

International Cadmium Association

Health and Safety committee meeting

Brussels, June 24th, 2015
9:30 -16:00

Agenda

- **Welcome, agenda, competition law compliance**
- **Agenda**
 - Approval of the Minutes of the 12th H&S committee (June 26th, 2014)
 - REACH developments
 - Follow-up of the authorization process
 - Status of restriction proposals
 - Prepare for authorisation dossier
 - Lunch (12h45-14h00)
 - Lobbying actions and strategies
 - Monitoring Cd exposure of workers
 - OCdAIR-2: results, analysis, discussion
 - OCdBIO-7: results, analysis, discussion
 - Conclusions and way forward
 - Inventory of Air releases (IAR)
 - Other business:

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.

REACH developments

- Follow-up of the authorization process
 - Scoring of Cd, CdO, CdS CdCl₂ : actual status
 - New classification proposals for CdCO₃, Cd(NO₃)₂, Cd(OH)₂
- Status of restriction proposals
 - RAC/SEAC reports
- Prepare for authorisation dossier
 - Compliance with DNEL 4µg/m³ ?
 - Importance of data collection through monitoring program OCdBio and OCdAir for demonstration of compliance.
 - Timing

REACH/ Authorisation: Cd and Cd-compounds

- ❑ Cd and CdO were not included in the 6th draft recommendation (2014) of ECHA to the Commission for substances to be considered with priority for inclusion in Annex XIV
- ❑ For the 7th recommendation, ECHA will score CdS, and CdCl₂ ; we updated those files in February, and Cd, CdO as well. In principle, all co-registrants confirmed their individual updates
 - ✓ With proper codes for Intermediate uses
 - ✓ With their tonnages and the final substance in which they are transformed
 - ✓ With indication of uses advised against >> professional & consumer uses
- ❑ ECHA has been informed of those updates
- ❑ We should hear in the coming days by our Eurométaux colleagues whether there is a risk for having a Cd-compound appearing on the 7th list
- ❑ Potential external support for SEA reporting ?

Scoring forecast and results...

... in case of grouping

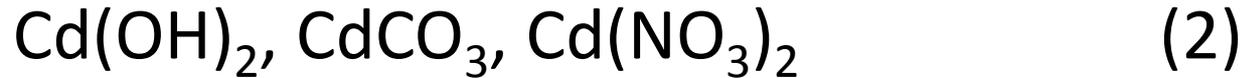
	Cd	CdO	CdS	CdCl ₂	CdSO ₄	CdF ₂	Cd(OH) ₂
Inherent properties	1	1	1	1	1	1	1
Volume	9	9	3	3	0	0	12
Dispersiveness	5	5	5	5	5	5	5
TOTAL	15	15	9	9	6	6	18

In case of grouping, Cd(OH)₂ scoring could be taken

Harmonized classification & labelling: $\text{Cd}(\text{OH})_2$, CdCO_3 , $\text{Cd}(\text{NO}_3)_2$ (1)

- Public consultation on Annex XV (>KEMI) during 45 days- ended 11/05
- KEMI's Harmonized classification proposed for consideration by RAC focuses on mutagenicity, carcinogenicity and STOT RE
- The proposed harmonized classification (as future entry in Annex VI, CLP regulation) is the result of the Annex VI group entry, i.e. Acute Tox. 4* (H302, H312, H332), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) and the harmonized classification proposed for consideration by RAC (muta, carc, STOT RE).
 - However, for this proposed harmonized classification the hazard classes coming from the group classification (acute tox!) are not re-assessed in this Annex XV dossier but taken over as such.
- Kemi's classification proposal for consideration by RAC \neq REACH joint submission (self-classification), notably "muta 1B" proposal for $\text{Cd}(\text{OH})_2$ and CdCO_3 instead of "muta 2"
- Comments on the muta proposal were submitted by ICdA

Harmonized classification & labelling:



RAC work-programme is to be followed:

- $\text{Cd}(\text{OH})_2$, CdCO_3 , $\text{Cd}(\text{NO}_3)_2$ dossiers planned for RAC 35 (end November-beginning December)
- RAC proposed CMR-classifications in line with our self-classifications
- However, what with the other hazard endpoints because not addressed in the KEMI proposal
- Future entry in Annex VI, CLP ?

Cd compounds at RAC 35

Substance	DL for adoption	DS C&L proposal
Cadmium carbonate	3/08/2016	Carc. 1B; H350 Muta. 2; H341 Repr. 2; H361fd STOT-RE 1; H372 (Target organ: kidney and bone)
Cadmium dihydroxide	3/08/2016	Carc. 1B; H350 Muta. 2; H341 Repr. 2; H361fd STOT-RE 1; H372 (Target organ: kidney and bone)
Cadmium dinitrate	3/08/2016	Carc. 1B; H350 Muta. 1B; H340 Repr. 1B; H360FD STOT-RE 1; H372 (Target organ: kidney and bone)

In line with our CMR, STOT classifications. What about acute tox?

Overview classification proposals

	REACH self classification	KEMI proposal	RAC proposal
$\text{Cd}(\text{OH})_2$	Acute tox 2 (inh) Muta 2 Carc 1B STOT RE 1 Repro 2 Aquatic acute 1 Aquatic chronic 1	Muta 1B Carc 1B STOT RE 1 + Cd group classification: Acute tox 4 (oral, inh, dermal) Aquatic acute 1 Aquatic chronic 1	Muta 2 Carc 1B STOT RE 1 Repro 2
CdCO_3	Acute tox 2 (inh) Muta 2 Carc 1B STOT RE 1 Repro 2 Aquatic acute 1 Aquatic chronic 1	Muta 1B Carc 1B STOT RE 1 + Cd group classification: Acute tox 4 (oral, inh, dermal) Aquatic acute 1 Aquatic chronic 1	Muta 2 Carc 1B STOT RE 1 Repro 2
$\text{Cd}(\text{NO}_3)_2$	Acute tox 2 (inh) Acute tox 3 (oral) Muta 1B Carc 1B STOT RE 1 Repro 1B Aquatic acute 1 Aquatic chronic 1	Muta 1B Carc 1B STOT RE 1 + Cd group classification: Acute tox 4 (oral, inh, dermal) Aquatic acute 1 Aquatic chronic 1	Muta 1B Carc 1B STOT RE 1 Repro 1B

REACH: Restriction

Were on the agenda the last months:

- The administrative restriction amendment (antifouling paints Taric 3208-3209): => will probably be proposed to COM
- The final outcome of the KEMI-proposal to restrict cadmium pigments in Artists paints: => is not supported and advised against by RAC/SEAC . Will COM react ?
- The proposal to enlarge the current restriction of Cd-compounds to more plastics than the 16 restricted resins: => is withdrawn and no longer on the agenda

Academic support (1)

- Contract with UCL (Prof Van Maele) is signed on 27/01 covering:
 - 1) **Cadmium and breast cancer in general population**
 - Systematic review + meta analysis → publication
 - Timing: 6 weeks after signing of contract; first draft delivered end March
 - Publication is submitted mid June to Peer Reviewed Journal and will be presented at the 2nd Cadmium Symposium in Sassari end of June by Prof Van Maele
 - Main conclusion: ‘no statistically significant increased risk of breast cancer among postmenopausal women related to dietary Cd intake’
 - 2) **threshold/non-threshold carcinogen:**
 - Monitoring survey: study of genotoxic effects in human lymphocytes (blood) of a well defined cohort

Academic support (2)

– Genotoxicity study: feasibility study

- Literature study on genotoxicity of cadmium
- Budget proposal based on quotes of competent genotoxicity labs
- Study feasibility of the 2 different study design:
 - A) dose response curve: genotoxicity study in different workers covering a broad range of 'doses' (low to mid doses) to determine a NOAEL (threshold)
 - B) compare 2 exposure groups (no dose response curve):
 - ⇒ study low dose exposed workers ($\ll 10 \mu\text{g/L}$) in comparison to controls
 - ⇒ need for *positive control* to prove if no genotoxic effect seen, the test system is validated
- Timing: 6 weeks after the submission of the publication on Cadmium and breast cancer in general population
 - part 2 not started yet

□ Budget part 1 +2 : 25k€

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

- ❑ Public consultation on 'Human health Tier II assessment for pigments related to cadmium sulfide' ended 19/06
- ❑ Assessment (mainly based on read across from CdS) is not in line with our CSRs on cadmium pigment yellow, cadmium pigment red/orange:

Proposed classifications: acute tox 4, STOT RE1, Muta cat2, Carc cat1B, repro cat2

"However some or all of the classifications recommended may not be required if substantial evidence can demonstrate that the occupational risks can be mitigated through industrial surface treatment processes."

