CADMIUM Working Towards a Sustainable Future

ICdA International Cadmium Association

International Cadmium Association

15th Health and Safety committee meeting

Brussels, June 13th, 2017
10:00 -16:00

Agenda

10.00	Welcome and statement of Compliance
10.10	Update on REACh C.Canoo and N.Lombaert
10:40	Coffee break
11:00	Reporting on monitoring of Cd in urine and blood OCdBio-9 M.Gilles
11:30	Reporting on workplace air monitoring OCdAir-4 M.Gilles
12:15	Lunch
13:00	Status of recently started revision of the OEL for cadmium by the EU Commission: are we facing a further reduction of the OEL to 1µg/m³ inhalable? P. de Metz
14:00	What can ICdA and its members do to avoid the setting of an unrealistic OEL? P. de Metz
15:00	Coffee break
15:15	Revision of ICdA (edition 2013) Guidance P. de Metz
15:55	A.o.b.
16:00	End of the 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.

REACH/ Authorisation: Cd and Cd-compounds

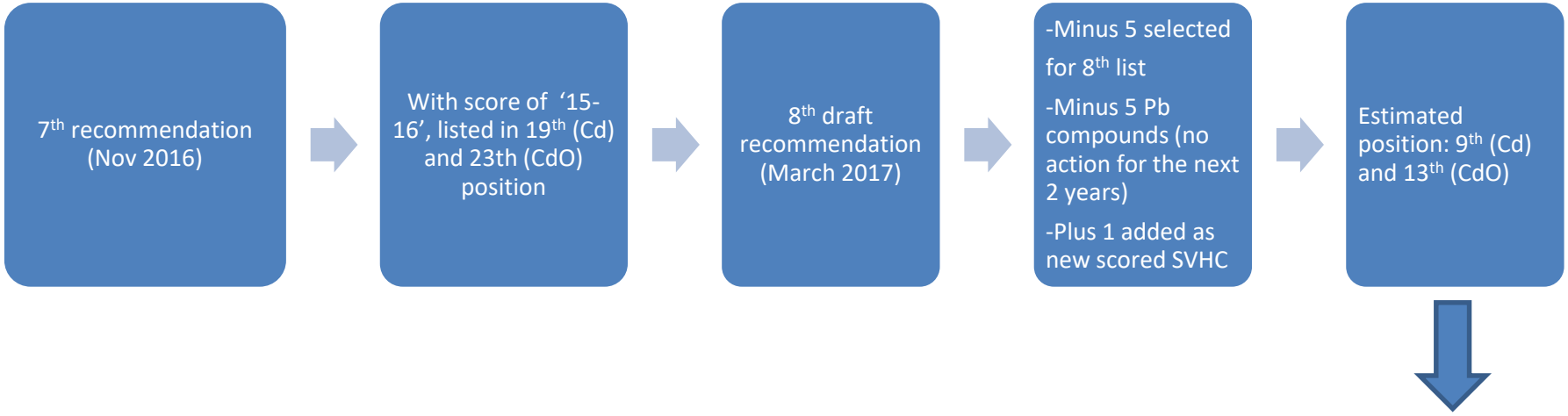
ECHA Recommendations of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation):

- ✓ **7th** recommendation (published 10th Nov 2016):
  - 11 substances listed
  - Cd, CdO, CdS, CdCl2 not included

- ✓ **8th** draft recommendation (published 2nd March 2017):
  - 7 substances listed
  - Cd, CdO, CdS, CdCl2 not included
  - A potential consideration of Cd, CdO and possibly other Cd-compounds by grouping is thus delayed by minimum one year
  - Public consultation ended June 2nd; there was also a parallel call for information by the European Commission on the possible socio-economic consequences of the inclusion of the substances in the Authorisation List

Status on authorisation listing Cd and CdO

Scoring update:



Cd and CdO come in a more borderline position for a recommendation next year(s)

POTENTIAL CANDIDATES for 9 or 10th list

Next steps
(with regard to the 9th recommendation)

Currently foreseen timeline:

- All substances not recommended reassessed for priority at beginning of 2018, taking into account any registration updates done by **end of 2017**
- Discussion on prioritisation results in preparation of the **9th recommendation at MSC-59** (April 2018)
- Discussion on draft 9th recommendation at MSC-60 (June 2018)
- Public consultation: around September 2018
- Submission to the Commission: Summer 2019

Authorisation process starting from Annex XIV inclusion

- ECHA distinguishes 2 ways of submitting a dossier
  1) **Adequate control route**: the risk is adequately controlled during the substance's lifecycle

     → Threshold route

  2) **Socio-economic assessment (SEA) route**: demonstrating that the social and economic advantages outweigh the risks to human health or the environment, which arise from the use of the substance

Threshold/non-threshold carcinogen : Genotoxic effects in workers exposed to low levels of Cadmium (1)

- Aim of the study:
  - ✓ to analyse the shape of the dose-effect relationship for the genotoxic effects of Cd at low doses in occupational settings
  - ✓ to test the hypothesis of a threshold dose for the genotoxic effects of Cd
  - ✓ a secondary hypothesis is that the Cd-U threshold for genotoxic effects is >10 µg/g creatinine, i.e. higher than the current occupational exposure limit (2 µg/g creatinine)

Threshold/non-threshold carcinogen : Genotoxic effects in workers exposed to low levels of Cadmium (2)

Current status study:

- Agreement for volunteering participants in the cadmium industry is finalised (2 sites: similar industrial settings with no confounding exposure; cohort of ~60p)
- a dossier for the university ethical committee is submitted by UCL and approved last February 2017
- In the finalisation of obtaining similar approvals by the two local ethical Committees– 1 local Committee approval received recently, other expected for June 2017
- The goal is to start the blood/urine sampling by September 2017

