium/m³ (inhalable Cd). A re-evaluation of the German dose-response curves for renal & cancer effects is possible in an update of the technical background paper AGS document 2014.

The procedure for a re-evaluation of the German ERB (Exposition-Risiko-Beziehungen) = ERR, exposure risk relationship) on cadmium and its inorganic compounds comprises the following steps:

- AK Metalle Working group through their members Martin Wieske and Fritz Kalberlah will start with the revision work

- Presentation of the revision will be presented to the AK Metalle working group which meets 2x/year. We aim for a presentation at the next meeting on June 2019.
- AK Metalle presents their concluded background document to Subcommittee III (UA III)
- When there is a conclusion on the background document in UA III (suspected timing till end 2019/early 2020), it will be forwarded to the AGS (at the earliest May 2020 or rather Nov 2020)
- AGS concludes
- Publication of the AGS conclusions in a legal note and the AGS document with value(s) will becoming binding.

We can only work on the first steps of the process. In the contract with Dr Kalberlah, the following timing was agreed:

- January: start contract project with Dr Kalberlah with the aim to derive an exposure risk relationship (ERR) and an occupational exposure limit (AGW-analogue) for cadmium and inorganic cadmium compounds (CMR) in an updated 2019 Technical background paper
- April 26th: Conf call with Dr Kalberlah and prof Drexler (AGS expert for bio-monitoring). The aim of this call is: a brief summary of Kalberlah's approach so far and discuss possibilities of setting a more effective combination of an air limit value with a biological limit for cadmium.
- April 30th: receival of Dr Kalberlah first draft report (in German). The report will be in German because it needs to be presented at the German AK-Metalle working group.
- May 3rd: Meeting in Frankfurt where Kalberlah will present his approach. Discussions and way forward are on the agenda

3.2.2 Threshold/non-threshold carcinogen study at UCL:

Noömi Lombaert informed the group that the paper on the sponsored Genotox study at UCL has been published in Toxicology Letters. She recalled the conclusion of the study:

1. Absence of genotoxic effects (Micronuclei (MN)) in lymphocytes of workers with substantial occupational exposure (up to 20 µg/L CdU)
2. No dose-response relationship for MN frequency
3. Cd-U threshold for systemic genotoxic effects is >10 µg/g creatinine, beyond the range of internal exposure levels considered in this study i.e. higher than the current BLV (2 µg/g creatinine)
4. Current BLV (2 µg/g creat.) is protective for systemic genotoxicity

The demonstrated absence of a dose-response relationship is consistent with the existing knowledge on the mechanisms governing the genotoxic activity of Cd, which are all non-stochastic and thresholded (SCOEL 2010; 2017). Cd is considered by SCOEL as a Category C carcinogen, i.e. a genotoxic carcinogen for which a mode of action-based threshold can be identified, also called 'practical threshold'. The threshold for 'systemic' genotoxic effects of Cd is beyond the range of internal exposure levels considered in the present investigation. The current BLV (2 µg/g creat) is therefore protective for systemic genotoxicity.

Up to substantially high concentrations there is no evidence for systemic cancers (e.g renal) but this study cannot conclude on local lung cancer.

3.2.3 Importance of limit values and Dose Response Relationships (DRR):

Authorisation dossier:

An authorisation dossier (AfA) requires always a Chemical Safety Report, including a risk assessment of exposure to cadmium (ES) of workers at the workplace, of professional users and of the general public. Additionally, there is a Socio-Economic Assessment (SEA) and an Analysis of Alternatives (AoA).

A limit value and a DRR make it possible to quantify exposure risk. When we have monitoring data together with a DRR and limit values, it is easier to demonstrate no/low risk in all Exposure Scenarios (ES). Carcinogens are in general considered non-threshold which implies that there is never a zero risk. But with the conclusions of the 2018 genotoxic study, we have now scientific evidence that there is a threshold for Cd for systemic effect. This opens the option of following the "adequately controlled conditions" route in the authorisation process.

Exemption dossier:

There is also an option of filing an exemption according to Reach Art.58(2). This needs to be done before the Com. Decision on inclusion in Annex XIV !!! Such an exemption is not lightly given by the Commission and requires:

- Demonstration of no exposure risk or risk controlled by other regulations during the full life cycle and both for humans as for the environment
- Demonstration that it will not stop the development of non-hazardous alternatives

The international Lead Association (ILA) and the Reach Pb Consortium are now lobbying for achieving such exemption. We will follow-up on this process closely. (Pb was on the 9th list) As compared to Pb, there are only industrial uses of Cadmium registered in our Reach dossier, which makes our cases easier than the Pb case. Pb has also professional and consumer uses. The exemption route is more challenging but makes it possible to permanently exit the need for authorization.

Christian Canoo stated that there is no legal obligation to search for alternatives, only an obligation to report on the existence of alternatives.

4 Status of EU Commission proposal for amendment of the CMD which sets an OEL for cadmium at 1 µg Cd/m³ inhalable (MikGilles ICdA) (cfr.Annex 2, slides 16-25)

4.1 Political discussion

We had some very intense discussion on cadmium with MEPs, rapporteurs and shadow rapporteurs, national authorities and permanent representatives. Many of our members were actively involved. Our lobbying resulted in massive support from the EP for the ICdA proposal to combine air monitoring with bio-monitoring with only one small nationalist fraction not supporting us. But there were split views in the Council. France, UK, Finland, Netherlands were very supportive to the ICdA position, but heavy weight Germany was very opposed to biomonitoring. Finally, the EP and Council both agreed on a compromise text which was confirmed by an EP Plenary vote on March 27. A final Council vote somewhere in April will conclude the political process. We do not expect any changes in this last formal vote because all parties want an agreement in first reading (before the EU elections). With an expected Council vote mid-April, we expect a publication of the

Amendment in the EU Official Journal soon afterwards. The Amendment will enter into force by mid-May, 20 days after the publication date.