- ❑ Comments ICdA:
 - Explained our case for non-classification for any hazard as outlined in the REACH CSR: reference to CdTe (sparingly soluble) and very low bioaccessibility of Cd pigments
 - Reference to the Annex VI CLP EU group classification which covers 'cadmium and compounds' but excludes cadmium sulfoselenide and cadmium zinc sulphide → cadmium pigments not classed hazardous
 - Emphasised cadmium sulphide is not used as a pigment and that all cadmium pigments covered by EU REACH registration are specifically treated to achieve extremely low levels of extractable cadmium

About Chinese RoHS II: Comments made on behalf of ICdA

- Ministry of Industry and Information Technology (MIIT) requested public comments to the recent published draft of a revised Decree No. 39, commonly referenced by industry as China RoHS II (Restriction of Hazardous Substances)
- Public consultation ended 17/06
- RoHS II includes e.g. Cadmium and its compounds.
- Main comments ICdA:
 - RoHS II does not include exemptions as in EU RoHS
 - ‘its compounds’: includes cadmium pigments which are not hazardous
 - Urged MIIT to consider the benefits of cadmium pigments’ use, as well as the lack of suitable alternatives being less hazardous and equally socio-economically viable
 - Urged MIIT to allow greater consistency with similar RoHS implementations + consideration of exemptions to be specified

Lobbying actions and strategies

- Overview of past and future actions

OBSERVATORIES:

Monitoring Cd exposure of workers

- OCdAIR-2: results, analysis, discussion
 - Presentation of reported data from members
 - Observed diversity in monitoring procedures and data interpretation
 - Which standards do we need to comply with
 - Recommendations for personal air monitoring.
 - Conclusions
- OCdBIO-7: results, analysis, conclusions
 - Presentation of reported data from members: CdU, CdB, Post 2000 hires
 - Conclusions
- Way forward
 - CdU, CdB, CdAir
 - How to demonstrate that we adequately control the exposure to cadmium
 - What is feasible for plant operators (realistic targets)
 - What is convincing for REACH authorities
 - Conclusions and way forward

OCdAIR

Occupational Cadmium Air-monitoring Observatory

OCdAir

- Personal air sampling at the workplace
 - Second year of data collection
 - Good response in 2014

	2013	2014
Plants	12	22
SEGs	67	142
Workers	994	1548

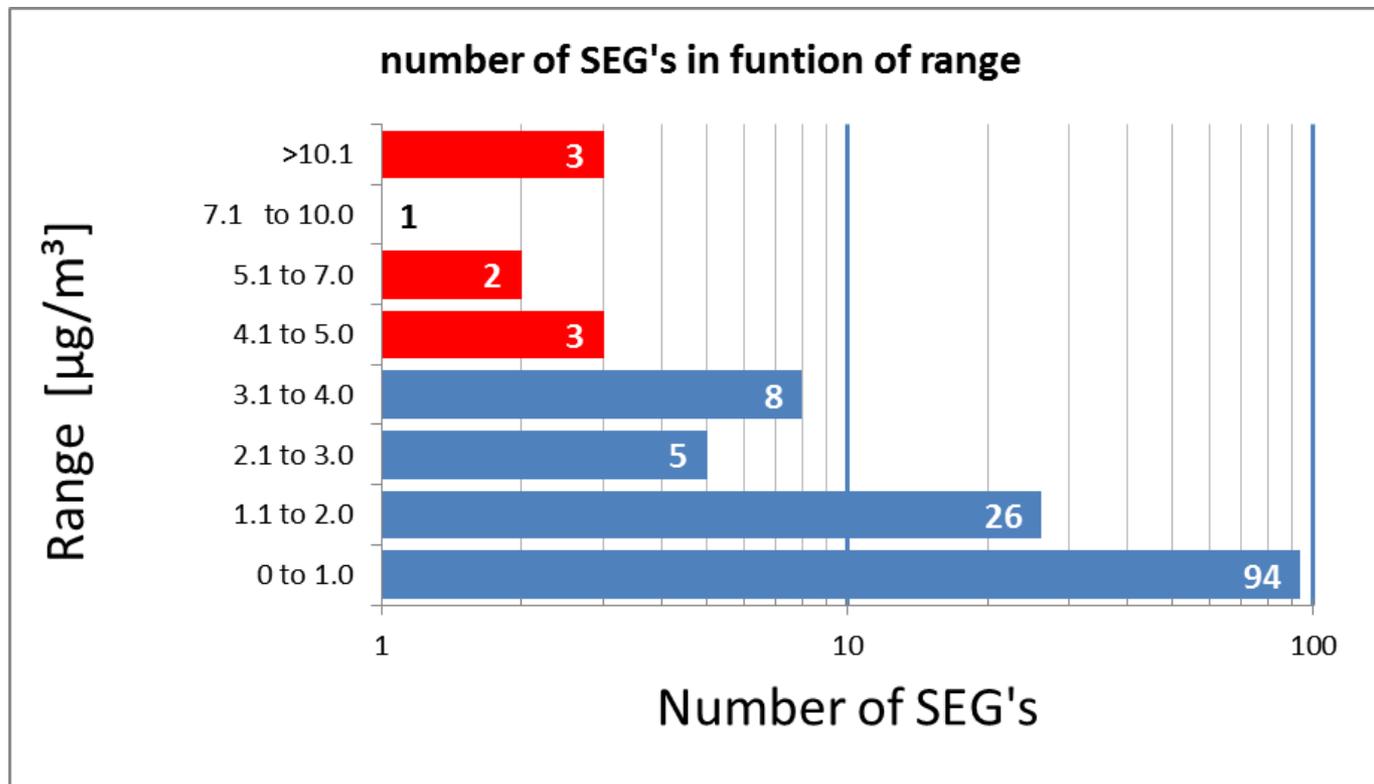
- Sampling procedure needs refining
 - Required number of samples per SEG
 - All measures should be of respiratory fraction
 - Masks and sampling?

OCdAir

- Air quality should be under control to assure $< 4\mu\text{g Cd/m}^3$ **respirable** air, always and for all workers
- Remarks on sampling:
 - Sampling and data treatment not yet in line with standards
 - Amount of samples per SEG not yet in line with standards
- Can we exceed this DNEL level in individual samples?
 - Not according to EN 689
 - Even more stringent with the upcoming revision of EN 689
 - All samples below 0,1 DNEL (minimum 3 samples) or
 - In a log-normal distribution (graph calculated from 9 samples), min. 95% of the workers should be below the DNEL.
 - From all reporting plants, only 2 demonstrated already full compliance with prEN 689 and DNEL of $4\mu\text{g Cd/m}^3$ respirable (=requirement for all in 3-4 years from now)

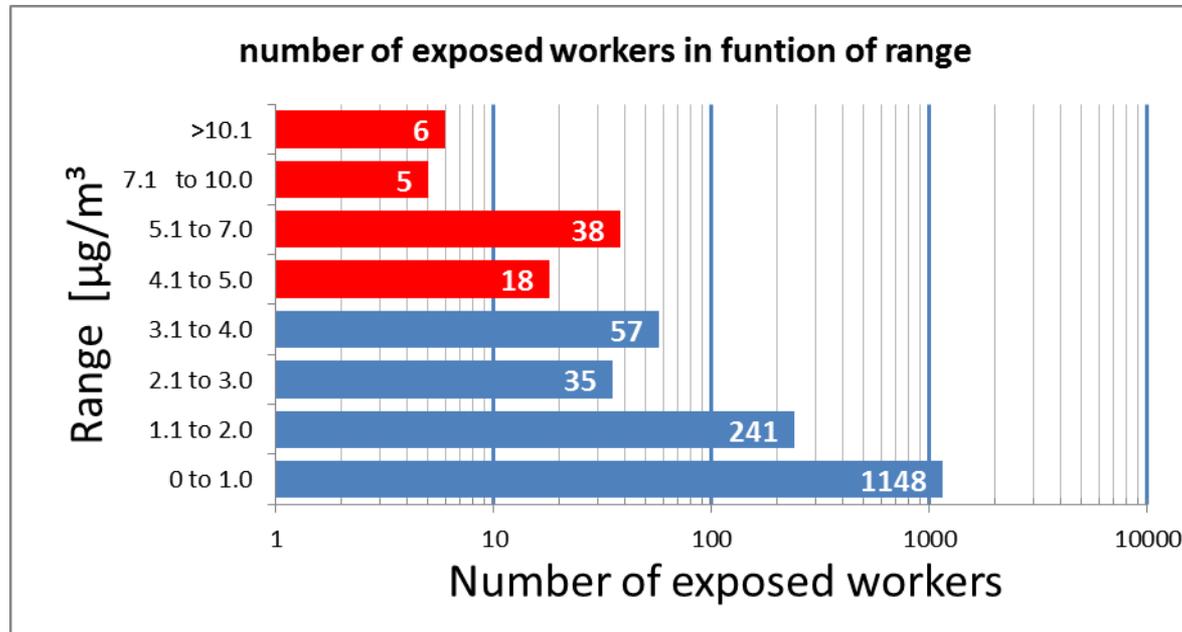
Reported results of SEG's

- In **9 SEGs** or **6,3%** of monitored SEGs the average measured value was above $4\mu\text{g}/\text{m}^3$
- First impression: not too bad, high degree of compliance, but...