Coffee break

Cadmium Occupational monitoring

OBSERVATORIES: Monitoring Cd exposure of workers

- OCdBIO-9: results, analysis, conclusions
  - Presentation of reported data from members: CdU, CdB, and post-2000 hires subgroup
  - Conclusions
- OCdAIR-4: results, analysis, discussion
  - Presentation of reported data from members
  - Conclusions
- Way forward

OCdBio

Observatory of Occupational Cadmium Bio-monitoring

OCdBio - Occupational Cadmium Bio-monitoring Observatory

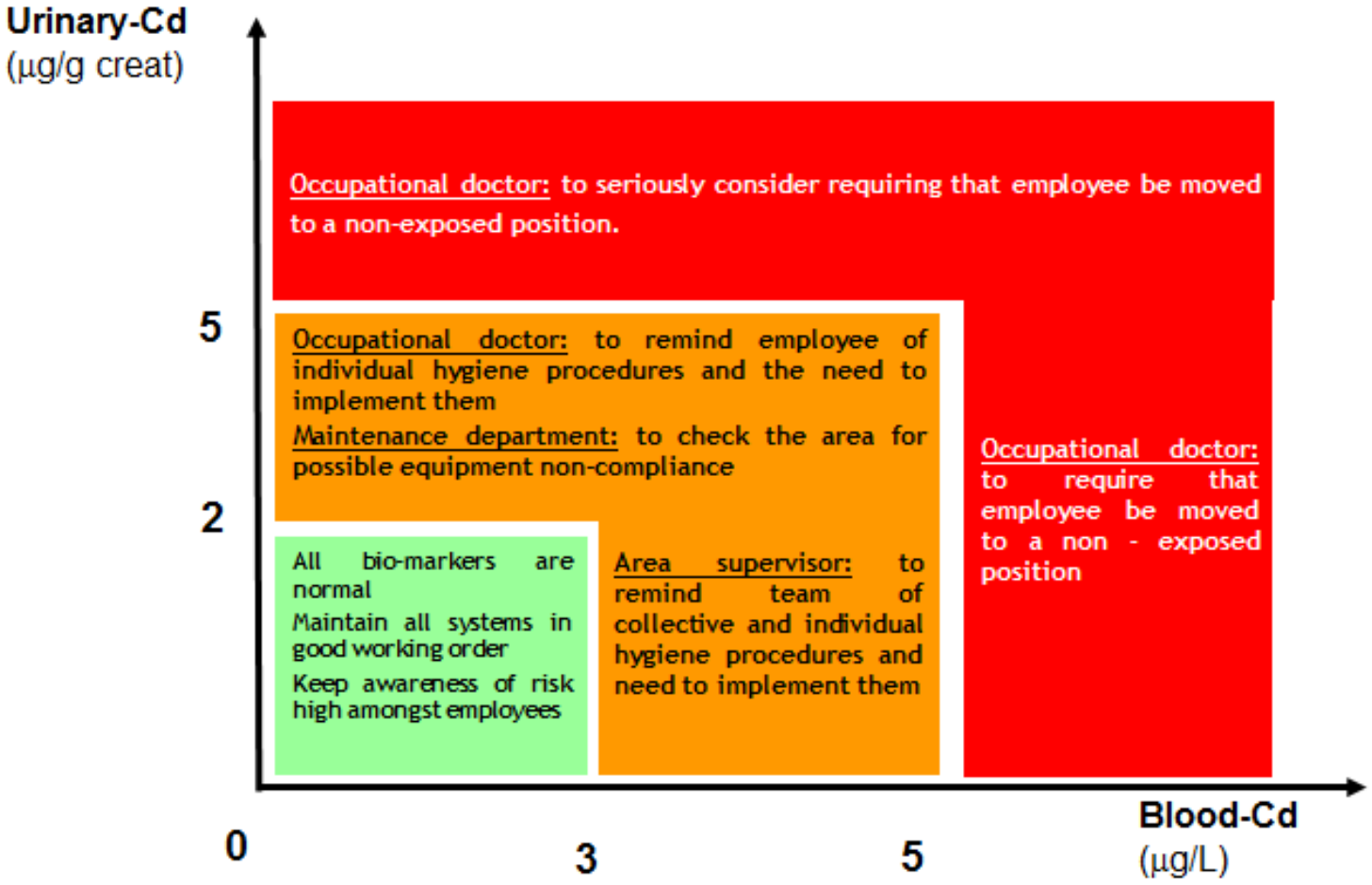
- Since 2008, Cd bio-monitoring data is collected in the Cd industry in order to convince ourselves and authorities on:
  - the efficiency of our risk management program
  - the compliance of the current exposure levels with the OELs
- It is interesting for ICdA members to compare their own data with 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 9 years follow-up!
  - A strong coverage of EU industrial sites for OCdBio-9 (2016 data):
    - 30 EU sites participating
    - 28 sites reporting CdU (3155 workers)
    - 26 sites reporting CdB (2907 workers)

Selected biomarkers of exposure

- Cadmium in blood – CdB:
  - indicator of recent (and older) exposure
  - Measurement: Cadmium in 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
  - Measurement: Cadmium in urine (µg Cd/g creatinine)
  - If study Prof. Van Maele can demonstrate that Cd is threshold carcinogen based on CdU => CdU is indicator to show compliance.