4.2 Amendment text

Annex III is amended as follows: in point A, the following rows are added:

Name of agent	Limit values 8 hours (III) mg/m³ (V)	Transitional measures
Cadmium and its inorganic compounds	0,001 (11)	Limit value 0,004 mg/m3 (12) until … [eight years after the date of entry into force of this Directive].

(III) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).

(V) mg/m3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).

(11) Inhalable fraction.

(12) Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine.

4.3 Implications

The final OEL is set at 1µg/m³ inhalable and applicable by May 2027.

There is an 8 years transition period with higher limit value. This is one extra year of delay as compared to the Commission proposal.

During the transition period, the limit is set at 4µg/m³ inhalable. Only under specific conditions, there is also an option to set a combination of a binding air limit value (BOELV) and a biologic limit value (BLV). In that case, the limit value is set at 4µg/m³ respirable and the biologic limit value at 2µg Cd/g creat. The issue with this option is timing. The amendment text reads: “Respirable fraction in those member States that implement, on the date of entry into force of this Directive, a biomonitoring system with a biologic limit value not exceeding 0,002mg Cd/g creatinine in urine.” With the expected entry into force somewhere by 15th May 2019, it is quasi impossible to make any legislative changes in such short delay. This time constraint was pushed in by Germany as an ultimate effort to get the implementation of biologic limit values out. Creative solutions will be explored.

Deadline for transposition in national regulation is May 2021 (2 years delay). It should be noted that Member States can do this earlier...or later (not all MS respect EU deadlines).

The Commission intends to maintain the momentum and fill up Annex III with BOELV for all carcinogens and mutagens. There is also the intention to periodically review Annex III.

Howard Winbow regrets that there was no explicit note in Annex III to remind national authorities that the limit values apply to cadmium and its carcinogenic compounds and are not applicable to the non-carcinogenic cadmium pigments. In many Member States, there is no separate legislation for carcinogens like in EU (where there is the Chemical Agents Directive and the Carcinogens and Mutagens Directive). Therefore, many MS will not make this discrimination when transposing the

Amendment into national legislation. JMB has contracted Jose Lalloum to check if anything is possible. At this stage of the process, it is extremely unlikely that any changes will be applied to the text. Next occasion could during the wave 4 revision.

4.4 Important remark

The EP gave a task to the Commission and added this explicitly to the amendment:

"The EU Commission will assess by May 2022 if biologic limit values can be integrated in this Directive. If the outcome is positive, the Commission will propose a new amendment to set an alternative to the 1µg Cd/m³ workplace air limit value."

This will create for us a new opportunity to enter a combination of air- and biologic limit values in the CMD Directive before the value of 1µg/m³ enters into force in 2027. It is highly unlikely that a revised limit value will be confirmed before May 2021 (deadline for National implementation of current CMD amendment).

During a recent meeting at Eurometaux Alick Morris from DG Employment informed us that the task of doing this assessment was given to the European Agency for Safety and Health at Work (EU-OSHA) in Bilbao. Mik has given his business card to Mr Morris and informed him about the ICdA Guidance and EU monitoring program on cadmium and our interest in working with OSHA for this assessment.

Howard asked ICdA to take contact with OSHA. Mik will check with Eurometaux if and how this can be done.

4.5 National implementation of the Amendment of the CMD

Although the use of bio-monitoring is often mentioned in the regulations, very few member states have a biologic limit value explicitly implemented in the legislation. In most regulations, implementation of bio-monitoring is left to the discretion of plant occupational doctor.

In practice: many plants have implemented a bio-monitoring plan (compliance with ICdA Guidance). In member states with no biologic limit values (BLVs), we will try to argue that the cadmium industry has acted on recommendations in the national regulations and implemented a number of health surveillance measures, including BLVs. Therefore, we consider that a BLV is implemented.

Members or now in discussion with their national authorities. The following information was shared at this meeting:

UK: Discussion still ongoing but it seems that UK is keen to consider implementation of the ICdA Guidance as fulfilling the requirements of the amendment. Therefore, they will most likely set air and biologic limit values. They will also discriminate between carcinogens/mutagens and non CM substances like Cd pigments.

France: New law should be ready by end of May and foresees air and biologic limit values.

Spain & Finland: BLVs were already implemented.

Sweden: BLV implemented but for blood only, not urine.

Germany: obviously opposing. Main objection of Germany is privacy issues. (although they have implemented it for Pb).

Netherlands: Due to an error in writing the current legislation, the term "respirable" disappeared. As a result, the current legislation has an inhalable limit of 4µg Cd/m³, which is not consistent with the conclusion and recommendation of the Dutch Health Council who proposed 4µg Cd/m³ respirable + 2µg Cd/g creatinine in urine. The issue with this error is still under discussion.

Admitting an error is difficult in the Netherlands. Latest info is that during the transition period, the inhalable fraction will be considered and not the respirable.

Belgium: No feedback received yet. A meeting with the ministry of social affairs is scheduled for April 29th. We will propose a similar position as taken by the UK.

Others: no feedback.

Howard requested ICdA to make an update of todays regulations in the EU Member States, with special attention to the position of non-carcinogenic cadmium compounds like cadmium pigments, and update on planned meetings and feedback of meetings with national authorities on implementation of the revised CMD.

A tour de table was done to check how control on occupational exposure is done by the authorities.

UK: no obligation to provide exposure data, nor regular inspections.

France: no obligation to provide exposure data. Sometimes, there is an inspection.

Belgium: no obligation to provide exposure data. Most years there is no inspection.

