International Cadmium Association

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Minutes of the 18th ICdA H&S Committee

June 30th, 2020
9:00 h – 12:30h
Meeting by video conference

1 Introduction

Welcome by Mik Gilles to the participants (cfr. Annex 1 Attendance list).
The 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 (cfr. Annex 2, slide 3).

2 REACH developments (Noömi Lombaert - ICdA)

2.1 Authorisation procedure: Cd, CdO and $Cd(OH)_2$ (cfr. Annex 2, slides 4-7)

Cd, CdO and $Cd(OH)_2$ were not picked up for the 10th list. Instead, ECHA made recommendations for 7 newly listed persistent, bio-accumulative and toxic substances (PBT). There was not yet any endocrine disruptor within this selection of 7 substances.

During the workshop with downstream users (12/02)- organised by the REACH Cadmium Consortium- which took place before the ECHA decision was made, Hugo Waeterschoot from Eurometaux predicted that in case cadmium would not be picked up in the 10 list, it may not be picked up in the 11th list either. Hugo's view was based on the fact that a non-election for the 10th list would be an indication that ECHA would give priority to those substances for which there is no workplace regulation in place yet. With the Amendment of the carcinogens and mutagens Directive in 2019, Cd has an EU wide occupational exposure limit (OEL). Cadmium may also be superseded on the scoring list by new entries of higher scoring substances.

The 11th recommendation list will be issued in June 2021. Since Hugo's view is no guarantee, ICdA recommends still to continue the preparation for an authorisation. We ask everyone, who has not yet done so, to fill in the Commission questionnaire which was presented at the workshop with downstream users (12/02) and to return it to the cadmium REACH consortium (correspondence address: amutombo@zinc.org).

2.2 Update on REACH files (Noömi Lombaert - ICdA) (cfr. Annex 2, slides 8-15)

The REACH consortium needs to update in the Cadmium registered REACH dossiers the Exposure Scenarios (ES) for each identified use, which includes an Exposure Assessment (EA). This updating process is formalised under the Metals and Inorganics Sectorial Approach (MISA) agreement between ECHA and industry.

The EA must demonstrate that operational conditions and risk management measures are adequate for controlling the related risks. For occupational exposure, ES usually cover multiple contributing tasks/activities for which separate EA are required.

The set of Conditions of Use (CoU) addressing one task/activity and the related EA is called a contributing ES (CES). If the EA is based on monitoring data, the data must originate from the same type of activity/process as described in the CES. The REACH Consortium has engaged consultants EBRC to assist with this work.

For an adequate derivation of exposure estimates for use in REACH EA, EBRC needs as a minimum:

- individual raw data for companies (not aggregated, no means, no percentiles),
- corresponding sampling information (type of monitoring, sampling duration, measured fraction of dust, etc.), and
- corresponding contextual information (CoU of the substance, incl. PPE).

EBRC sees the reported monitoring data and the Cap Ingelec questionnaire on engineering control in place to reduce exposure as a very good starting base to update the ES.

Since ICdA has only an agreement with the plants to use the data in a consolidated way, we will send out a mail to ask explicit authorisation from each plant to use the received information for doing the ES update. EBRC will assure confidentiality of individual data.

It is possible that there are information gaps. In such event, EBRC will ask for specific additional info.

ICdA and the REACH Consortium will ensure there is sufficient exchange with its members to be sure that the ES are correctly described before being used in updated REACH registration dossiers.

Mark Booth, Venator, asked for clarity on whether the requirements of EA and ES were only for hazardous substances and therefore not applicable to Cd pigments– to be checked.
After the meeting advise was asked from EBRC on the requirements. This is the answer we received:

Exposure scenarios are only required for hazardous substances (classifiable and non-classifiable hazards, considering environment, human health and phys-chem properties) manufactured and/or imported at or above 10 t/a. The indication of a DNEL (as currently reported for Cadmium zinc sulfide yellow and Cadmium sulfoselenide red) may indicate to ECHA that the substance has hazardous properties and that exposure scenarios are required. If "no hazard identified" is stated for all routes and types of exposure, an exposure assessment and exposure scenario is not required. However, if the substance is not classified at all, it is very likely that the substance would not be checked.

3 EU Commission initiative to amend the Carcinogens and Mutagens Directive with a Biologic Limit Value (BLV) (Mik Gilles and Noömi Lombaert - ICdA) (cfr. Annex 2, slides 16-31)

To help the Commission in its task, it requested opinion from ECHA and OSHA:

- Scientific assessment by RAC/ECHA and proposal of airborne limit and a biological limit value for cadmium and its inorganic compounds

- Assessment by OSHA of introducing biologic limit values as a tool for workplace monitoring

The conclusion of the above studies will be discussed by the Working Party on Chemicals within the Advisory Committee for Safety and Health at work (ACSH). This tripartite body (Unions, Employers and Member states) will formulate a final opinion to the Commission.
On completion of an Impact Assessment (IA) the Commission will then draft an amendment text to the CMD for approval by the European Parliament (EP) and Council.

3.1 ECHA Call for evidence (Mik Gilles and Noömi Lombaert - ICdA)

ICdA has submitted to ECHA new/updated information on:

- Uses
- Occupational exposure
- Genotoxicity and modes of action
- Repeated dose toxicity and carcinogenicity

ECHA accepted to have a virtual meeting with ICdA to further elaborate on our submission which is now set for 21st August 2020.

ECHA will then draft a background document which will be submitted to 2 experts from the Risk Assessment Committee (RAC) to build a 'RAC Opinion document' on the scientific evaluation of occupational exposure limits for Cd and its inorganic compounds. Here again, there will be a public consultation to comment on the RAC opinion before it is finalized and submitted to the ACSH.

3.2 Work at OSHA (Mik Gilles– ICdA)

EU-OSHA has been asked by the Commission to assess if biomonitoring and biologic limit values can be implemented in EU workplace legislation. This study is not element specific but obviously, experience with Pb, Ni and Cd will be key considerations. The report will be shared with the ACSH.
OSHA has accepted to meet with ICdA on this subject in autumn 2020. We will align with the International Lead Association (ILA) and the Nickel Institute to develop a common message.
Important elements in our discussion with OSHA will be:

- Industry ability to address occupational exposure, documented with data from the ICdA workplace monitoring activities.
- Information from industry on practical experience with biomonitoring. For this, we have asked all plants to fill in a dedicated questionnaire. So far, we have received 22 replies. There seems to be much support amongst employers and employees for biomonitoring. To be sure we capture all views and our poll is representative, it is important that we receive as many replies as possible. Those that have not yet filled in the questionnaire are encouraged to do so.
- Position of the workers: we have already letters signed by unions from 4 plants, but we hope we can have more such letters.
- The ICdA Guidance. How to deal with workers that exceed the urinary Biologic Limit Value of 2µg Cd/g creatinine once this BLV is set in the CMD? Peter Hermans from Lamifil suggested that we should only use integer values only because that is the case of the CMD entry, and of errors on the sampling. A value of 2.5 should therefore be rounded to 2. A number above 2.5 should be rounded to 3. It would not make sense to report digits that have no meaning. After

some further discussion on all kind of errors that can occur on CdU sampling and measurement and how to quantify them, it was proposed so set up an experts group which will develop a well-documented position as well as consider necessary revisions to the Guidance. Peter Hermans, Marc De Groof, Patrick de Metz and Howard Winbow volunteered to participate. Anyone else who wants to contribute is kindly invited to inform Mik Gilles.