Using “exposure biomarkers” to conduct adequate advanced medical surveillance

(2013 ICdA Guidance)



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

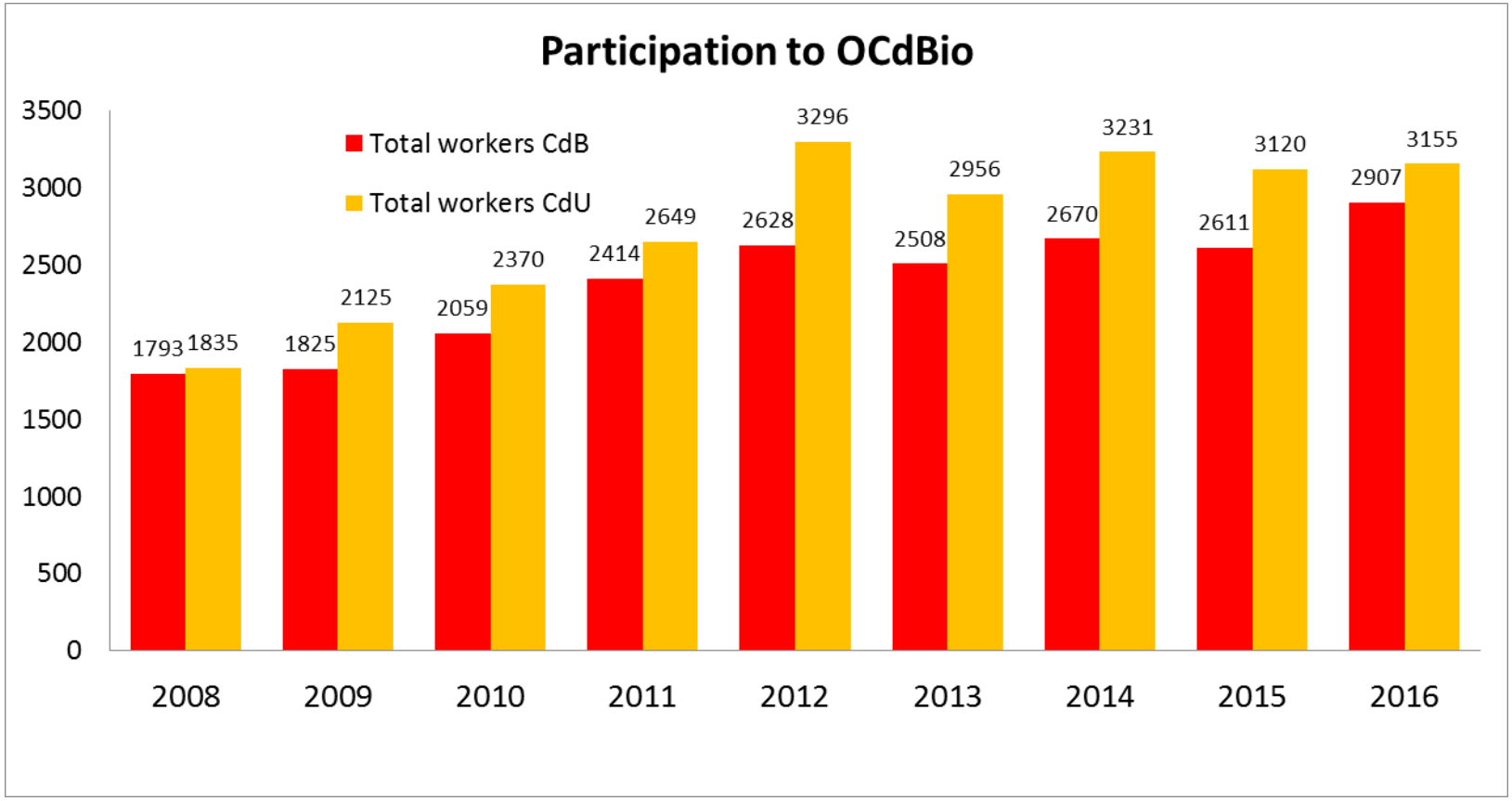
- **How:**
  - Revision and further implementation of ICdA guidance with the goal of further reducing occupational exposure of their employees

- **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.