Netherlands: no obligation to provide exposure data, but data measured conform EN689 procedure are provided on a voluntary basis. Some SEGs are problematic when no correction for PPE is applied. There is pressure from authorities to improve the situation to achieve air quality where PPE is not needed.

Germany: 1x/y an inspection audit. In Germany, you have to improve the situation when above the limit value as long as there is no BAT technology implemented. During transition, PPE are mandatory. When limits are exceeded but BAT is implemented, PPE's are accepted.

Sweden: Annual reporting with monitoring data is required. There is also an annual inspection. The statistical technique that should be implemented to assess the results is now discussed.

There was a short discussion on how to deal with smokers that are exposed to > 1µg Cd/m³ just by smoking. It is a delicate topic. At JMB, smokers are not hired, but none of the other participants had a similar policy at their plant.

5 OCdAIR-6: results, analysis, discussion (Mik Gilles, ICdA) (cfr.Annex II, slides 29-35)

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 will enter into force on a national level at latest by May 2021 and will become binding.

Participation and quality of reporting

The data presented today is an overview of what was received so far. Some latest supplementary information on correction for PPE is not yet integrated in the slides. A number of plants indicated that air monitoring data are not yet available. ICdA will issue a final version of the 2018 monitoring in June.

We see less SEGs that are non-conclusive because the number of samples has increased. Previous year samples can be added to a data set of a SEG as long as the exposure did not change due to material changes in the equipment and infrastructure or changes to the working procedures with an impact on exposure. We expect that the number of non-conclusive SEGs will further decrease next year.

The quality of the reporting improved. Most plants reported which fraction was measured and if corrections were applied for PPE. For next year reporting, an extra line will be included to enter the PPE protection factor. This will allow a consistent and automatic correction for all plants.

Consistent reporting for the whole group is still a challenge, mainly because differences in national limit values. Some have respirable, some have inhalable, some have both, and Sweden has also the total. Although there is a desire to have a conversion factor to "translate" concentrations from one fraction to another, any suggested number is scientifically not sound. Even in a given SEG, our members experimentally noticed large variations in the ratio respirable/inhalable. The ratio depends on the particle size distribution of the airborne dust which can vary to a large degree.

For 2018, the degree of participation dropped as compared to 2017, but higher as in 2016. This drop is probably related to the early deadline for reporting this year which was 2 months earlier than the previous years. Many plants had not yet received the results.

Performance in 2018

With reference of an OEL at 4µg/m³ respirable

- Geometric mean : 2 % non-compliant workers
- 90 percentile: 14 % non-compliant (and 18% are non-conclusive)

With reference of an OEL at 1µg/m³ inhalable (= +/- 0,25 µg/m³ respirable): as proposed by the Commission

- Geometric mean : 43 % non-compliant
- 90 percentile : 62 % non-compliant
- EN689 : 71 % non-compliant

Obviously, some further efforts are needed.

Conclusion:

- Exposure to Cd is under control in most workplaces but for a number of SEGs, statistics require more samples to draw conclusions.
- Some attention is needed in a few SEGs.

A remark was made by Marc Bariand, Saft Bordeaux, about the detection limits of analytical equipment. When compliance is required with a limit value of 1µg/m³, a detection limit of 0.1µg/m³ should be achievable to demonstrate exposure is <10% of the OEL. Today, many labs do not offer such low detection limit.
Mik replied that there is no need to comply with 10% of the limit value but frequency of sampling can be much lower when exposure is <10% OEL.

Even when regulations refer to EN689 as monitoring standard, inspectors often do not ask statistics and just look if the numbers are below the limit value.

6 OCdBIO-11: results, analysis, way forward (Mik Gilles, ICdA) (cfr. Annex 2, slides 36-50)

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. For plants with low exposure and no workers with historic cadmium burden, Cd in blood might be a more relevant indicator in a medical surveillance.

The number of plants participating was again high. Some plants announced to report later this year because reports were not yet received from the doctor. Therefore, we expect again a record high of more than 4000 reported workers in OCdD-BIO-11 from 36 sites. Most plants have both urine and blood monitoring.

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. We recommend everyone to look at the data from his plant to identify if actions are required towards personal hygiene or reduction of exposure to Cd in air.

Conclusions:

- Over the past 10 years, our industry has consistently improved the workplace exposure of its workers…and these efforts should continue
- exposure to Cd is continuously going down but levels are likely too high to keep all workers <2µg Cd/g creat.
- Plants should aim not to have workers with CdB > 2µg/L in order to reduce accumulation of Cd and keep them below 2µg Cd/g creat.
- Plants should take actions as described in the ICdA Guidance when CdB>2µg Cd/L

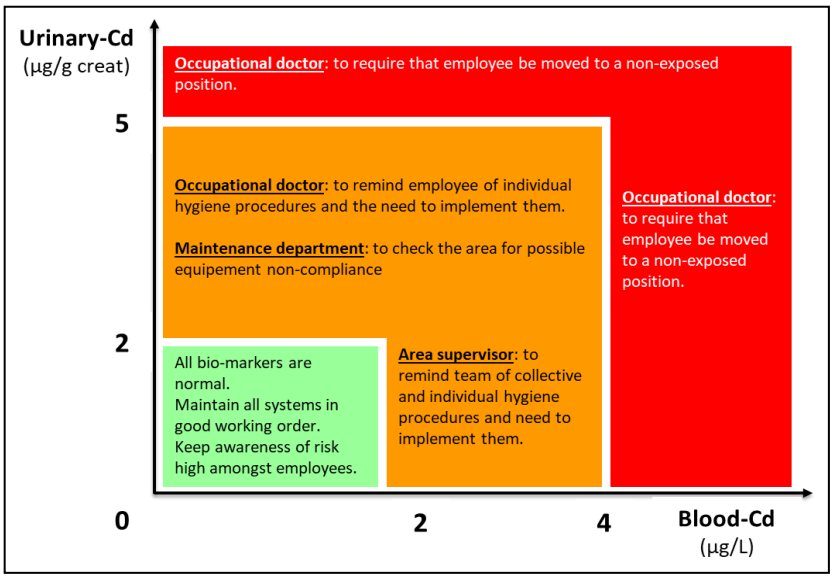
For CdU, the following observations were made:

Positive elements:

- Effect of reduced exposure as reflected by lower CdB values translates in a reduction of CdU values (but further efforts are needed at some workplaces)
- The group with high cadmium burden (>5µg Cd/g creat) is disappearing from the workplace (retirement, removed from exposure, lower exposure).
- Some plants should remind the medical doctor that removal from a workplace with cadmium exposure is highly 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 2021, but this number is going down due to retirement

Conclusions:

- Increase of workers in the segment 2-5 µg Cd/g creat.!!!
- 28 workers (0,7%) with CdU> 5 µg Cd/g creat. are not removed from exposure. For plants that have such workers, please check assessment procedures with doctor ad consider changing workplace for these workers.
- Follow the ICdA guidance!



7 Other business

Emissions to the environment (water&air) are important data for an authorisation dossier.
ICdA has done collection of emissions to air in the past but discontinued this exercise. The attendants were in favour of ICdA restarting such data collection. Mik will take appropriate action.
There were also questions about the water quality. If we need to reach 0 Cd in water, there is no other possibility to achieve this than by distilling the water. SNAM has such WWT equipment. According to Christian Canoo, there will be a practical 0 (not sure how low it will be) and not this legal absolute 0. Al participants to the meeting have internal waste water treatment facilities onsite and discharge into a river system. None of them discharges in a public sewer/public WWTP.

The meeting was closed at 15.00h.

ANNEX 1

Attendance list

Meeting	**ICdA_16th H&S Committee**
Date	***4 April 2019, from 10h am to 15h30 pm***
Place	***Blue Point Meeting Center***

Names	Company	Names	Company
WINBOW Howard	JAMES M BROWN	LOMBAERT Noömi	ICdA
BARIAND Marc	SAFT	GILLES Mik	ICdA
VANMOL Thierry	FLAUREA	CANOO Christian	Cadmium REACH Consortium
VOS Ann	NYRSTAR		
JANSSEN Joop	NYRSTAR		
OFLYNN Jessica	FIRST SOLAR		
HEINECKE Mario	GLENCORE/NORDENH AMER		
MARQUEYROL Muriel	SOFRADIR		
MATTSSON Sven-Erik	SAFT		
BOOTH Mark	VENATOR		
KREHER Philippe	ARTS ENERGY		
By conference call			
RENARD Alain	5NPLUS		
WADE Andreas	FIRSTSOLAR		
OLAUSSEN Sirpa	BOLIDEN		

ANNEX 2

Slides presented at the ICdA 17th H&S Committee

International Cadmium Association

16th Health and Safety committee meeting

Brussels, June 25th, 2018
10:00 -17:00

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Agenda

10.00	Welcome, tour de table, statement of Compliance, approval of meeting minutes 16th H&S Committee
10.10	Update on REACh REACh Authorisation process and workplace limit values Initiative with German experts on workplace limit values *C.Canoo and N.Lombaert*
10:40	Amendment to the Carcinogens and Mutagens Directive (CMD) *M.Gilles*
11:15	**Coffee break**
11:35	National implementation of the Amendment to the CMD *M.Gilles*
12:30	**Lunch**
13:30	Reporting on Cd in workplace air monitoring: OCdAir-6 *M.Gilles*
14:30	Reporting on monitoring of Cd in urine and blood: OCdBio-11 *M.Gilles*
15:15	A.o.b.
15:30	End of the meeting

2

STATEMENT OF COMPLIANCE

- The purpose of the meeting is to address, under the applicable confidentiality rules, issues concerning Cadmium and Cadmium compounds producers and importers and more particularly their obligations under the several regulations.
- The minutes kept during the meeting will have to reflect all significant matters discussed during the meeting.
- No discussions will be held, formally or informally, during specified meeting times or otherwise, involving, directly or indirectly, express or implicit agreements or understandings related to: (a) any company's price; (b) any company's terms or conditions of sale; (c) any company's production or sales levels; (d) any company's wages or salaries; (e) the division or allocation of customers or geographic markets; or (f) customer or suppliers boycotts; or (g) any disclosure of information which may affect applicable rules on Competition Law.
- The International Cadmium Association (ICdA), as a group will make no recommendations of any kind and will not try to reach any agreements or understandings with respect to an individual company's prices, terms or conditions of sale, production or sales levels, wages, salaries, customers or suppliers.

3

Update on REACH

- REACh Authorisation process
- Initiative with German experts on workplace limit values
- Genotoxicity study published

4

REACH/ Authorisation

- Up to now, each year, ECHA (1) adjusts scores of substances and (2) recommends substances from the SVHC-list, the highest ranked first, for being included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation).
- This procedure is now changed at ECHA due to revision of Annex XIV recommendation process. One recommendation round will take now approximately 1.5 years
- Normally first draft of the next 10th recommendation list was announced around end-of-April.
- 10th recommendation list will now only be debated for the first time at the MSC 67 meetings of December
- So far and up to now, there has been always upfront transparent communication on the priority scorings table. However, most probably and unfortunately this will not anymore be the case!
- Difficult to predict if Cd-substances ($Cd(OH)_2$,CdO & Cd) will be part of the 10th recommendation-list of ECHA, since 4 additional PBT and ED substances are under SVHC review which could score higher than the Cd substances.