OCdAIR-7: results, analysis, discussion (Mik Gilles - ICdA) (cfr. Annex II, slides 35-46)

For 2019, ICdA received exposure data of 3499 workers in 31 EU plants. Both number and quality of reporting improved significantly.
If we consider the geometric mean as assessment criteria, there were only 3 Similar Exposure Groups (SEGs) representing 21 workers, where the exposure limit of 4µg Cd/m³ respirable was exceeded.
When implementing statistical more complex methods like a 90 percentile, 28% of the SEGs have not sufficient samples to do valid statistical calculations.

4 OCdBIO-12: results, analysis, way forward (Mik Gilles - ICdA) (cfr. Annex 2, slides 47-61)

For 2019, ICdA received exposure data of 5020 workers in 36 EU plants. A new record!

For CdB, the following observations were made:

- Good progress was made: Exposure of workers was again reduced in 2019
- 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 of workers hired post 2000 shows that 21 workers (3.6%) have CdB >5µg Cd/L while only 9 workers (1.1%) have a CdU >5µg/g creat. Therefore, these high CdB values are not related to high historic burden but may be a sign of too high recent exposure. We recommend to advise occupational doctors to check for this trend on an individual basis for all workers with CdB > 5µg Cd/L.
- Future compliance with BLV of 2µg Cd/g creatinine?
  - We should keep all workers below 4 µg Cd/L in blood and take pro-active measures when exceeding 2µg Cd/L as recommended in the ICdA Guidance.
- Continued attention is 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.
- The new CdB action levels now respectively set at 2µg/L and 4µg/L (see Guidance 2018) need to be strictly implemented by the occupational doctor to ensure that CdU of recent workers (hired since 2000) does not rise above 2 µg/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 steadily going down due to retirement.

Conclusions:

- 20 workers (0,4%) with CdU > 5 µg Cd/g creat., including 9 workers with CdU > 10µg Cd/g creat., are not removed from exposure. For plants that have such workers, please check assessment procedures with doctor and consider changing workplace for these workers or report correctly to ICdA when workers were removed.
- A general remark on biomonitoring is that all H&S managers should share the ICdA Guidance with their occupational doctor. Do not forget to update them when the Guidance is updated or when the doctor is replaced.
- Howard Winbow made a suggestion to update the % compliance targets set from a few years ago by making a new calculation of the reduction on Cd-U BLV exceedance due to known info on age/retirement.

5 Other business

With no other business to report, the call was closed at 12:20h.

Summary of Actions:

- Form an Expert sub-group to review and draft updates to the Guidance in terms of text, values and practical advice in advance of the Fall meeting with OSHA - MG
- Reminder to the H&S Reps that their Occupational Doctors etc should have a copy of the Guidance and the target values. - ALL
- Make a new calculation of the reduction on BLV exceedance with time due to known info on age/retirement. MG/PdM.

List of abbreviations

ACSH	Advisory Committee on Safety and Health at work
BLV	biologic limit value
CdB	cadmium in blood
CdU	urinary cadmium
CES	Contributing Exposure Scenarios
CMD	Carcinogens and mutagens Directive
CMR	carcinogenic, mutagenic, or toxic for reproduction
CoU	conditions of use
creat.	creatinine
EA	exposure assessment
ECHA	European Chemicals Agency
ED	endocrine disruptor
EN	EU standard on workplace monitoring
EP	European Parliament
ES	exposure scenarios
H&S	health and safety
IA	impact assessment
ILA	International Lead Association
MISA	Metals and Inorganics Sectorial Approach
OEL	occupational exposure limit
OELV	occupational exposure limit value
OSHA	occupational safety and health agency
PBT	persistent, bio-accumulative and toxic substances
PPE	personal protective equipment
RAC	risk assessment committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCOEL	Scientific Committee on Occupational Exposure Limits
SEG	Similar exposure group
WPC	Working Party of Chemicals

International Cadmium Association

ANNEX 1

Attendance list

Meeting	**ICdA 18th H&S Committee**
Date	**30 June 2020, from 9h00 am to 12h20 pm**
Place	**By video call**

Names	Company	Names	Company
Frank Henneman	5Nplus	Inge Maes	Metallo
Marielle Nicollet	Amphenol Socapex Fr	Vanessa Germonpré	Metallo
Robin Montpellaz	Amphenol Socapex Fr	Marc De Groof	Nyrstar Belgium
Erica Moore	Amphenol UK	Roel Damen	Nyrstar Netherlands
P.-R. Kreher	Arts-Energy	Patrick de Metz	Saft Corporate
Kai Nykanen	Boliden Kokkola	Ondrej Jochymek	Saft Ferak
Leah Carpentier	First Solar	J.-C. Vaslin	Saft Nersac
Christophe Laubignat	Flaurea Chemie	Mark Booth	Venator
Robert Van Quickelberghe	Flaurea Chemie	**STAFF**	
Ana Cuevas	Glencore AZSA	Howard Winbow	IZA
Mario Heinecke	Glencore NZH	Noömi Lombaert	ICdA
Andrea Gabba	Glencore PV	Mik Gilles	ICdA
Ian Shackley	JamesMBrown		
Peter Hermans	Lamilfil		
Muriel Marqueyrol	Lynred		

ANNEX 2

Slides presented at the ICdA 18th H&S Committee

International Cadmium Association

18th Health and Safety committee meeting

Webinar, June 30th, 2020
9:00 -12:00

Agenda

AGENDA

09.00 Welcome, statement of Compliance
09.10 REACh dossier updates and status of the Authorization process.
09:35 Ongoing assessment by RAC/ECHA and OSHA of introducing biologic limit values for cadmium and its inorganic compounds into the Carcinogens and Mutagens Directive(CMD)
- Timeline of the process
- Actions towards ECHA
- Actions towards OSHA
- Feedback on ICdA questionnaires to industry

10:30 Workplace monitoring
- Reporting on workplace Cd in air monitoring OCdAir-7
- Reporting on monitoring of Cd in urine and blood OCdBio-12
- Review of implementation of ICdA guidance and assess need for updates.
- Guidance on workers with historic cadmium body burden

12:00 End of meeting

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.