OCdBio

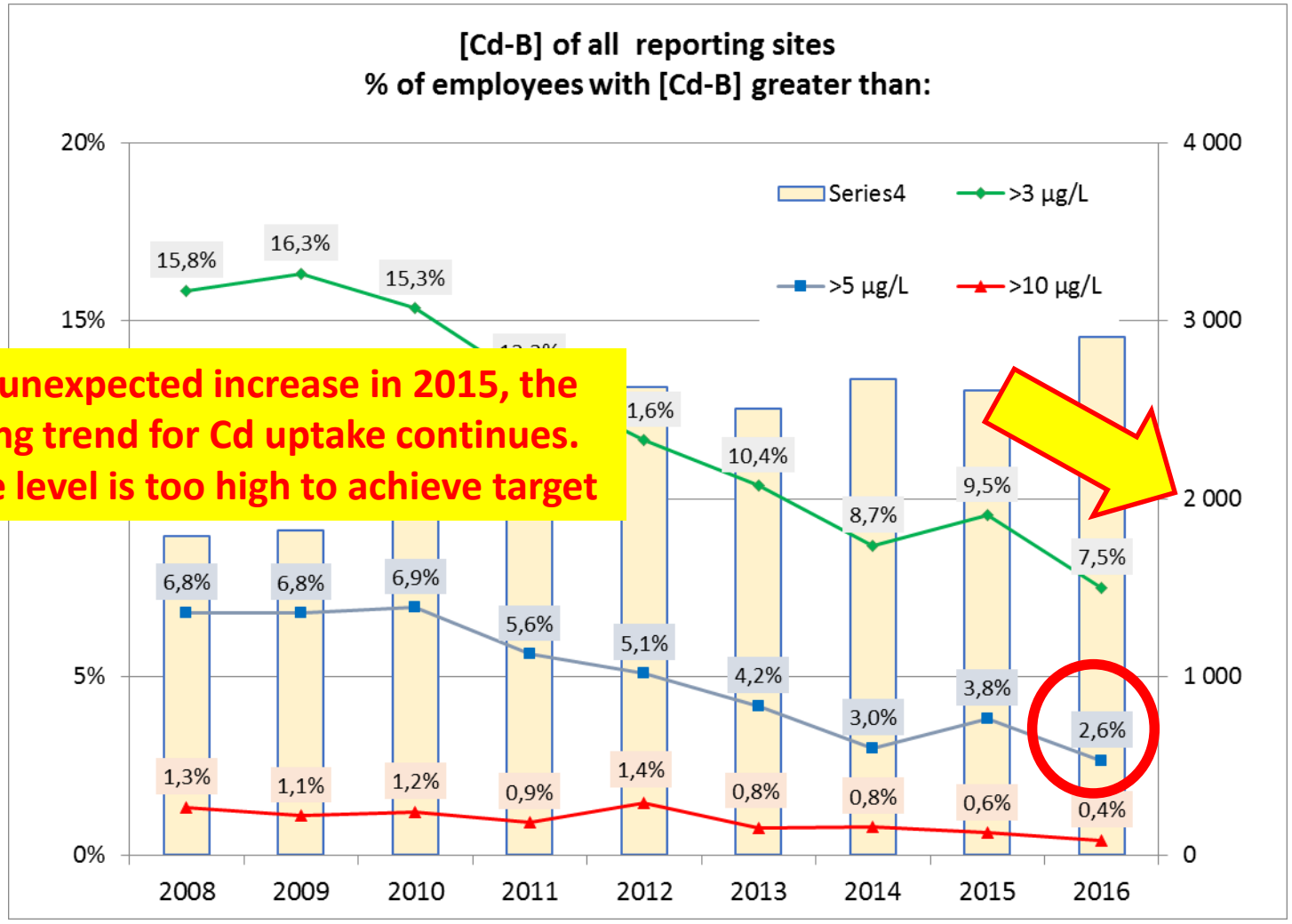
Results of data collection of 2016 monitoring exercise