5

Draft recommendation: 10th list

If selected, the expected timing is :

- Draft 10th recommendation proposed and reviewed at MSC-67 (9-13 December 2019)
- Public consultations: Feb-April 2020 for 3 months, one with ECHA and another one with the Commission.
- MSC voting and submission to the Commission: October 2020
- Commission decision: fall 2022???
- From that moment you have 18 months (until the Latest Application Date - LAD) to submit an Application for Authorization (AfA) .
- If no AfA submitted, the application will have to stop after 3 years (2025) at the sunset date.

6

Preparing for Authorisation (1)

- A second workshop aiming at preparing the Applications for Authorization (AfAs) was organised on June 22nd 2018, with the participation of manufacturers of substances but also with a broad participation of downstream users
- Main conclusions were:
  - The Consortium will not be in charge of submissions of AfAs
  - Interested companies in the supply-chain will have to organize themselves and choose for the best structure for preparing the several AfAs
  - The Consortium could look for potential consultants specialized in AfAs, if requested
  - The Consortium could, in cooperation with a specialized consultant prepare the 2 dose-response curves for renal and cancer effects

7

Preparing for Authorisation (2)

- A third workshop for manufacturers and also downstream users was scheduled for July 3rd ,but it is proposed to be postponed due the recent news of delay on the 10th draft recommendation list
- Points for discussion:
  - Outcome of the 10th recommendation list
  - Preparation of the 2 Public consultations
  - preparation of the Applications for Authorization (AfAs)

8

Initiative with German experts on workplace limit values (1)

- Why with Germany? In the Council, Germany opposed very much to the ICdA proposal of having air monitoring with biomonitoring in the CMD amendment text. It is seen now as opportunity to revise at German level the occupational exposure limits
- Discussions with Wirtschafts Vereinigung Metalle (M Wieske) has lead to appoint by the REACH Cadmium consortium consultant Dr Kalberlah (ex-FoBiG)
  - Dr Kalberlah is the author of the current AGS document 2014, in which the Occupational exposure limit analogue value (non-carcinogenic effect) = 1 µg cadmium /m³ (inhalable Cd)
  - A re-evaluation of the German dose-response curves for renal & cancer effects is possible in an update of the technical background paper AGS document 2014

9

Procedure for a re-evaluation of the German ERB on cadmium and its inorganic compounds

- AK Metalle Working group (members e.g. Wieske and Kalberlah) can start with the revision work
- Presentation of the revision work to AK Metalle working group (next meeting June 2019)
- AK Metalle presents their concluded background document to Subcommittee III (UA III)
- When there is a conclusion on the background document in UA III (suspected timing till end 2019/early 2020),
- forward to AGS (at the earliest May 2020 or rather Nov 2020)
- AGS concludes
- Publication in a legal note and AGS document with value(s), becoming binding

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Initiative with German experts on workplace limit values (2)

Timings:

- Since January: contract project with Dr Kalberlah with the aim to derive an exposure risk relationship (ERR) and an occupational exposure limit (AGW-analogue) for cadmium and inorganic cadmium compounds (CMR) in an updated 2019 Technical background paper
- April 26th: Conf call with Dr Kalberlah and prof Drexler (AGS expert for biomonitoring). The aim of this call is: a brief summary of Kalberlah's approach so far and discuss possibilities of setting a more effective combination of an air limit value with a biological limit for cadmium
- April 30th: receival of Dr Kalberlah first draft report (in German)
- May 3rd: Meeting in Frankfurt where Kalberlah will present his approach. Discussions and way forward are on the agenda

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Genotox paper published

Toxicology Letters 303 (2019) 72–77

Contents lists available at ScienceDirect

Toxicology Letters

journal homepage: www.elsevier.com/locate/toxlet

Absence of genotoxic impact assessed by micronucleus frequency in circulating lymphocytes of workers exposed to cadmium

D. Lison[a,*], G. Van Maele-Fabry[a], A. Vral[b], S. Vermeulen[b], P. Bastin[c], V. Haufroid[a,c], A. Baeyens[b]

[a] Louvain Centre for Toxicology and Applied Pharmacology (LTAP), Avenue Hippocrate, 57-1200, Brussels, Belgium
[b] Laboratory of Radiobiology, Department of Human Structure and Repair, Ghent University, C. Heymanslaan, 10-9000, Gent, Belgium
[c] Laboratory of Industrial and Environmental Toxicology, Clinical Chemistry Department, Cliniques universitaires Saint-Luc, Avenue Hippocrate, 10-1200, Brussels, Belgium

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Conclusions genotoxicity study

- ✓ Absence of genotoxic effects (MN) in lymphocytes of workers with substantial occupational exposure (up to 20 µg/L CdU)
- ✓ No dose-response relationship for MN frequency
- ✓ Cd-U threshold for systemic genotoxic effects is >10 µg/g creatinine, beyond the range of internal exposure levels considered in this study i.e. higher than the current BLV (2 µg/g creatinine)
- ✓ Current BLV (2 µg/g creat) is protective for systemic genotoxicity

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Relevancy of genotoxicity study

- The demonstrated absence of a dose-response relationship is consistent with the existing knowledge on the mechanisms governing the genotoxic activity of Cd, which are all non-stochastic and *thresholded* (SCOEL 2010; 2017)
  - *Cd is considered by SCOEL as a **Category C carcinogen**, i.e. a genotoxic carcinogen for which a mode of action-based threshold can be identified, also called 'practical threshold'*
- The threshold for 'systemic' genotoxic effects of Cd is beyond the range of internal exposure levels considered in the present investigation
- The current BLV (2 µg/g creat) is protective for systemic genotoxicity
- Up to substantially high concentrations there is no evidence for systemic cancers (e.g renal) but this study cannot conclude on local lung cancer

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Importance of DRR and limit values in the Authorisation process