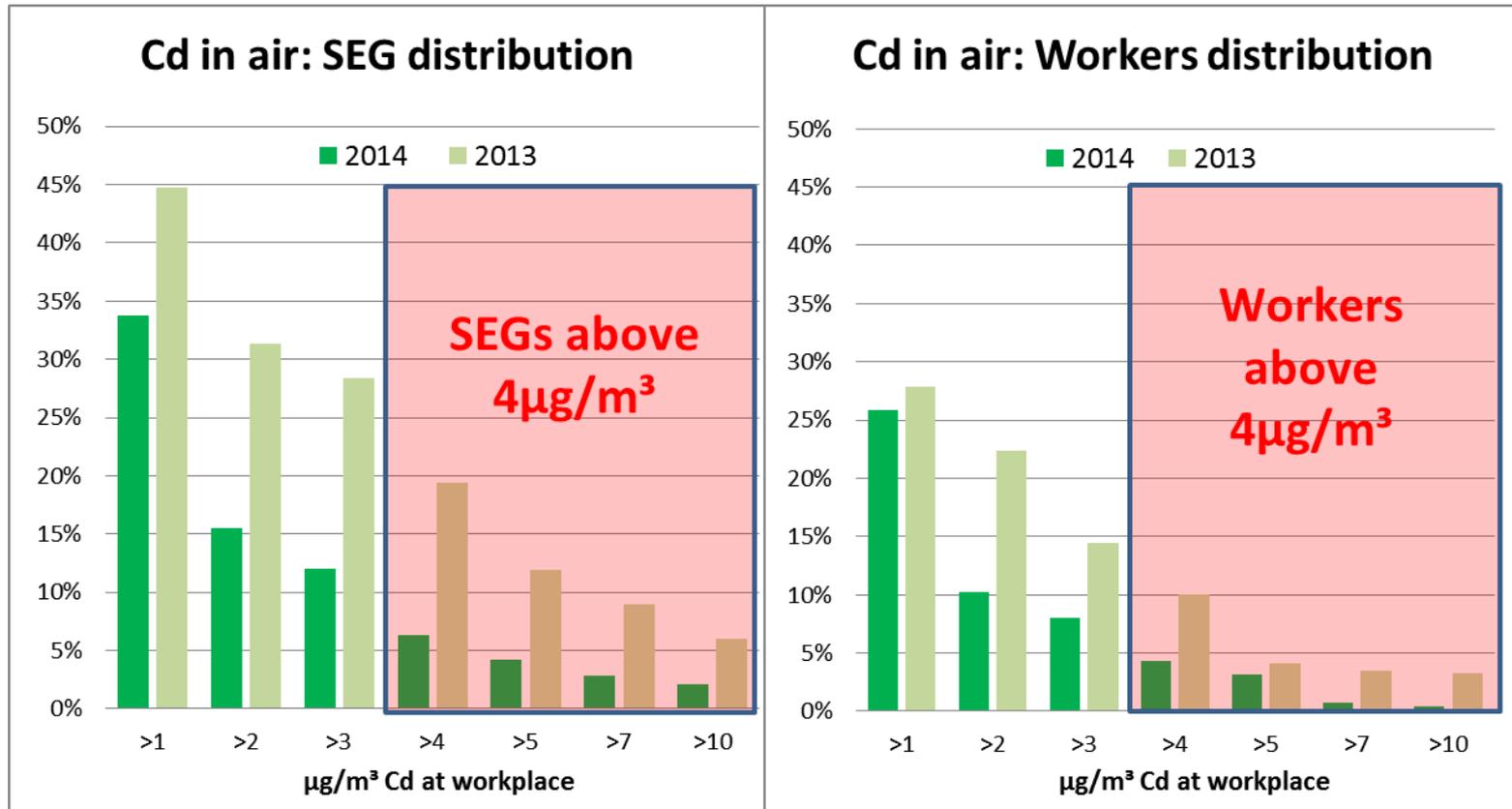


Reported results of workers

- **67 workers** or **4,3%** of monitored population are in SEG's which have an average exposure above $4\mu\text{g Cd}/\text{m}^3$ respirable.



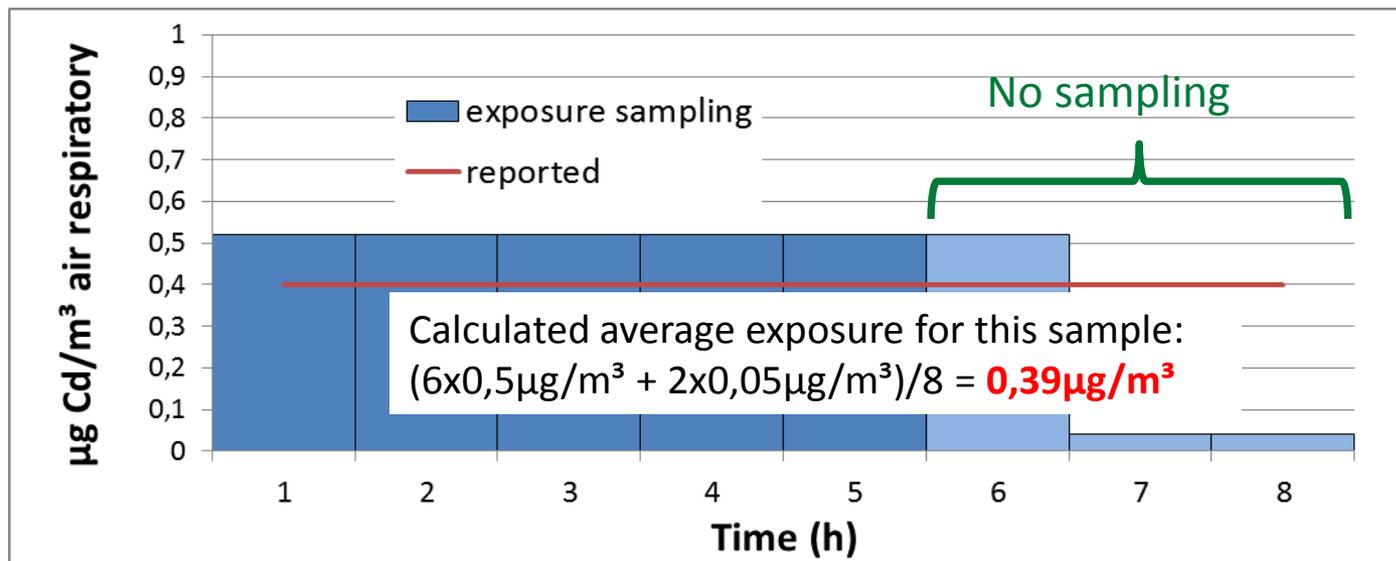
Good progress



- Clear improvement but not yet on target

Lack of coherence in sampling and reporting: some guidelines to improve

- Correct calculation of the value of a sample
 - Total exposure is the time average of periods of exposure and no exposure over an 8h shift.
 - If there are non-sampled periods of zero exposure, these should be integrated in the time average mentioned and/or included in the value.