Number of reported workers



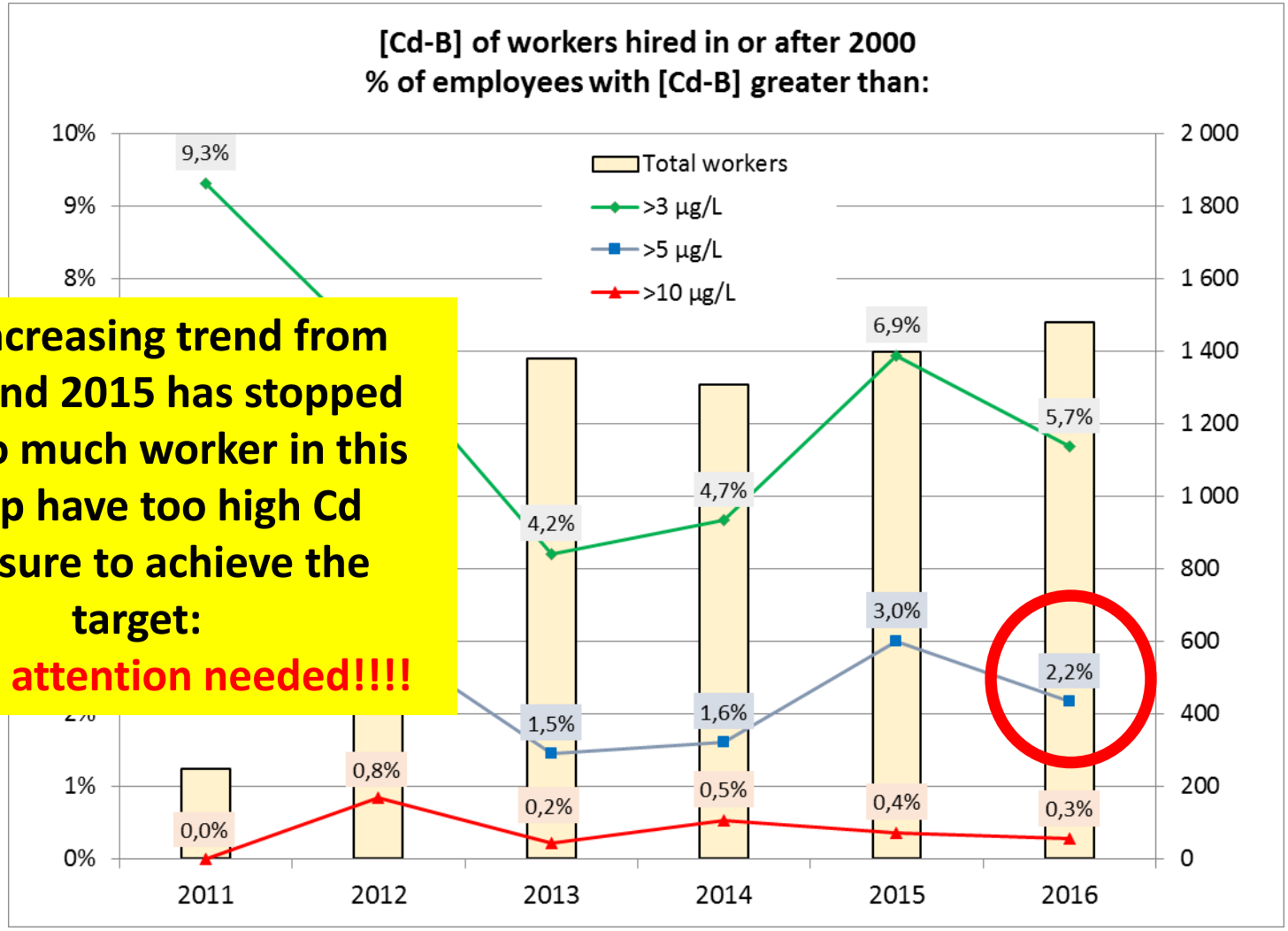
- Response at high and constant level

CdB distribution
- all sites in % -



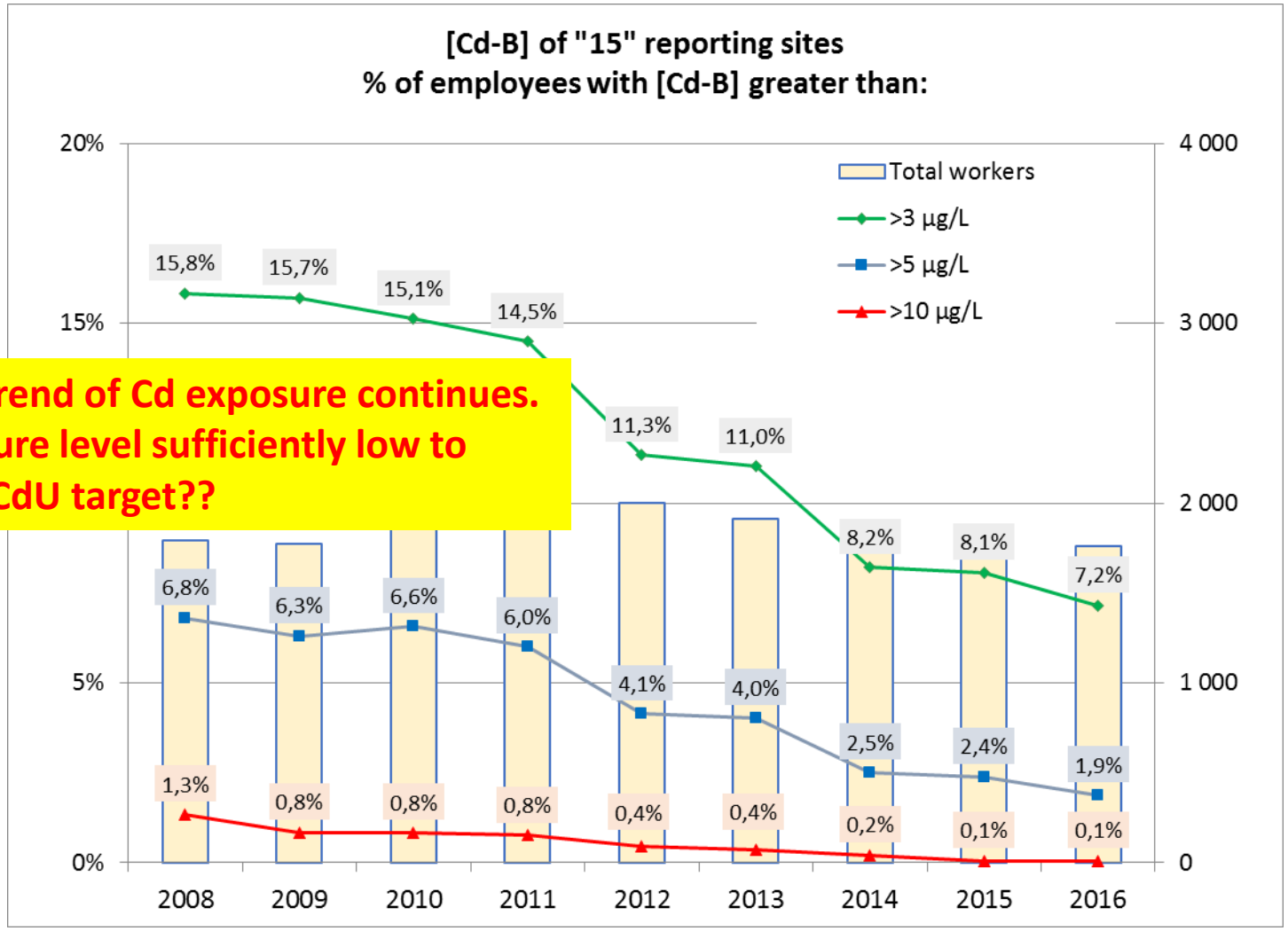
- **After an unexpected increase in 2015, the decreasing trend for Cd uptake continues.**
- **Exposure level is too high to achieve target**

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



The increasing trend from 2014 and 2015 has stopped but too much worker in this group have too high Cd exposure to achieve the target:
further attention needed!!!!