Update on REACH

- REACh Authorisation process
- Update of REACh dossiers (MISA)

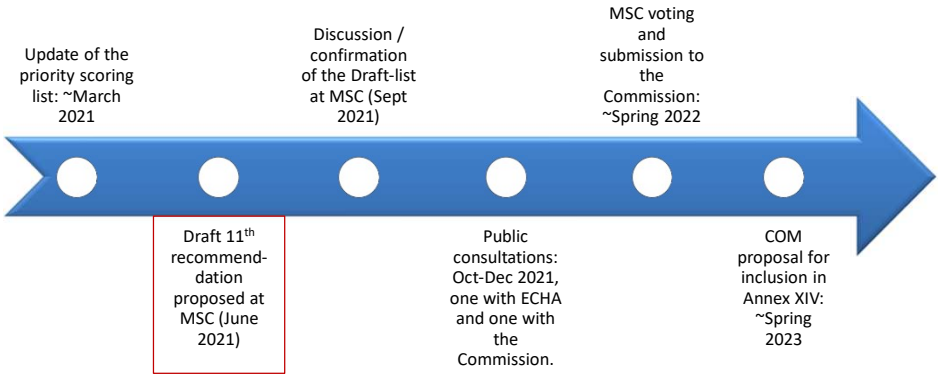
Update on REACH

Authorization procedure

Cadmium substances

Authorization
Draft recommendation listing: 11th list

Again with high probability, Cd-substances (notably $Cd(OH)_2$, CdO & Cd) might be nominated in the 11th recommendation-list of ECHA, around June 2021



Authorization (2): Commission questionnaire

- During the workshop with downstream users (12/02), it was suggested to all downstream users to fill in the Commission questionnaire that is expected to be submitted during the Public Consultations next year
- We received so far ~13 filled questionnaires:

Nb	Type	Detail
1	NiCad battery	- Cd and CdO => n X 100 tpa - no alternative - probable submission for Afa
4	LMP-Alloys	- Cd (also with Pb) => n X <1-2 tpa - Al tube bending - no alternative - probable submission for Afa through supplier
8	Cd plating	- Cd and CdO => n X <1 tpa - essentially aeronautic sector - no alternative or maybe Zn-Ni (not for screws) - submission for Afa by supplier or contractor
2	CdTe / pigments	- Cd and Cd compounds - Intermediate uses - no submission for Afa

Update on REACH

Update of REACh files (MISA)

Exposure scenarios are not reflecting the reduced cadmium exposure!

Importance and use of occupational exposure data under REACH

EBRC Consulting GmbH

EBRC's background

- EBRC has been involved in exposure monitoring campaigns for many metals (e.g. Cu, Co, Ni, Hg, As, Sb, Pb, precious metals…)
- EBRC has been involved in many occupational exposure assessments for metals and inorganic substances under REACH
- Not only external (inhalation & dermal) monitoring data but also bio-monitoring data have been collected and analyses by EBRC
- Bilateral confidentiality agreements can be signed by EBRC

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Introduction REACH Exposure Scenarios

- Exposure scenarios (ES) are required under REACH for each identified use in the life cycle of a hazardous substance.
- An exposure assessment (EA) needs to be included in the ES.
- The EA must demonstrate that operational conditions and risk management measures are adequate for controlling the related risks.
- For occupational exposure, ES usually cover multiple contributing tasks/activities for which separate EA are required.
- The set of conditions of use (CoU) addressing one task/activity and the related EA is called a contributing ES (CES).
- If the EA is based on monitoring data, the data must originate from the same type of activity/process as described in the CES.

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Exposure estimation (ECHA Guidance R.14*)

- The exposure assessment may be based upon:
  - measured representative data for the substance assessed,
  - monitoring data from a substance with an analogous use, or
  - modelled estimates of exposure levels.
- However, representative exposure data (if adequately generated) may best reflect the real life exposure situation.
- When deriving exposure estimates it is required to take account of the variability within and between tasks, and for users and sites.
- Exposure estimates should be consistent and representative for the safe use conditions described.

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*Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.14: Occupational exposure assessment, Version 3.0, August 2016

Use of monitoring data 1/2

- For an adequate derivation of exposure estimates for use in REACH EA, EBRC needs as a minimum:
  - individual raw data for companies (not aggregated, no means, no percentiles),
  - corresponding sampling information (type of monitoring, sampling duration, measured fraction of dust, etc.), and
  - corresponding contextual information (CoU of the substance, incl. PPE).
- EBRC will conduct quality checks on the data as such.
- EBRC will assign quality checked data to "assessment subjects" or "similar exposure groups" based on conducted activities, conditions of use and corresponding exposure potential.

  → Data from different companies will be pooled.

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Use of monitoring data 2/2

- Statistical analyses of monitoring data are conducted by EBRC, only summary tables are displayed (in a separate "methodology paper").
- Exposure monitoring data are always treated confidential and only used in an aggregated and anonymised format in occupational ES.
- In case personal monitoring data of different fractions of dust are taken simultaneously or bio-monitoring data and personal inhalation monitoring data from the same worker are available, this could be indicated to EBRC (will be treated strictly confidential).
- Regarding bio-monitoring data, the use of an individual worker-ID could indicate the development of exposure over time. In addition, for workers who are monitored more often due to higher exposure levels, an average could be calculated to avoid any bias.

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Any concerns / questions / remarks?

Please write us:

occupational.exposure@ebrc.de

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CMD Revision

Cadmium and its Carcinogenic Compounds

Revision process of the Carcinogens and Mutagens Directive (CMD)

Reminder: CMD revision 2019/983

"No later than 11 July 2022, the Commission shall assess the option of amending this Directive to add provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds."

- Scientific assessment by RAC/ECHA and proposal of airborne limit and a biological limit value for cadmium and its inorganic compounds
- Assessment by OSHA of introducing biologic limit values as a tool for workplace monitoring

Working Party on Chemicals and ACSH Opinion
Impact Assessment
Commission Draft amendment
EP and Council Approval

Activities at the RAC (ECHA)

- Review of safe workplace limit values with inclusion of biologic limit values
- Covers all (CMR) Cadmium substances
  - ECHA – call for evidence (March-June)
  - Follow-up process: timings

Reminder: previous Cadmium assessment was done by the SCOEL.

ECHA call for evidence: March 2nd => June 2nd

Reason of the call for evidence:

ECHA asked for '**support in** the **assessment of the rationale to revise the airborne occupational exposure limit and/or to include a biological limit value** for cadmium and its inorganic compounds under the Annexes to the Carcinogens and Mutagens Directive'

ECHA asked for **any new scientific information since the scientific evaluations by SCOEL (2017)** on uses, exposure, health effects, toxicology, epidemiology and modes of action on cadmium and its inorganic compounds.