Lack of coherence in sampling and reporting: some guidelines to improve

- Monitoring outside PPE (mask) is not representative for the exposure, but exposure conditions requiring PPE should become exceptional rather than standard practice.
- How many samples per SEG?
 - 3 samples minimum! (at this moment, recommend by ICdA)
 - When all 3 samples are $<0,4\mu\text{g}/\text{m}^3$ ($<10\%$ of DNEL)
 - 9 samples (future standard to comply with, apply on voluntary basis only)
 - When 1 sample within the original 3 samples is $>0,4\mu\text{g}/\text{m}^3$
 - Sampling should be done at 3 different moments or shifts
 - Not mandatory yet... but be prepared (budgetary) for the future

When is a SEG result compliant?

- Actual standard (EN 689): often no conclusion
 - 1 sample $< 0,1$ DNEL: **compliant**
 - 3 samples from 3 shifts, all $< 0,25$ DNEL: **compliant**
 - 3 samples from 3 shifts $<$ DNEL and geom. avg $< 0,5$ DNEL: **compliant**
 - 1 sample $>$ DNEL: **non-compliant**
 - All other cases: **no conclusion**
- Future standard (prEN 689): always a conclusion
 - 3 samples and all samples $< 0,1$ DNEL \Rightarrow **compliant**
 - 9 samples
 - One sample $>$ DNEL: \Rightarrow **non-compliant**
 - All samples $<$ DNEL : make log-normal distribution
 - Download excel tool for statistical assessment and check
 - <http://ohshub.com/ihstat-statistical-analysis-of-health-safety-data/>
 - At least 95% $< 4\mu\text{g}/\text{m}^3$ \Rightarrow **compliant**
 - More than 5% $> 4\mu\text{g}/\text{m}^3$ \Rightarrow **non-compliant**

IHSTAT tool (excel document)

Enter OEL

OEL	DESCRIPTIVE STATISTICS	
4	Number of samples (n)	13
	Maximum (max)	3
	Minimum (min)	0,09
	Range	2,91
	Percent above OEL (%>OEL)	0,000
	Mean	0,945
	Median	0,940
	Standard deviation (s)	0,911
	Mean of logtransformed data (LN)	-0,594
	Std. deviation of logtransformed data (LN)	1,192
	Geometric mean (GM)	0,552
	Geometric standard deviation (GSD)	3,295
	TEST FOR DISTRIBUTION FIT	
	W-test of logtransformed data (LN)	0,909
	Lognormal (a = 0.05)?	Yes
	W-test of data	0,834
	Normal (a = 0.05)?	No
	LOGNORMAL PARAMETRIC STATISTICS	
	Estimated Arithmetic Mean - MVUE	
	LCL _{1,95%} - Land's "Exact"	0,612
	UCL _{1,95%} - Land's "Exact"	3,328
	95th Percentile	3,925
	UTL _{95%,95%}	13,325
	Percent above OEL (%>OEL)	4,838
	LCL _{1,95%} %>OEL	0,927
	UCL _{1,95%} %>OEL	17,767
	NORMAL PARAMETRIC STATISTICS	
	Mean	0,945
	LCL _{1,95%} - t statistics	0,495
	UCL _{1,95%} - t statistics	1,396
	95th Percentile - Z	2,444
	UTL _{95%,95%}	3,38
	Percent above OEL (%>OEL)	0,040

Enter samples

Log-normal distribution?

Compliant? (value <DNEL)

Not compliant?

1. Analyse cause of exceedance
2. Take appropriate precautionary actions
3. Conduct a new exposure survey
4. Check compliance

Iterate until compliance is achieved

OCdBio

Observatory of Occupational Cadmium Bio-
monitoring

OCdBio -Occupational Cadmium Bio-monitoring Observatory

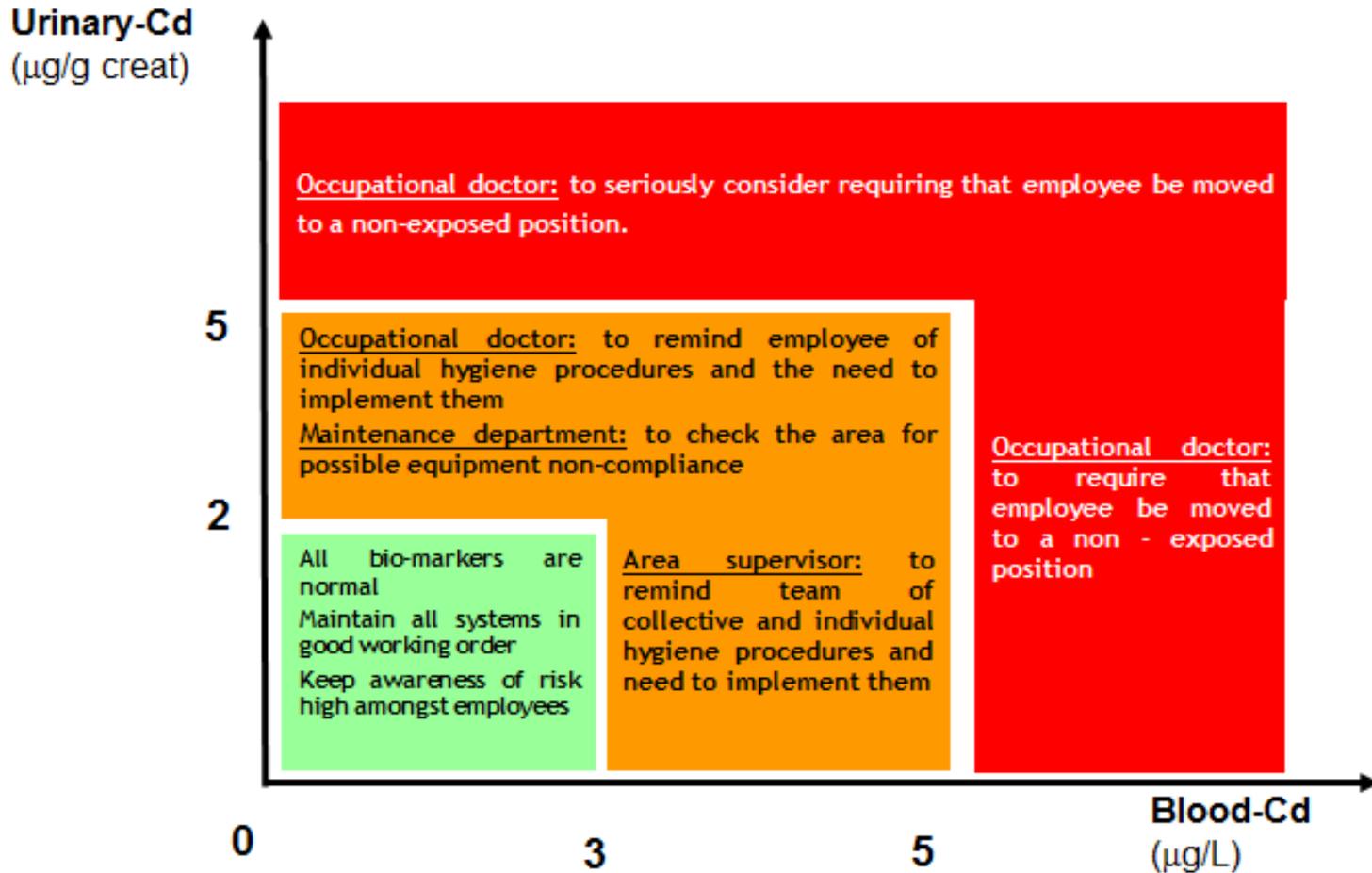
Since 2008, Cd bio-monitoring data is collected in the Cd industry in order to convince ourselves and authorities on:

- 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 follow-up is interesting only if:
 - There is a long-term involvement of the companies; currently 6 years follow-up!
 - A strong coverage of EU industrial sites in for OCdBio-6 (2014 data):
28 sites participating, **25** sites reporting CdU and **22** sites reporting CdB