CdB distribution original “15”

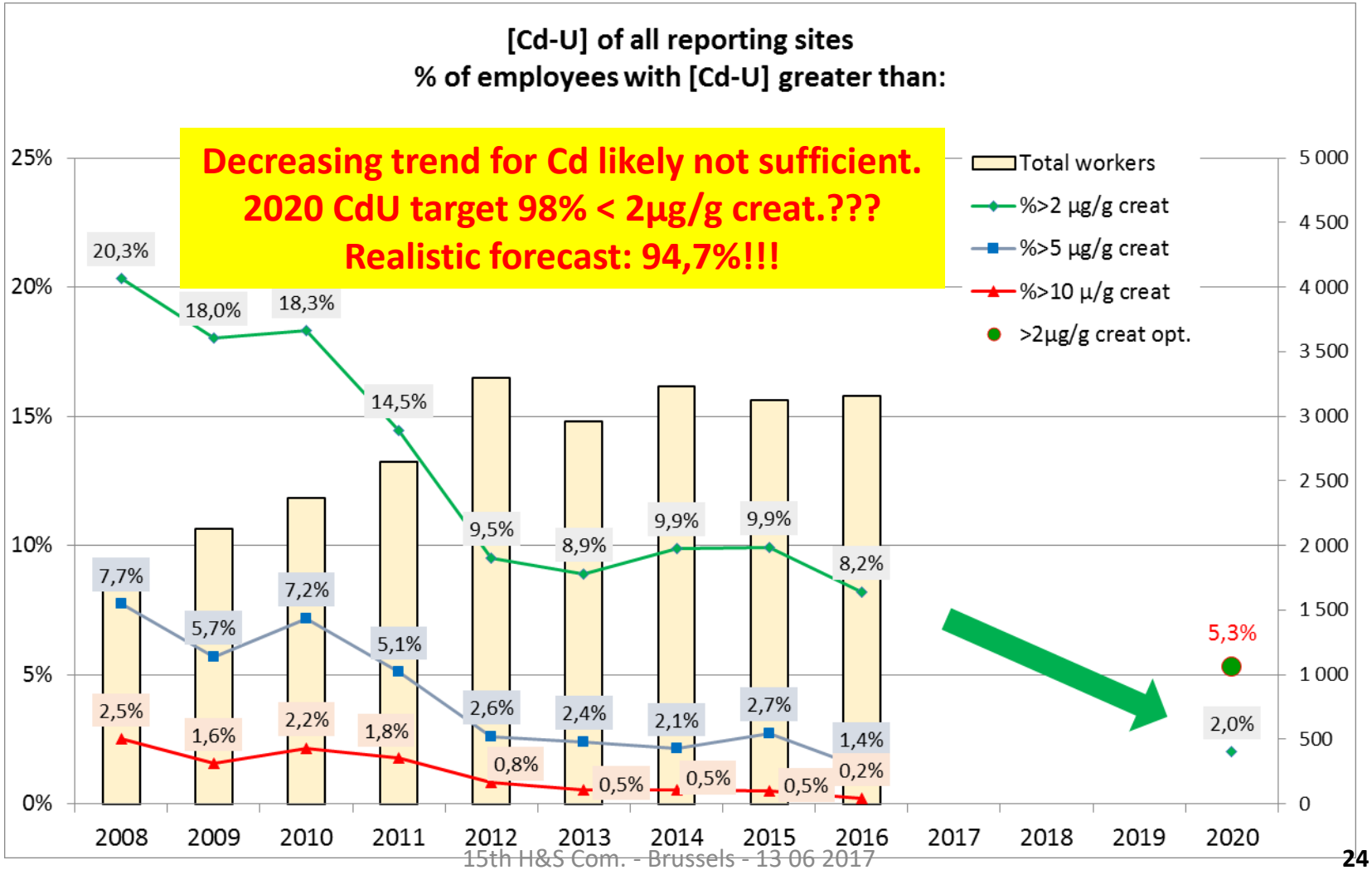


- **Decreasing trend of Cd exposure continues.**
- **Is this exposure level sufficiently low to achieve the CdU target??**

Cd in Blood: conclusion

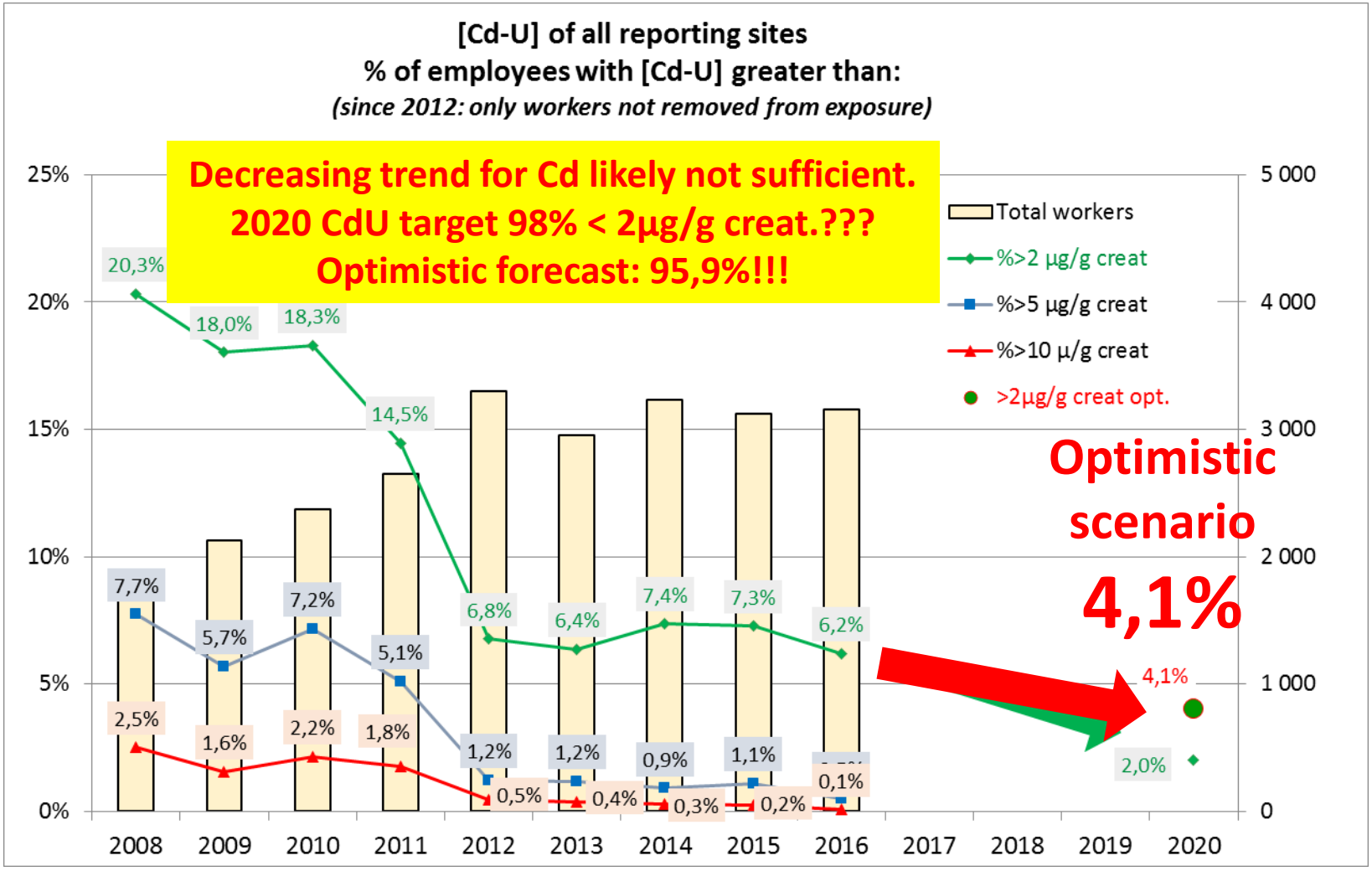
- Good progress was made: Exposure of workers was reduced in 2016
- We are not yet there: still too many workers have too high level of exposure to reach the ambitious 2020 target!!!
- The increasing trend in the group of new hired reversed but exposure level is still too high to achieve the target.
  - Is the actual level of CdB sufficient to reach the CdU target of 98% of workers <2µg Cd/g creatinine???
  - We should strive not to have (>1%) workers >5 µg Cd/L in blood
- Continued attention is required