- Authorisation dossier (AfA)
  - Chemical Safety Report: risk assessment of exposure to cadmium (ES)
    - At the workplace
    - By professional users
    - To the general public
  - Socio-Economic Assessment (SEA)
  - Analysis of Alternatives (AoA)
- Importance of monitoring, DRR and limit values
  - Demonstrate no/low risk in all Exposure Scenarios (ES)
    - A limit value and a DRR make it possible to quantify exposure risk
    - Carcinogens are in general considered non-threshold => there is no zero risk
      But… 2018 genotoxic study => threshold for Cd for systemic effect.
      =>This opens the option of following the "adequately controlled conditions" route
  - Option of filing an exemption (before Com. Decision on inclusion in Annex XIV !!!)
    - Demonstrate no exposure risk or risk controlled by other regulations (full life cycle human + envir.)
    - Demonstrate that it will not stop the development of non hazardous alternatives
      => more difficult route but makes it possible to permanently exit the need for Authorization

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Revision of the carcinogens and mutagens Directive (CMD)

Status of EU COM proposed amendment of the CMD to set an OEL for cadmium and its C&M compounds at 1µg Cd/m³ inhalable

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Political process

- Very intense discussion on cadmium
  - Our lobbying resulted in massive support from EP for ICdA proposal to combine air monitoring with bio-monitoring
  - But….split views in the Council
    - Mainly France, UK, Finland, Netherlands very supportive to ICdA position
    - Germany very opposed to biomonitoring
  - EP and Council both agreed on a compromise text
- Confirmed by EP Plenary vote on March 27.
- Final Council vote somewhere in April.
  - No changes expected because all parties want an agreement in first reading (before the elections)
- Forecast publication date: after Council vote mid April
- Entry into force: 20 days after the publication date
  - Expected: mid May

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CMD Amendment text

Annex III is amended as follows: in point A, the following rows are added:

Name of agent	Limit values 8 hours (III) mg/m³ (V)	Transitional measures
Cadmium and its inorganic compounds	0,001 (11)	Limit value 0,004 mg/m3 (12) until … [eight years after the date of entry into force of this Directive].

(III) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).
(V) mg/m3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
(11) Inhalable fraction.
(12) Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine.

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What does this mean for us

- Final OEL: 1µg/m³ inhalable by May 2027
- 8 years transition period with higher limit value
  - Transition to adapt was extended from 7 to 8 years
  - Transition limit set at 4µg/m³ inhalable
  - Compromise: 4µg/m³ respirable + BLV 2µg Cd/g creat.
    - Only under specific conditions (see next slide)
- Deadline for transposition in national regulation:
  - May 2021 (2 years delay)
  - Member States can do this earlier…or later (not all MS respect EU deadlines)

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What does this mean for us

- Issue: timing

  "Respirable fraction in those member States that implement, on the date of entry into force of this Directive, a biomonitoring system with a biologic limit value not exceeding 0,002mg/m³ Cd/g creatinine in urine."

  - Expected entry into force: May 2019.
  - Quasi impossible to make any legislative changes in such short delay.
  - Are creative solutions possible???
    - For discussion this afternoon

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Important remark

- The EP gave a task to the Commission and added this explicitly to the amendment:
  - *"The EU Commission will assess by May 2022 if biologic limit values can be integrated in this Directive. If the outcome is positive, the Commission will propose a new amendment to set an alternative to the 1µg Cd/m³ workplace air limit value."*
- *This will create for us a new opportunity to enter a combination of air- and biologic limit values in the CMD Directive before the value of 1µg/m³ enters into force in 2027.*
- *Highly unlikely that a revised limit value will be confirmed before May 2021 (deadline for National implementation of current CMD amendment)*

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take 30 minutes for a **Coffee break**

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National implementation of the Amendment of the CMD

Inhalable 4µg Cd/m³

or

Respirable 4µg Cd/m³

+

2µg Cd/g creatinine (urinary)

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Discussion on implementation…

- Very few member states have a biologic limit value explicitly implemented in the legislation
- Use of bio-monitoring is often mentioned in the regulations
  - Implementation of bio-monitoring is left to the discretion of plant occupational doctor
  - In practice: many plants have implemented a bio-monitoring plan (compliance with ICdA Gudance)

⇒Would national authorities consider this as "implemented" to justify a respirable limit???

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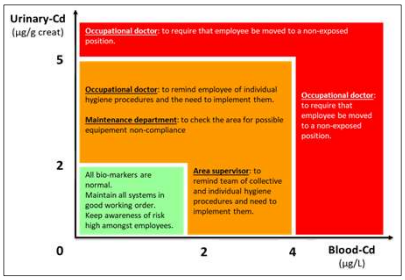
Biologic Limit values in ICdA Guidance

- **CdU:**
  - First action level: **2 µg Cd/g creat.**
  - Second action level: **5 µg Cd/L creat.**
- **CdB:**
  - First action level: **2 µg Cd/L**
  - Second action level: **4 µg Cd/L**

  Expected benefit: better control over CdU increase above 2µg Cd/g creatinine



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Now it is time for the **Lunch buffet**

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Cadmium Occupational monitoring

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OBSERVATORIES: Monitoring Cd exposure of workers

- OCdAIR-6: results, analysis, discussion
  - Presentation of reported data from members
  - Conclusions
- OCdBIO-11: results, analysis, conclusions
  - Presentation of reported data from members: CdU, CdB, and post-2000 hires subgroup
  - Conclusions
- Way forward

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OCdAIR-6

Occupational Cadmium Air-monitoring Observatory

Preliminary reporting
2018 monitoring results

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OCdAir-6

- Personal air sampling at the workplace
  - Sixth year of data collection
  - Lower response related to earlier data collection

	2013	2014	2015	2016	2017	2018
Plants	12	22	20	16	30	17
SEGs	67	142	131	124	162	141
Workers	994	1548	1369	1278	2249	1592

- Sampling quality improved
  - More samples for each SEG
  - All measures mentioned respirable or inhalable fraction
  - Correction for Personal Protection Equipment during sampling

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OCdAir-6

- ICdA guidance: Air quality should be under control to assure < 4µg Cd/m³ **respirable** air, always and for all workers

- Amendment of Carcinogens and mutagens directive:

  In absence of biomonitoring: < 4µg Cd/m³ **inhalable** air.