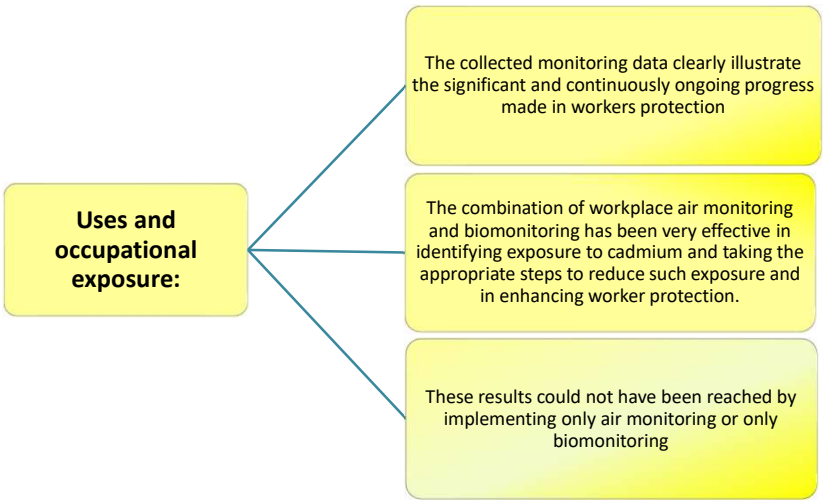
ECHA call for evidence: ICdA/REACH Cd Consortium provided input on 3 parts

Uses and workplace exposure:
- Updated info on uses
- Biomonitoring data (since 2008) and workplace air monitoring (since 2013)

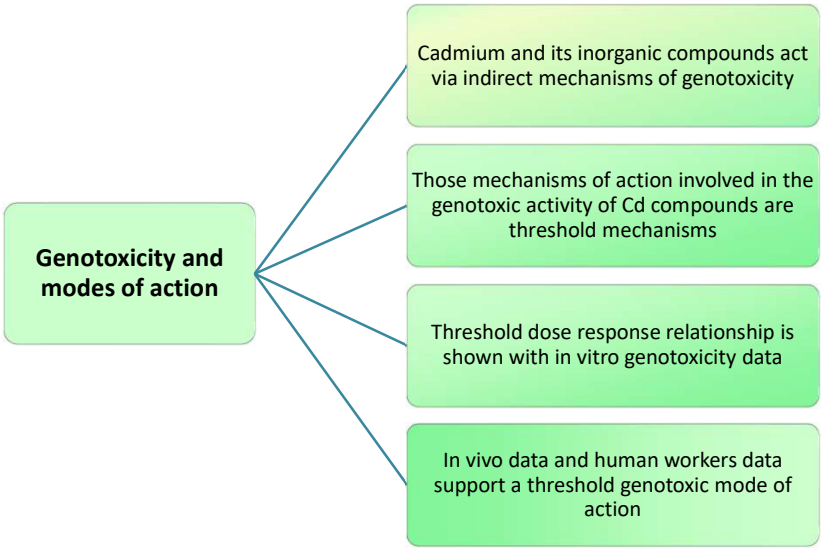
Mechanisms of action for the genotoxic activity of Cd and its inorganic compounds *(collaboration with UCL)*
- Overview/update on the genotoxicity literature
- Evidence for a mechanism of action-based threshold

Repeated dose toxicity and carcinogenicity of Cd and its inorganic compounds *(collaboration with EBRC Consulting)*
- Overview/update on the literature of non-cancer and cancer effects
- **Discussion on 4 questions**:
  - Is the kidney still the critical organ (systemic) after repeated exposure? And what is the effect level?
  - Are other systemic endpoints (bone, ED) covered by this effect level?
  - Is lung function impairment still the critical effect after inhalation exposure and what is the effect level? (Consequently can 4 µg/m³ respirable fraction still be retained as protective for this endpoint)?
  - Is an OEL-only based approach protective against renal effects?

ECHA call for evidence: ICdA submitted documentation conclusions (1)



ECHA call for evidence: ICdA submitted documentation conclusions (2)



ECHA call for evidence: ICdA submitted documentation conclusions (3)

Repeated dose toxicity and carcinogenicity

- the kidney is the critical organ for systemic effects after repeated exposure, with a *BLV of 2 µg Cd/g creatinine*
- other systemic endpoints (bone) are covered by this effect level of 2 µg Cd/g creatinine
- lung function impairment is the critical effect after inhalation exposure and 4 µg/m³ respirable fraction is protective for workers against local respiratory effects of Cd exposure
- A combined OEL of 4µg Cd/m3 respirable and 2µg Cd/g creatinine provides better protection against renal effects than a 1µg Cd/m3 inhalable OEL only

Follow-up process (1)

ECHA experts will write a '**background document**' based on info collected from call for evidence

During this period a meeting with ECHA to elaborate on our submission will be asked/planned

Background document of ECHA will be given to 2 RAC rapporteurs to build a '**RAC Opinion document**' on the scientific evaluation of occupational exposure limits for Cd and its inorganic compounds

Follow-up process (2)

ECHA
EUROPEAN CHEMICALS AGENCY

OEL requests: Jan 2020- July 2021

2 chemical agents	Timelines	RAC- milestones
Asbestos Directive 2009/148/EC	Start: January 2020 Duration: 18 months (of signature of agreement)	Key issues discussion **RAC-55** First draft opinion **RAC-56** Final draft opinion **RAC-57**
Cadmium and its inorganic compounds CMD	Start: January 2020 Duration: 18 months (of signature of agreement)	Key issues discussion – **RAC-54** First draft opinion **RAC-55** Final draft opinion **RAC-56**

RAC-54: Sept 7-11th

RAC-55: End Nov- Begin Dec

RAC-56: March 2021

ECHA.EUROPA.EU 05/06/2020 11

Assessment by the EU-OSHA

The European Agency for Safety and Health at Work (EU-OSHA) collects, analyses and disseminates information for those involved in safety and health at work.
EU-OSHA works to make European workplaces safer, healthier and more productive for the benefit of businesses, employees and governments. The agency promotes a culture of risk prevention to improve working conditions in Europe.

EU-OSHA has been asked by the Commission to asses if biomonitoring and biologic limit values can be implemented in EU workplace legislation. This study is not element specific but obviously, experience with Pb and cadmium will be a value element.

OSHA is asked to look at today's use and implementation of bio-monitoring in industry and by member states and also look at acceptance level and objections against biomonitoring.