CdU distribution
- all sites in % -



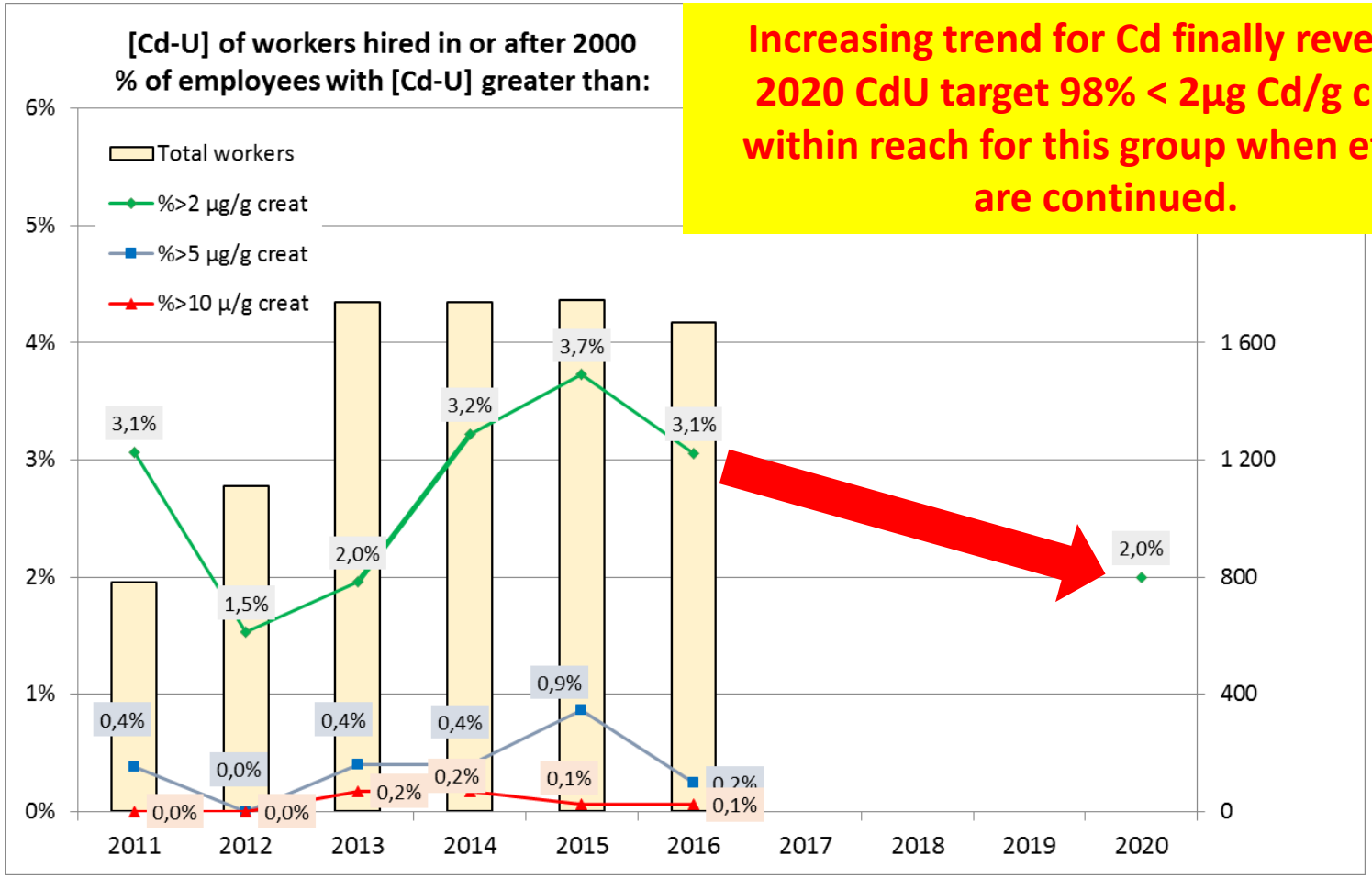
CdU distribution

- all sites in % - (removed workers excluded)