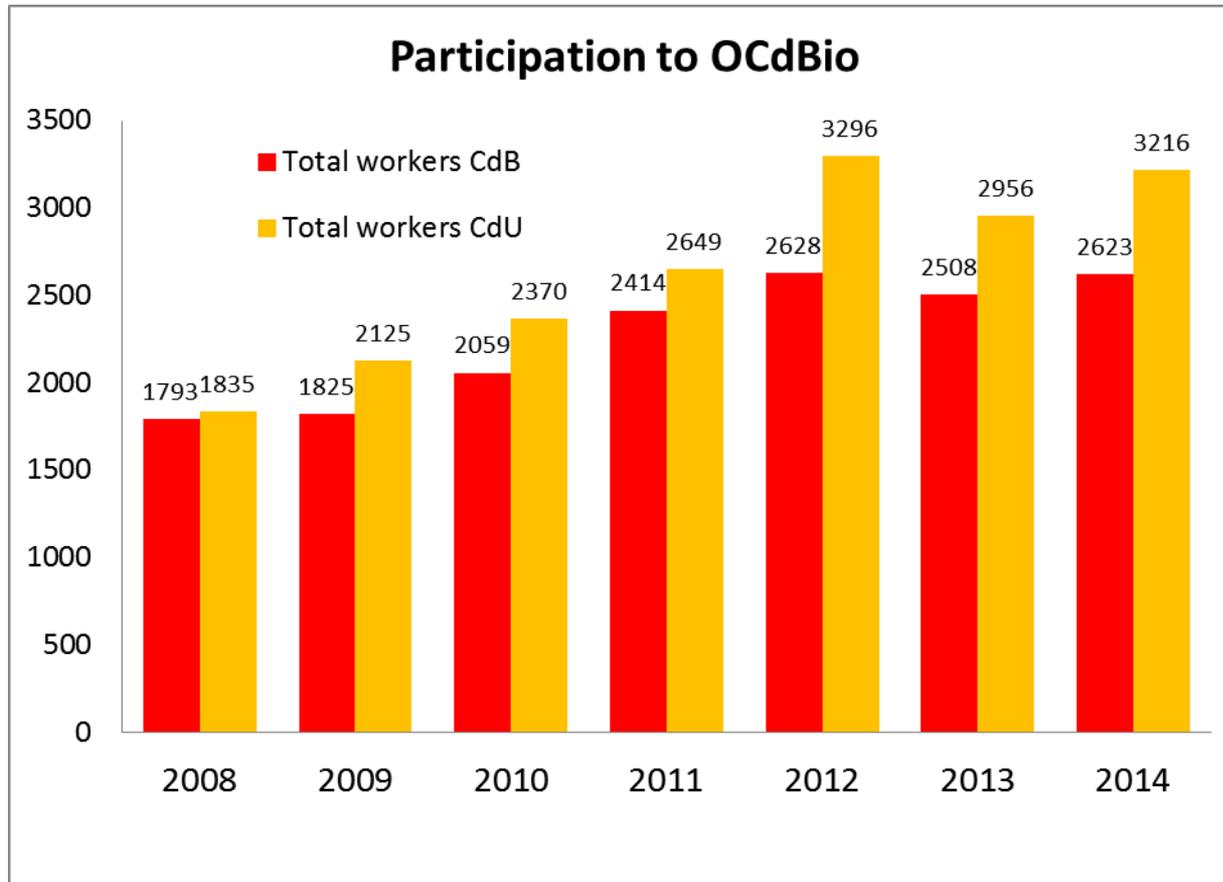
Selected biomarkers of exposure

- Cadmium in blood – CdB:
 - indicator of recent (and older) exposure
 - Cadmium in blood ($\mu\text{g Cd/L}$)
- 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
 - Cadmium in urine ($\mu\text{gCd/g creatinine}$)

Using “exposure biomarkers” to conduct adequate advanced medical surveillance (2013 ICdA Guidance)



Number of reported workers



- A good response was received for 2014

ICdA- 2017/2020 initiative

- **Aim:**

- Not an individual but a **collective commitment** to achieve challenging targets in terms of **biomonitoring results** of workers potentially exposed to Cd

- **How:**

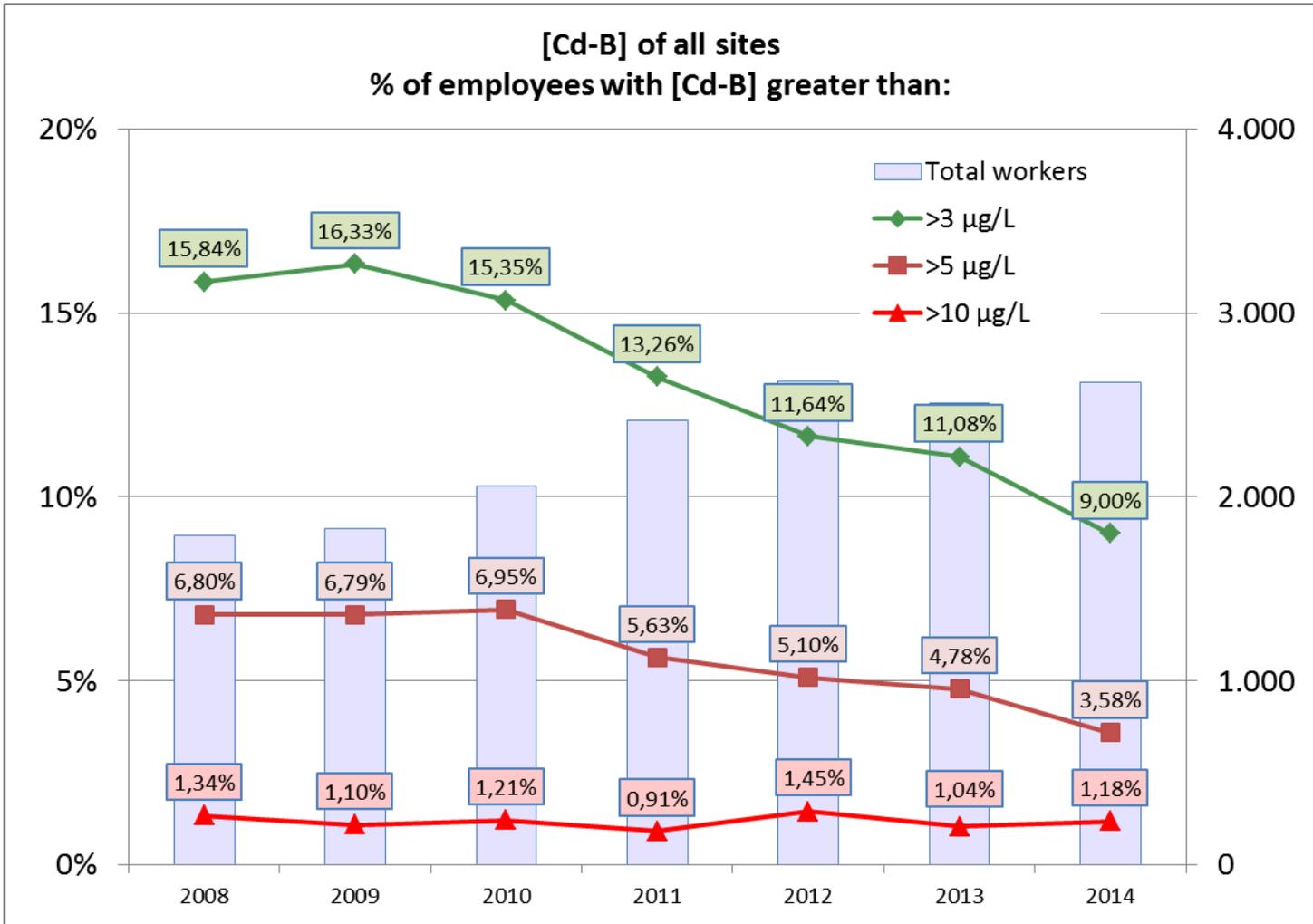
- Revision and further **implementation of ICdA guidance** with the goal of further **reducing occupational exposure** of their employees

- **Goal:**

- **95%** of European employees subject to medical surveillance and bio-monitoring as required by their occupational medical doctor, **<2 µg Cd/g creatinine at end of 2017.**
- **98%** of European employees subject to medical surveillance and bio-monitoring as required by their occupational medical doctor, **<2 µg Cd/g creatinine at end of 2020.**