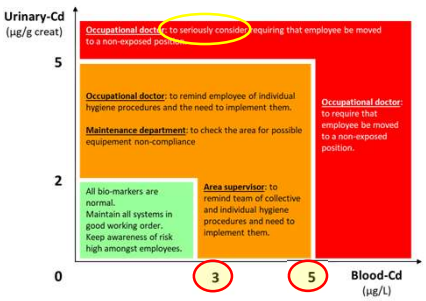
- Work at OSHA hasn't started yet. Project is managed by Elke Schneider.
- OSHA accepted to meet ICdA in fall 2020 to share our experiences with Cd biomonitoring.
- ICdA has contacted ILA and Nickel Institute to agree on a common message to OSHA.
- COM invites OSHA to intermediately report to the WPC.
- Timing to deliver the report to the Commission: Q4 2021

Prepare for meeting with OSHA

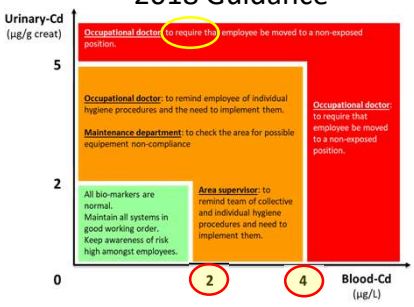
- Information gathering
  - Questionnaire to all participants of the cadmium workplace monitoring observatory
  - Workplace air monitoring
  - Biomonitoring
  - (Revised?) ICdA Guidance

ICdA Guidance: 3rd revision in 2018

2013 Guidance



2018 Guidance



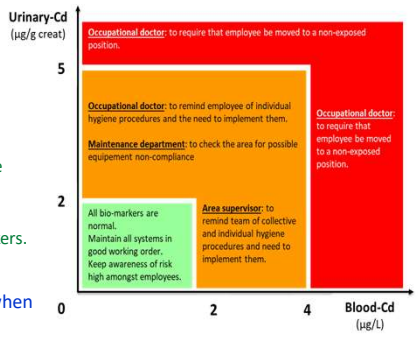
More stringent action levels since 2018:

1. Action levels for CdB were lowered from 3 to 2 and from 5 to 4.
2. More strict on removal at CdU>5
3. Enhanced monitoring of workers when exceeding effect biomarkers

ICdA Guidance: new update required???

- Content not in line with our targeted output of the RAC
  - 4µg Cd/m³ alveolar + 2µg µg Cd/g creatinine in urine
- Lower the removal criteria: removal at CdU > 2 µg Cd/g creatinine.
- Add recommendation when increasing AND approaching CdU = 2 µg Cd/g creat., especially for younger workers.
- How to deal with historic cadmium body burden (CdU > 2 µg Cd/g creat.)
  - Options for a more refined biomonitoring
    - Add effect markers biomonitoring: RBP, B2M
    - Set an absolute limit for CdU and RBP at which removal is always mandatory
    - Trend analysis
  - Increased frequency of monitoring
  - Lower limits to Cd in air for workers with CdU>2
    - Quantify an air limit for a "low-exposure" workplace (10% or 25% of OEL?) where workers with an increased CdU can work OR….
    - Apply an OEL of 1µg Cd/m³ inhalable for these workers.

Remark: an EU wide BLV of 2µg Cd/g creat. does not necessarily imply that the worker needs to be removed when exceeding. (cfr. Implementation of BLV for Pb in CAD)



Questionnaire to members on implementation of workplace monitoring

- 22 plants in 12 countries reported: if not yet done, please report to ICdA.
- Air monitoring
  - With exception of Finland and Italy, all plants have a binding national OEL
    - BE, DE, ES, FR and SE: alveolar fraction
      - 2 <-> 4 µg Cd/m³
    - All others: inhalable only
      - 4 <-> 50 µg Cd/m³
  - Multitude of applied assessment criteria
    - Free, max, geometric mean, 10% of OEL, EN689
- Bio-monitoring
  - BLV (Urine) is applied in CZ, ES, FI, FR, IT, NL, UK, SE
  - BLV (Blood) is applied in FI, FR, ES, SE
  - Biomonitoring is much appreciated by workers in all but 1 plant and stop biomonitoring would create strong opposition in all plants.
  - Info is shared with employer in a consolidated way only.
  - The occupational doctor is committed and give strong recommendation to address exposure and on removal of workers
  - 77% of workers have high trust in applied monitoring but no plant with low trust.
  - Most frequently co-biomonitored: Pb and Ni (in 50% of plants)

CMD Revision Process

- **ECHA/RAC Opinion** on limit values to address occupational exposure to cadmium and its carcinogenic compounds
- The Commission will give this report to the Advisory Committee for Safety and Health at Work (ACSH)

- **OSHA reporting** on biomonitoring and BLV as a tool to control workplace exposure.
- The Commission will share this report with the ACSH to enable them to take the OSHA conclusions into consideration.

- By Summer 2021, the tripartite Working Party on Chemical committee (with representatives from national administrations, trade unions and employers' organisations), will consider the reports from ECHA and OSHA and make a proposal to the ACSH. The ACSH will draft an Opinion to the Commission.
- The Commission will do an impact assessment.
- The Commission will draft a CMD amendment text for approval by EP and Council

take 5 minutes for a

Coffee break

Cadmium Occupational monitoring

OBSERVATORIES: Monitoring Cd exposure of workers

- OCdAIR-7: results, analysis, discussion
  - Presentation of reported data from members
  - Conclusions
- OCdBIO-12: results, analysis, conclusions
  - Presentation of reported data from members: CdU, CdB, and post-2000 hires subgroup
  - Conclusions
- Way forward

OCdAIR-7

Occupational Cadmium Air-monitoring Observatory

Preliminary reporting
2019 monitoring results

OCdAir-7

- Personal air sampling at the workplace
  - Seventh year of data collection
  - Excellent response related to earlier data collections

	2013	2014	2015	2016	2017	2018	2019
Plants	12	22	20	16	30	25	31
SEGs	67	142	131	124	162	165	204
Workers	994	1548	1369	1278	2249	1857	3499

- Good reporting quality
  - More samples for each SEG
  - All measurements mentioned respirable or inhalable fraction
  - Correction for Personal Protection Equipment during sampling

OCdAir-7

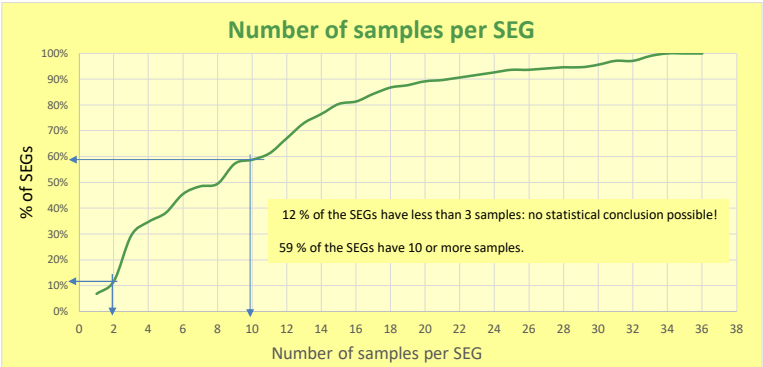
- ICdA guidance: Air quality should be under control to assure < 4µg Cd/m³ **respirable** air, always and for all workers

- Amendment of Carcinogens and mutagens directive:

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

Sampling

- Workplace exposure is not measured permanently for each worker. Therefore, a correct assessment requires a statistical approach to limit the number of samples.
- In SEGs with insufficient samples, no valid statistical calculation can be done and hence, no conclusion can be drawn on compliance.
- Minimum 3 to 10 samples are required! (EN689)
  - Minimum 3 samples when all values are below 10% of OEL.
  - Minimum 10 samples when some values are above 20% of OEL



Compliance check

- The OEL has been derived from a 40 year cumulative exposure at which no adverse health effect occurs after 40 years.
- It is based on the fact that Cd accumulates and only after long time will reach body levels that are harmful.
- How is this assessed in practice?
  - The **geomean** value would be a good reference that fits best with the way the OEL was derived because it reflects best a **40 year average exposure**.
  - In the EU there is also a general air monitoring standard EN689 which assumes that the OEL should only **exceptionally** be exceeded on a **daily** basis.
  - Further, some health inspectors look at the **maximum** value, even if EN689 is referred to in their national regulation.
  - Few inspectors seem to ask for a **sampling frequency**.
- We will present results according to different criteria to show how if affects compliance.