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OCdAir-6 Reporting: SEG level

			EN 689
	Geometric mean	90 percentile	70% conf. int. of 95 percentile
compliant	124	86	67
non-conclusive	14	38	46
non-compliant	3	17	28
4 <=> 7	3	9	8
7 <=> 10	0	6	9
> 10	0	2	7
other non-compliant	0	0	4
Total SEGs	**141**	**141**	**141**

- Only 3 SEGS have average value above 4µg Cd/m³.
- When assessed according to EN689, less than half the SEGs are compliant.
  - 35% of SEGs are non-conclusive due to low number of samples or non-log distribution.
  - 20% of SEGs are non-compliant due to exceedance of limit value.

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OCdAir-6 Reporting: workers

Compliance with 4µg/m³ respirable			EN 689
	Geometric mean	90 percentile	70% conf. int. of 95 percentile
compliant	1467	1080	818
non-conclusive	98	290	380
non-compliant	27	222	394
4 <=> 7	27	155	78
7 <=> 10	0	52	99
> 10	0	15	156
other non-compliant	0	0	61
total workers	**1592**	**1592**	**1592**

- For 27 workers (<2%) the average exposure is above 4µg Cd/m³, but none exceeding 7µg Cd/m³
- When assessed according to EN689, only half of the workers are operating in a compliant workplace.
  - 25% of workers are non-conclusive due to low number of samples or non-log distribution => this should improve when more sampling is done
  - 25% of SEGs are non-compliant due to exceedance of limit value.
  - At an OEL of 1 µg/m³ inhalable, less than 10% is compliant.

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OCdAir Reporting:

			EN 689
at 1 µg Cd/m³	Geometric mean	90 percentile	70% conf. int. of 95 percentile
compliant SEG	106	55	19
Total SEGs	**141**	**141**	**141**
compliant Workers	1331	754	350
total workers	**1592**	**1592**	**1592**

- When comparing to a future limit of 1 µg/m³, only 22% of workers are in a compliant workplace, when assessed according to EN689.

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Cd in Air monitoring: Conclusion

- OEL at 4µg/m³ respirable: ICdA guidance & option 2 CMD
  - Geometric mean: 2 % non-compliant workers
  - 90 percentile: 14 % non-compliant workers
  - EN689: 25 % non-compliant workers
- OEL at 1µg/m³ inhalable (= +/- 0,25 µg/m³ respirable): CMD in 2027
  - Geometric mean: 43 % non-compliant workers
  - 90 percentile: 62 % non-compliant workers
  - EN689: 71 % non-compliant workers

- ICdA target for limit values
  - OEL: advocate for option at 4 µg Cd/m³ respirable (in combination with bio-monitoring limit 2 µg Cd/g creatinine in urine)
  - For long term chronic effects: geometric mean is defendable (cumulated effect over 40y) but some countries follow EN 689

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OCdBio

Observatory of Occupational Cadmium Bio-monitoring

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OCdBio - Occupational Cadmium Bio-monitoring Observatory

- Since 2008, Cd bio-monitoring data is collected in the Cd industry in order to convince ourselves and authorities on:
  - the efficiency of our risk management program
  - the compliance of the current exposure levels with the OELs
- It is interesting for ICdA members to compare their own data with aggregated data from the whole Cd using industry
- A meaningful follow-up requires:
  - A long-term involvement of the companies; currently 11 years follow-up!
  - A strong coverage of EU industrial sites: in 2018 we expect reporting from +4000 workers on 36 sites!!!

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Selected biomarkers of exposure

- Cadmium in blood – CdB:
  - indicator of recent (and older) exposure
  - Measurement: Cadmium in whole blood (µg Cd/L)
- Cadmium in urine – CdU:
  - Biomarker of the amount of Cd stored in the body and in particular in the kidney cortex where the first signs of Cd toxicity develop
  - Representative for cumulative cadmium absorption in the body over past 20 years
  - Normalized measurement: Cadmium in urine (µg Cd/g creatinine)
  - Study Prof. Van Maele demonstrated that Cd is a threshold carcinogen for systemic effects with urinary limit value
    - ⇒ CdU is an indicator to demonstrate zero risk of systemic cancers
    - ⇒ Lung cancer is not covered by this indicator!!! => OEL (air) required.

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OCdBio

Results of data collection of 2018 monitoring exercise

(preliminary results)

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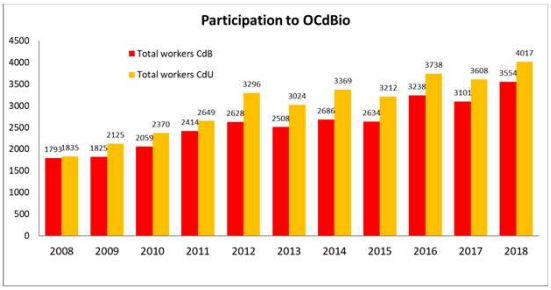
Number of reported workers



- Again good response from plants

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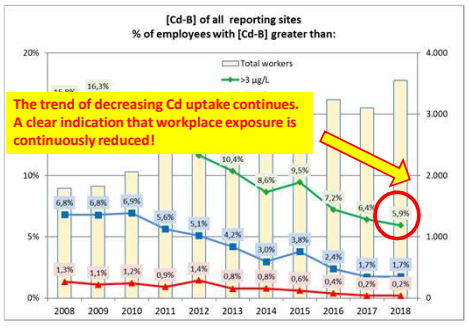
CdB distribution - all sites in % -