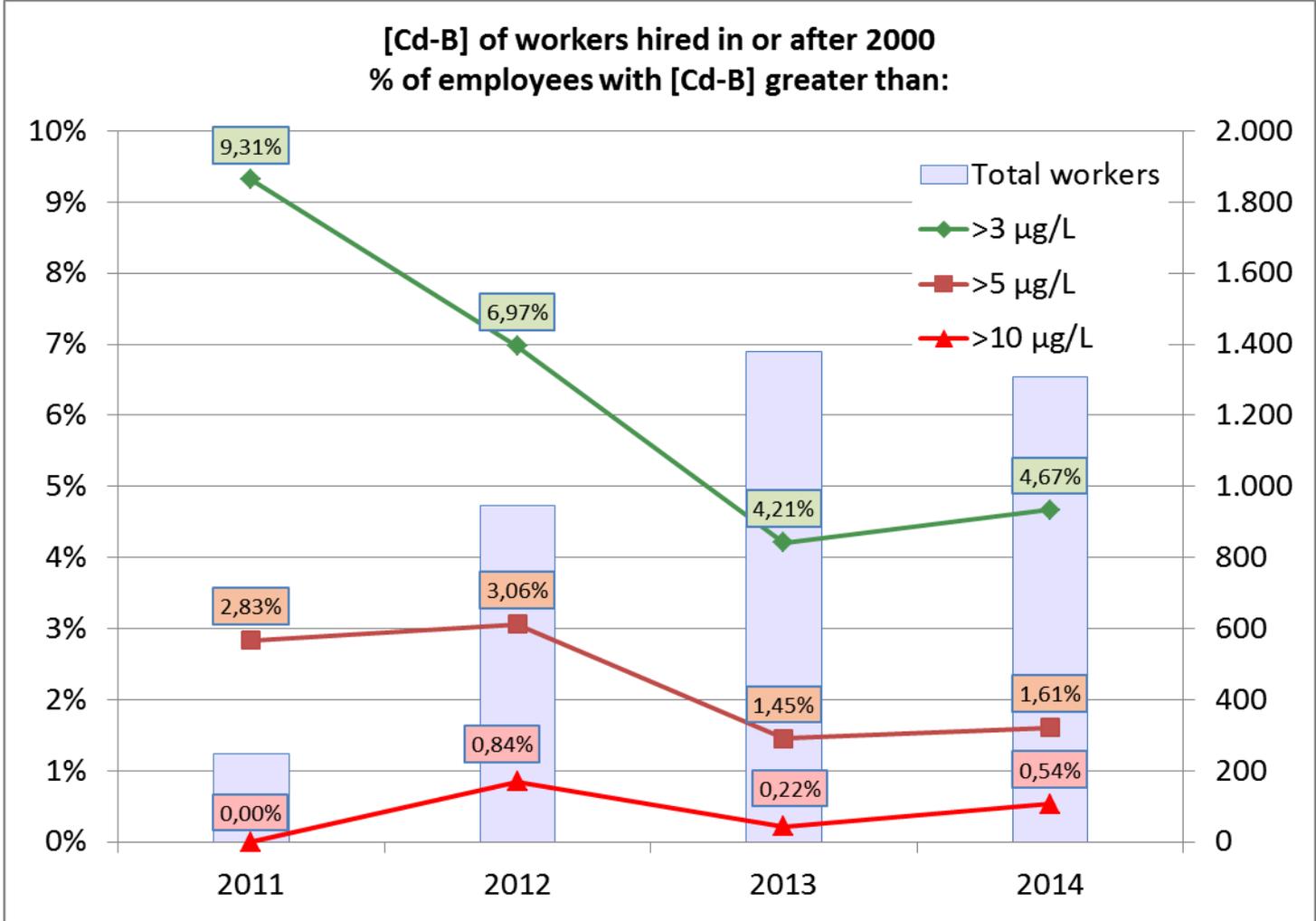
CdB distribution

- all sites in % -



CdB distribution **workers hired after 2000**

- all sites in % -

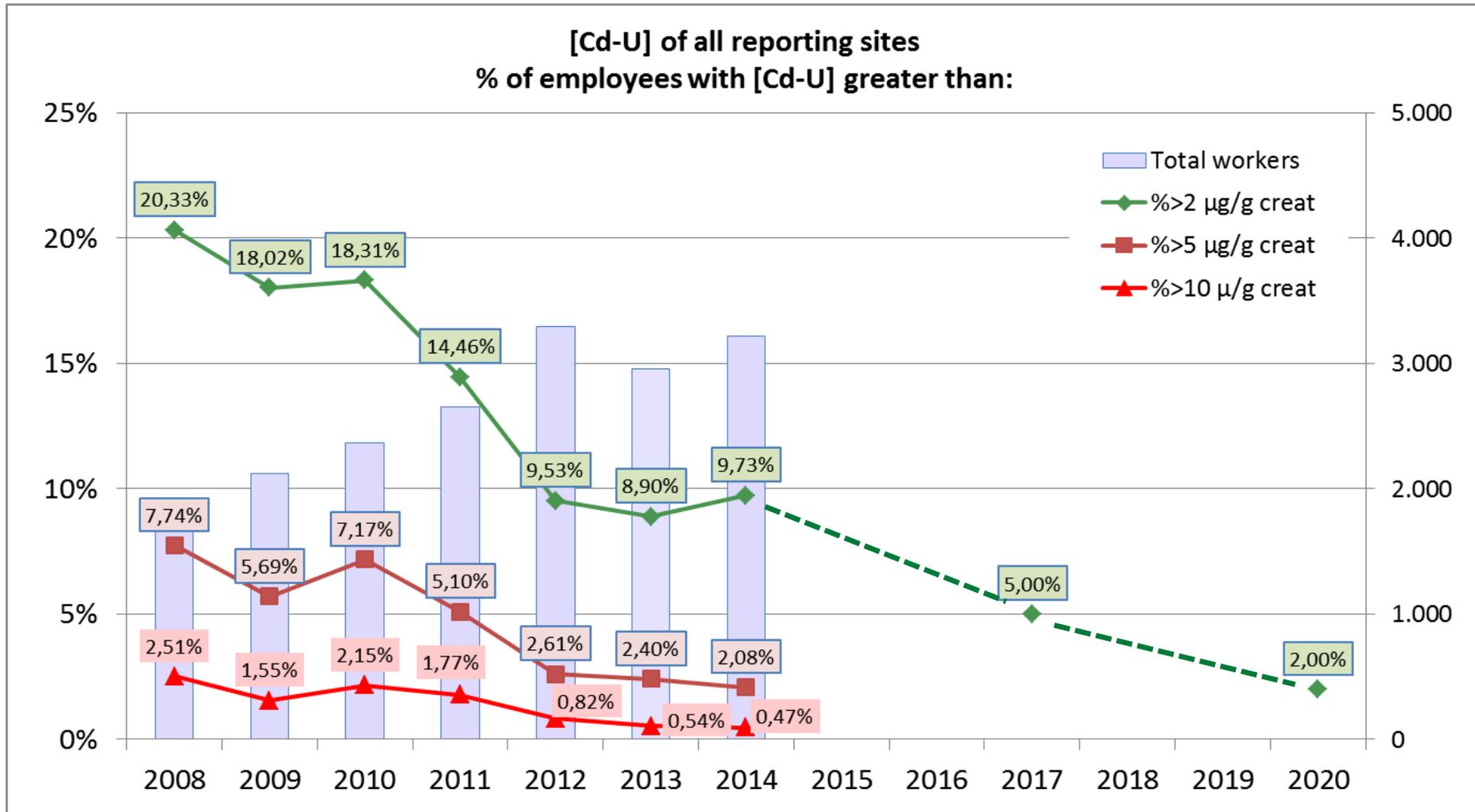


CdB conclusion

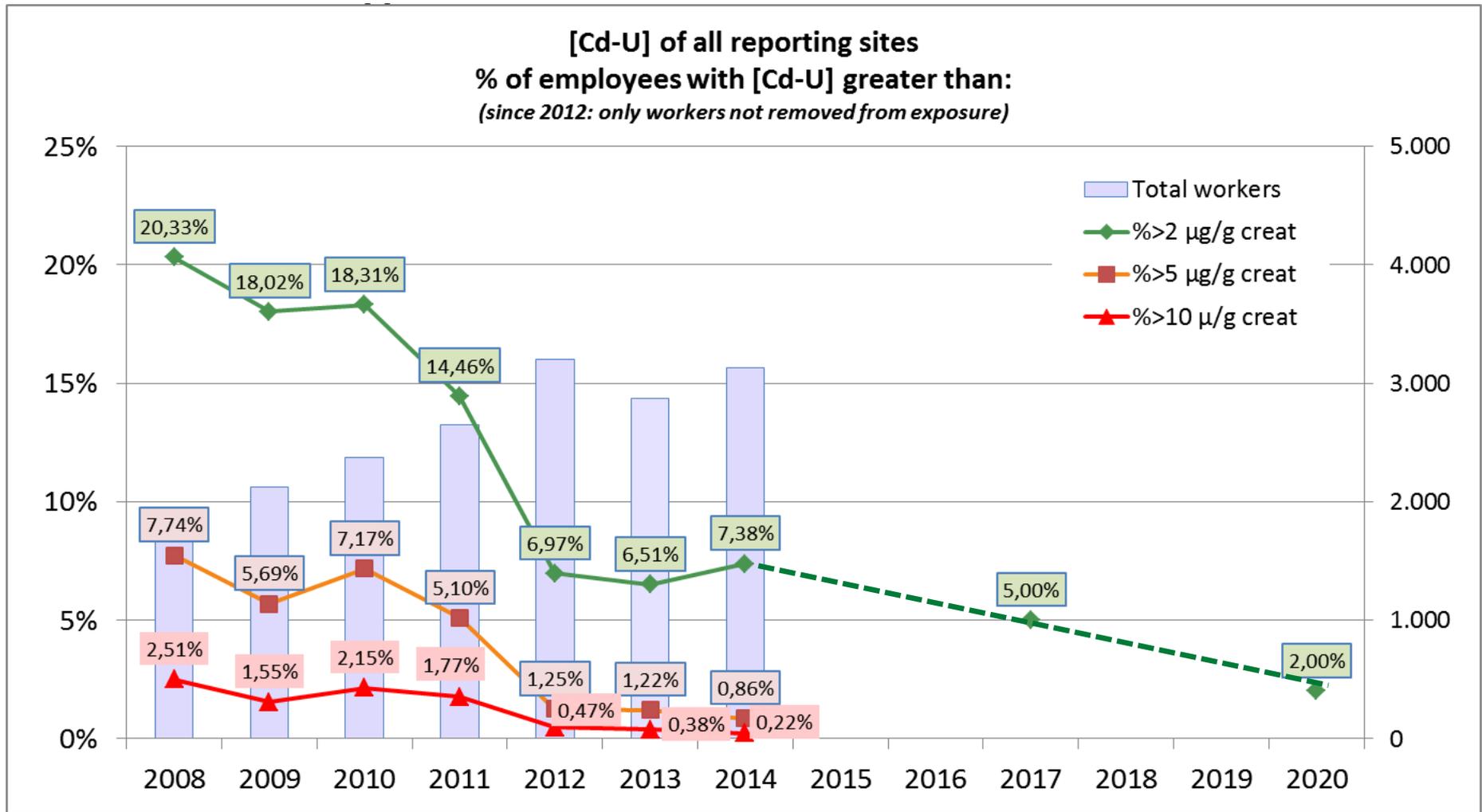
- Workers hired after 2000 have much lower exposure
 - half as high as total population
- Decreasing CdB levels are clear indicators that exposure to Cd at the workplace is reduced year by year
- From the new hired evolution, we see that there was on average no further improvement achieved in the last year.
 - Is the actual level of CdB sufficient to reach the CdU target of 98% $<2\mu\text{g Cd/g creatinine}$?
- Continued attention is required