Cd exposure in SEGs : geomean value

- In 3 SEGs the Cd concentration in air is too high!
- In 12% of SEGs, there are insufficient samples to assess the exposure.

Geomean	number of SEGs in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	52	107	150	143	177
non-conclusive	70	12	4	20	24
4 <=> 7	1	3	6	2	3
7 <=> 10	1	4			
> 10			2		
other non-compliant	7	1			
total	131	127	162	165	204

Geomean	% of SEGs in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	40%	84%	93%	87%	87%
non-conclusive	53%	9%	2%	12%	12%
4 <=> 7	1%	2%	4%	1%	1%
7 <=> 10	1%	3%	0%	0%	0%
> 10	0%	0%	1%	0%	0%
other non-compliant	5%	1%	0%	0%	0%
total	100%	100%	100%	100%	100%

Workers exposure: geomean value

- For 202 workers (6%), all samples are below 4µg Cd/m³ but insufficient samples to conclude (we ask for at least 3 samples per SEG)
- 21 workers (0,6%) are exposed to a too high Cd concentration
- No workers have an exposure > 6 µg Cd/m³

Geomean	number of workers in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	890	1195	2169	1711	3276
non-conclusive	411	114	28	126	202
4 <=> 7	29	21	48	20	21
7 <=> 10	4	33			
> 10			4		
other non-compliant	35	2			
total	1369	1365	2249	1857	3499
Geomean	**% of workers in this range**				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	65%	88%	96%	92%	94%
non-conclusive	30%	8%	1%	7%	6%
4 <=> 7	2%	2%	2%	1%	1%
7 <=> 10	0%	2%	0%	0%	0%
> 10	0%	0%	0%	0%	0%
other non-compliant	3%	0%	0%	0%	0%
total	100%	100%	100%	100%	100%

Cd exposure in SEGs : 90 percentile

- In 22 SEGs (10%) the Cd concentration in air is too high!
- In 57 SEGs (28%), there are insufficient samples to assess the exposure.
- In 3 SEGs, the Cd concentration is above 10µg Cd/m³

90 percentile	number of SEGs in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	31	79	100	99	125
non-conclusive	83	28	40	47	57
4 <=> 7	4	10	10	11	11
7 <=> 10	2	3	5	6	8
> 10	6	7	7	2	3
other non-compliant	5				
total	131	131	162	165	204
90 percentile	**% of SEGs in this range**				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	24%	60%	62%	60%	61%
non-conclusive	63%	21%	25%	28%	28%
4 <=> 7	3%	8%	6%	7%	5%
7 <=> 10	2%	2%	3%	4%	4%
> 10	5%	5%	4%	1%	1%
other non-compliant	4%	0%	0%	0%	0%
total	100%	97%	100%	100%	100%

Workers exposure: 90 percentile

- For 608 workers (17%), all samples are below 4µg/µg m³ but insufficient samples for statistical assessment.
- 287 workers (8%) are exposed to a too high Cd concentration
- 18 workers have (sometimes) an exposure > 10 µg Cd /m³

90 percentile	number of workers in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	483	975	1672	1207	2604
non-conclusive	648	309	441	405	608
4 <=> 7	29	100	56	178	68
7 <=> 10	49	19	40	52	201
> 10	143	48	40	15	18
other non-compliant	17				
total	1369	1451	2249	1857	3499

90 percentile	% of workers in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	35%	67%	74%	65%	74%
non-conclusive	47%	21%	20%	22%	17%
4 <=> 7	2%	7%	2%	10%	2%
7 <=> 10	4%	1%	2%	3%	6%
> 10	10%	3%	2%	1%	1%
other non-compliant	1%	0%	0%	0%	0%
total	100%	100%	100%	100%	100%

Cd exposure in SEGs : EN689

- 54% of all SEGs are compliant with EN689
- In 30 SEGs (15%) the Cd concentration in air is too high!
- In 63 SEGs (31%), there are insufficient samples to assess the exposure.
- In 4 SEGs, the Cd concentration can be above 10µg Cd/m³

EN689	number of SEGs in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	12	35	78	74	111
non-conclusive	102	66	54	60	63
4 <=> 7		6	10	9	9
7 <=> 10		3	5	9	7
> 10	1	6	15	8	10
other non-compliant	16	11		5	4
total	131	127	162	165	204

EN689	% of SEGs in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	9%	28%	48%	45%	54%
non-conclusive	78%	52%	33%	36%	31%
4 <=> 7	0%	5%	6%	5%	4%
7 <=> 10	0%	2%	3%	5%	3%
> 10	1%	5%	9%	5%	5%
other non-compliant	12%	9%	0%	3%	2%
total	100%	100%	100%	100%	100%

Workers exposure: EN689

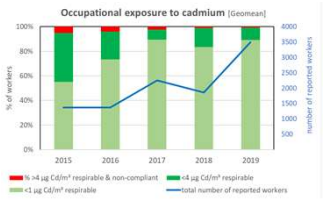
- For 636 workers (18%), all samples are below 4µg/µg m³ but insufficient samples for statistical assessment, or don't have a log normal distribution.
- 433 workers (12%) are exposed to a too high Cd concentration
- 202 workers (6%) have (occasionally) an exposure > 10 µg Cd /m³

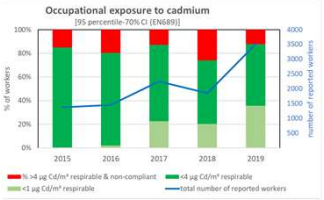
EN689	number of workers in this range				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	257	568	1441	852	2430
non-conclusive	904	597	517	521	636
4 <=> 7		95	158	147	124
7 <=> 10		22	41	99	67
> 10	18	104	92	166	202
other non-compliant	190	65		72	40
total	1369	1451	2249	1857	3499
EN689	**% of workers in this range**				
Range [µg/m³] respirable	2015	2016	2017	2018	2019
<4 µg Cd/m³ respirable	19%	39%	64%	46%	69%
non-conclusive	66%	41%	23%	28%	18%
4 <=> 7	0%	7%	7%	8%	4%
7 <=> 10	0%	2%	2%	5%	2%
> 10	1%	7%	4%	9%	6%
other non-compliant	14%	4%	0%	4%	1%
total	100%	100%	100%	100%	100%

Summary

- When applying the most realistic assessment criterium (geomean), performance is excellent with only 3 SEGs/21 workers in exceedance of the 4µg Cd/m³ respirable limit value.
- Obviously, more efforts are needed to address exposure in these SEGS.
- When assessed according to EN689, 15% of all SEGS and 12% of all workers exceed the limit value.
- More sampling is required in 28% of the SEGs.