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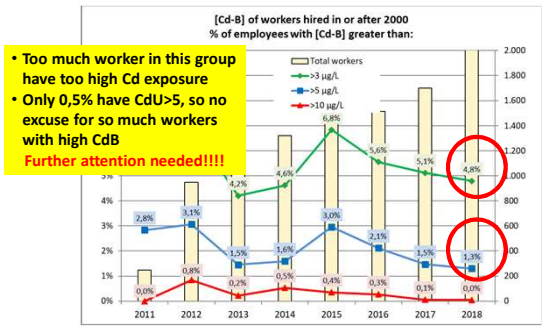
CdB distribution workers hired after 2000 - all sites in % -



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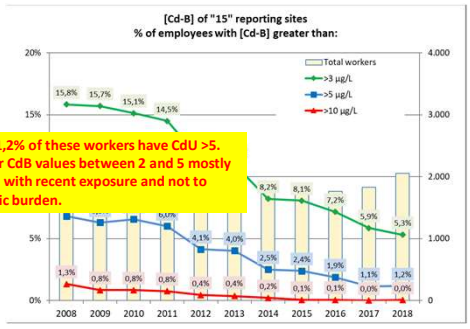
CdB distribution original “15”



- Only 1,2% of these workers have CdU >5.
- Higher CdB values between 2 and 5 mostly linked with recent exposure and not to historic burden.

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Cd in Blood: conclusion

- Good progress was made: Exposure of workers was reduced in 2018
- 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 then 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.

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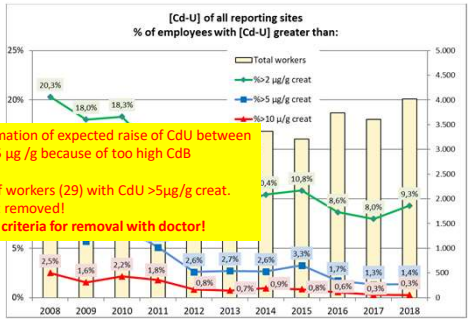
CdU distribution
- all sites in % -



- Confirmation of expected raise of CdU between 2 and 5 µg /g because of too high CdB
- 0,7% of workers (29) with CdU >5µg/g creat. are not removed!

=>Review criteria for removal with doctor!

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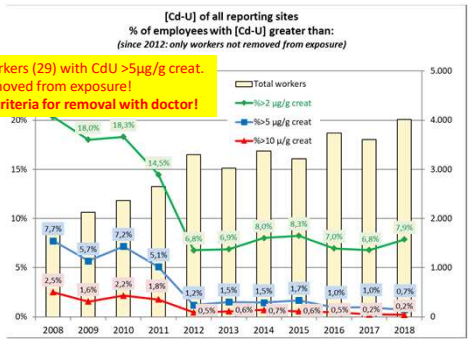
CdU distribution
- all sites in % - (removed workers excluded)



0,7% of workers (29) with CdU >5µg/g creat. are not removed from exposure!

=>Review criteria for removal with doctor!

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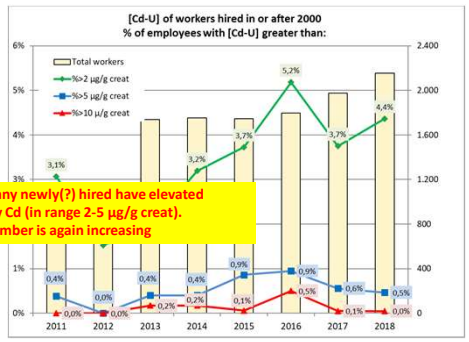
CdU distribution
- all sites in % - workers hired after 2000



- Too many newly(?) hired have elevated urinary Cd (in range 2-5 µg/g creat).
- The number is again increasing

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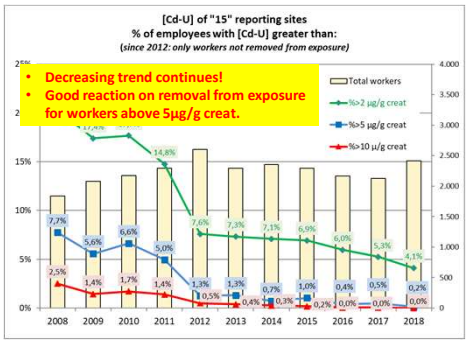
CdU distribution
- original “15” sites in % - (removed workers excluded)



- Decreasing trend continues!
- Good reaction on removal from exposure for workers above 5µg/g creat.

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Forecast of CdU by 2021

- Positive elements:
  - Effect of reduced exposure as reflected by lower CdB values translates in a reduction of CdU values (but further efforts are needed at some workplaces)
  - 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 cadmium exposure is highly 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 2021, but this number is going down due to retirement.

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Conclusion

- CdB
  - Over the past 10 years, our industry has consistently improved the workplace exposure of its workers…and these efforts should continue
  - exposure to Cd is continuously going down but levels are likely too high to keep all workers <2µg Cd/g creat.
  - Plants should aim not to have workers with CdB > 3µg/L in order to reduce accumulation of Cd and keep them below 2µg Cd/g creat.
  - Plants should take actions as described in the ICdA Guidance when CdB>2µg Cd/l
- CdU:
  - Increase of workers in the segment 2-5 µg Cd/g creat.!!!
  - 28 workers (0,7%) with CdU> 5 µg Cd/g creat. are not removed from exposure => check assessment procedures with doctor.

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Before going home…

- A.o.b.
- Closing of the meeting

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