CdU distribution

- all sites in % -

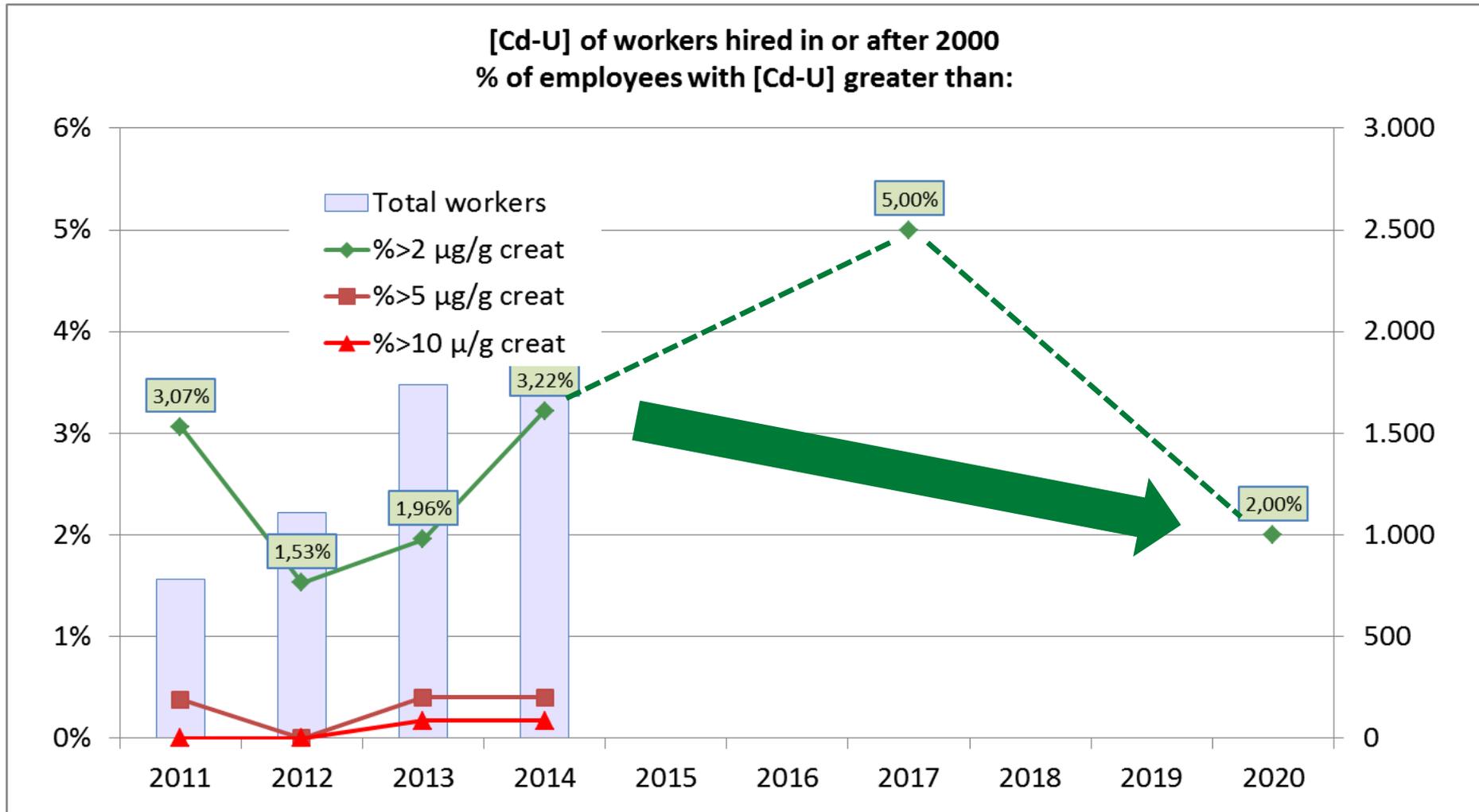


CdU distribution

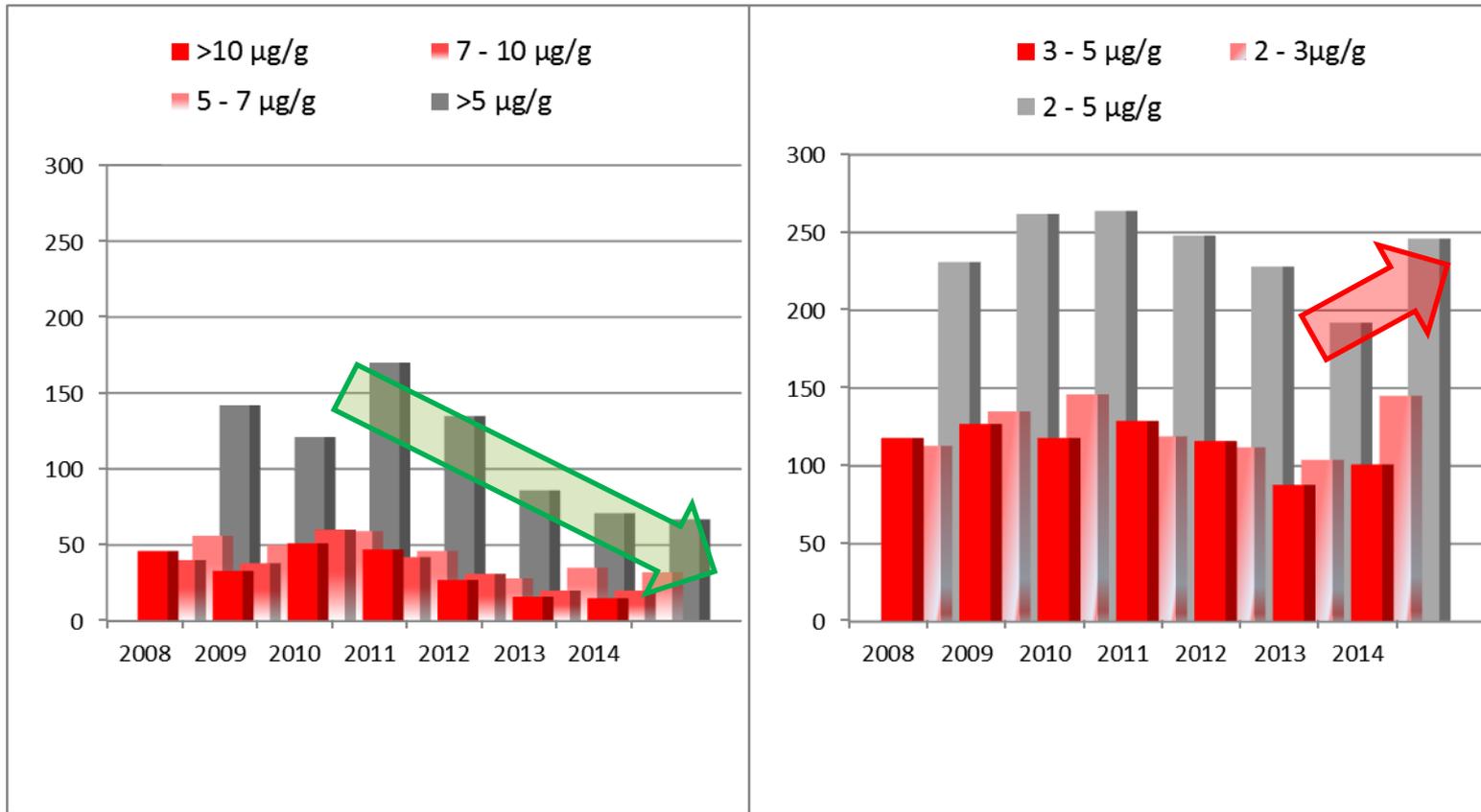


CdU distribution **workers hired after 2000**

- all sites in % -



Conclusion CdU



2020 Target: only 65 workers (2%) should be at levels Cd-U > 2 µg/g creatinine

- Fast decrease of the highest exposed workers (>5µg/g). From the 67 workers in 2014, 35 will retire by 2020. 32 will stay.
 - Decrease of the intermediate exposed workers (2-5 µg/g) has stopped and increased. In 2014 there were 246 workers in this group. By 2020, this number should decrease to 33 workers. Check retirement forecast in this group!!!
- Battle of evolution of highly exposed workers has been won but now we need to work on the intermediate levels of exposure where we had almost no gain.

Conclusion

- Most plant achieve already low level of Cd in air
 - But: standards are set at very low levels
 - Therefore: further improvement is still needed over the next years
- CdB
 - Decreasing values are clear indicators that workplace conditions have improved over the past years.
 - Plants should aim not to have workers with CdB > 3µg/L in order to achieve the CdU target of 2µg/g in 2020,
- CdU:
 - Good evolution of the highest exposed over the monitoring period
 - To little reduction of the intermediate exposed workers
 - It will be very challenging to achieve the ambitious 2020 target
 - Adapt communication to anticipate the missed Cd-U target?

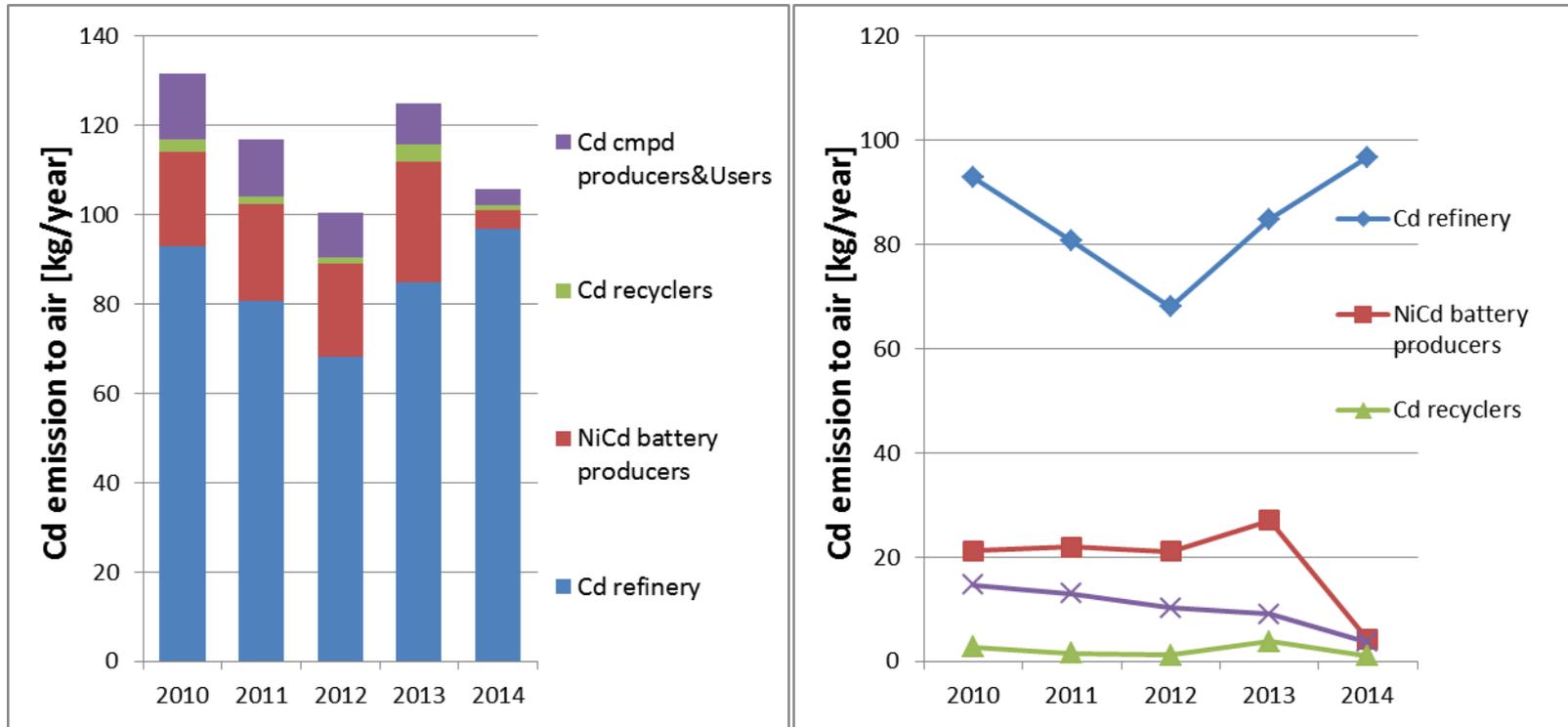
Way forward

- Monitoring
 - CdAir => REACH requirement (DNEL)
 - CdU, CdB => voluntary, to show adequate control
 - => additional info on retirement in OCdBio8
- How to demonstrate that we adequately control the exposure to cadmium
- What is feasible for plant operators (realistic targets)
- What is convincing for REACH authorities
- Conclusions and way forward

IAR-Inventory of Air releases

	Kg emission to air					Nr of reporting plants				
	2010	2011	2012	2013	2014	2010	2011	2012	2013	2014
Zn refinery	53,6	63,0	23,6	20,3	22,7	4	4	4	4	4
Cd refinery	92,9	80,6	68,1	84,8	96,8	5	5	5	5	5
NiCd battery producers	21,2	21,9	21,1	27,1	4,2	6	6	6	7	6
Cd recyclers	2,8	1,5	1,2	3,8	1,1	3	3	3	3	3
Cd cmpd producers&Users	14,7	12,9	10,3	9,1	3,7	6	7	8	7	6
Cd ref.+bat.+rec.+cpds.+users	131,5	117,0	100,6	124,9	105,8	20	21	22	22	20
+Zn ref.	185,2	180,0	124,2	145,2	128,6	24	25	26	26	24

IAR-Inventory of Air releases



- Significant reductions in most segments