Remark: When, according to the revised CMD, the inhalable fraction needs to be considered, more SEGs will exceeds the OEL.





OCdBio

Observatory of Occupational Cadmium Bio-monitoring

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 12 years follow-up!
  - A strong coverage of EU industrial sites: in 2019 we received reporting from +4000 workers on 36 sites!!!

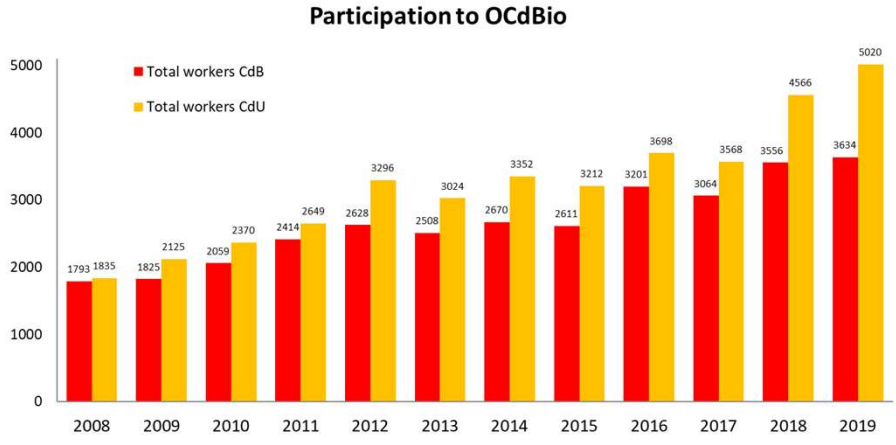
Selected biomarkers of exposure

- 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.

OCdBio

Results of data collection of 2019 monitoring exercise

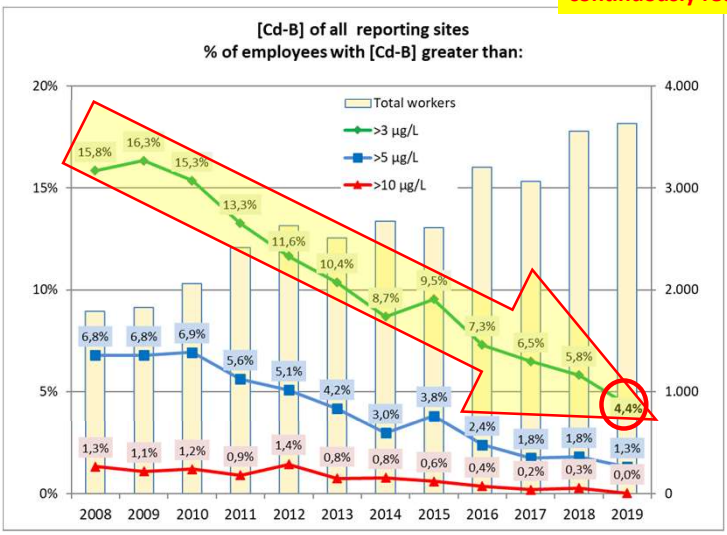
Number of reported workers



- Excellent response from **36 plants**
- Reporting data from more than **5000 workers**

CdB distribution - all sites in % -

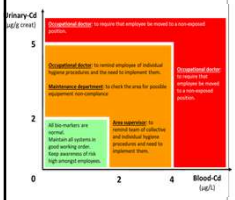
The trend of decreasing Cd uptake continues. A clear indication that workplace exposure is continuously reduced!

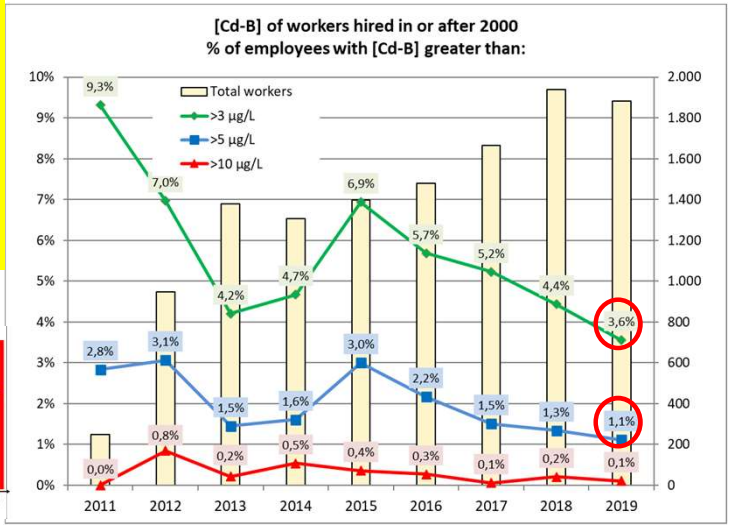


CdB distribution workers hired after 2000
- all sites in % -

- When for this subgroup comparing number of workers with CdB>5µg/L with number of workers with CdU>5µg/g creat., we see that more than the double of workers exceed CdB limit as compared to CdU limit.

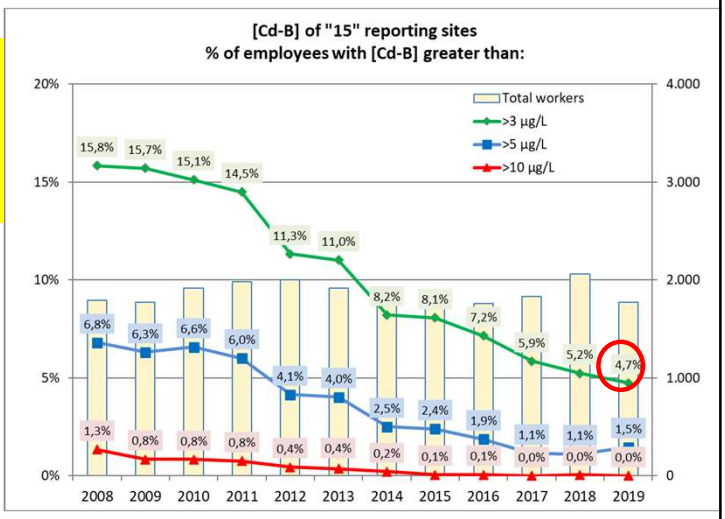
An indication of too high recent Cd exposure???





CdB distribution original "15"

CdB values above 5 µg/L mostly linked with historic burden: same amount of workers have CdB>5µg/g creat.

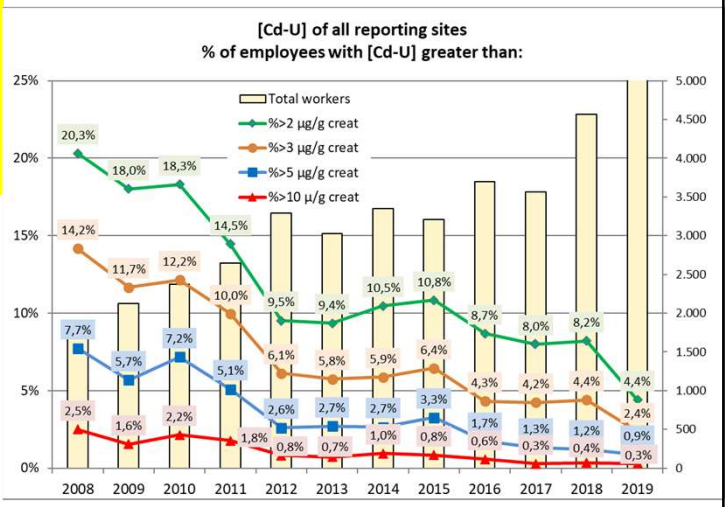


Cd in Blood: conclusion

- Good progress was made: Exposure of workers was reduced in 2019
- 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 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 4 µg Cd/L in blood
  - We should strive not to have more then 1% workers above 2 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.

CdU distribution - all sites in % -

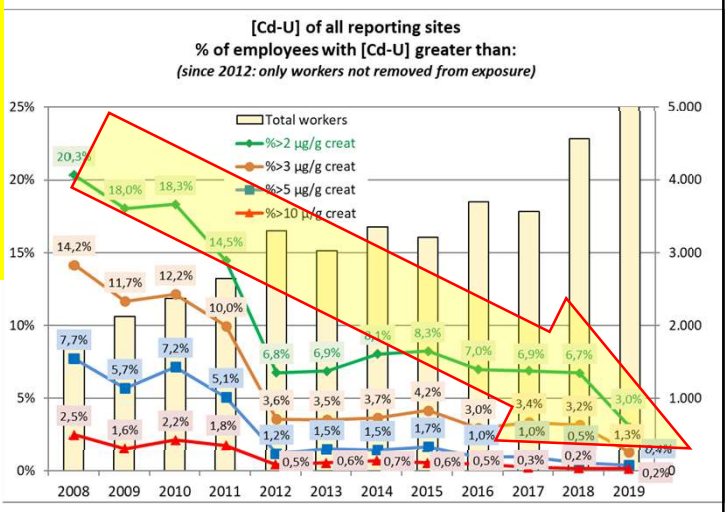
- Reduction of cadmium body burden continues
- 4,4% of workers above proposed BLV (CdU>2 µg/g creat.)



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

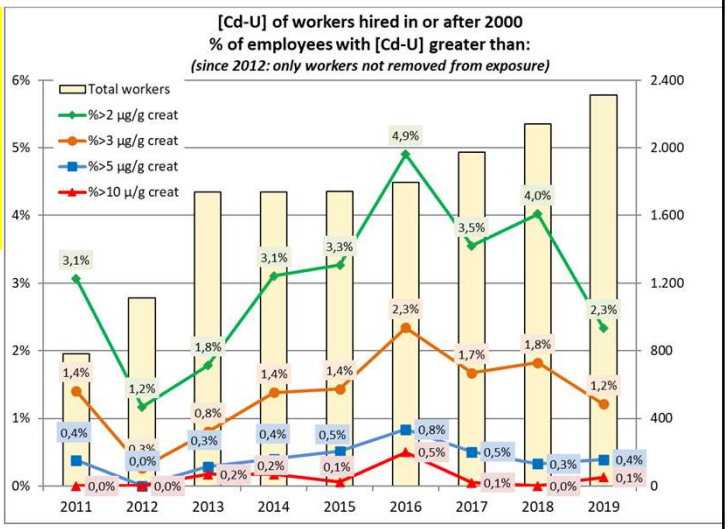
- 3,1 % of workers above proposed BLV (CdU >2 µg/g creat.)
- 20 workers with CdU >5µg/g creat. are not removed, including 9 above 10µg/g creat.

Review criteria for removal with doctor!



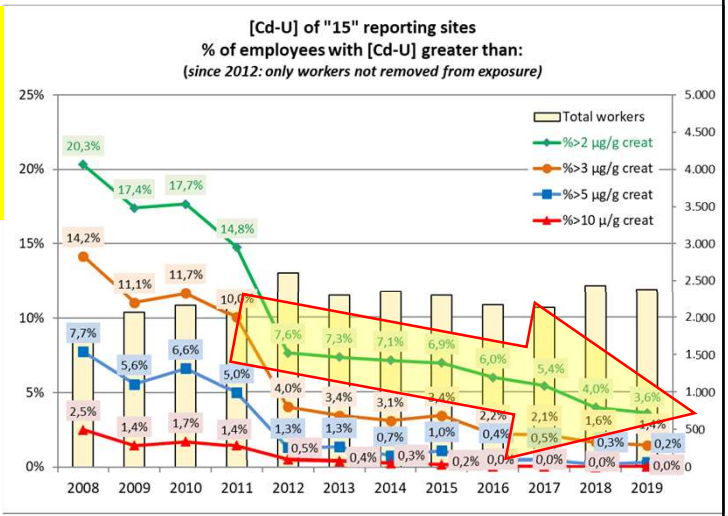
CdU distribution
- all sites in % - workers hired after 2000

- Situation continues to improve!!!
- Also here we see 9 workers above 5µg/g creat. and 3 above 10 µg which are not removed



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

- Decreasing trend continues!
- Attention should be given to 7 workers above 5µg/g creat. that are not removed.



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 of workers with high cadmium body burden is going down due to retirement.

Conclusion

- CdB
  - Over the past 12 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.
  - The new CdB action levels now respectively set at 2µg/L and 4µg/L (see Guidance 2018) need to be strictly implemented by the occupational doctor to ensure that CdU of recent workers (hired since 2000) does not rise above 2 µg/g creat.
- CdU:
  - Decrease of workers in the segment 2-5 µg Cd/g creat.!!!
  - 20 workers (0,4%) with CdU> 5 µg Cd/g creat. are not removed from exposure => check assessment procedures with doctor.
  - 221 workers have > 2µg Cd/g creat and 118 of them above 3µg.
    Today 69 workers are removed from exposure.
    should a very stiff compliance with CdU>2 be regulated, this would mean that an additional 152 workers will have to be removed, yielding severe operational disruptions. ICdA advice is to ensure this number continues to go down through strict compliance with existing 2018 Guidance.

Before going home…

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