CdU distribution

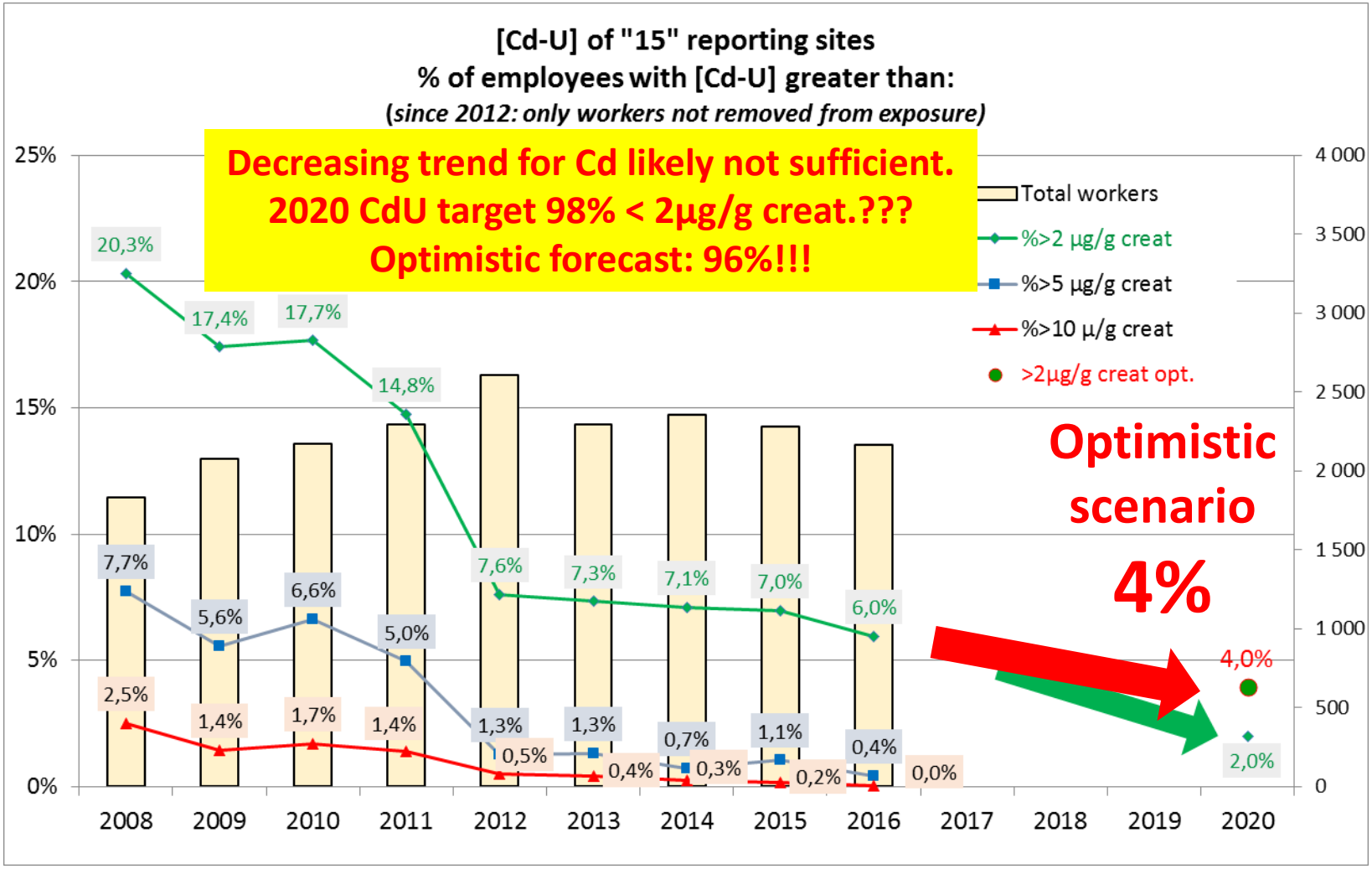
- all sites in % - workers hired after 2000



Increasing trend for Cd finally reversed. 2020 CdU target 98% < 2µg Cd/g creat. within reach for this group when efforts are continued.

CdU distribution

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



Conclusion CdU: 2020 target

- 2017 CdU target 95% workers < 2µg Cd/g creat.
  - We are very close to achieve this target
- 2020 CdU target 98% workers < 2µg Cd/g creat.
  - will not be achieved for the total population
  - Is within reach for the subgroup of workers hired after 2000
- The optimistic forecast indicates we could reach a value of 95,9% below the target value 2µg Cd/g creat. by 2020. (remember: we come from 79,7% in 2008)
- Positive elements:
  - Effect of reduced exposure as reflected by lower CdB values translates in a reduction of CdU values
  - 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 the workplace is recommended for workers with CdU > 5µg/g creat.
  - Historic Cadmium burden of some workers is still too high to bring them below 2µg Cd/g creat. by 2020.

Conclusion

- CdB
  - exposure to Cd is back under control.
  - Over the past 9 years, our industry has consistently improved the workplace exposure of its workers.
  - Plants should aim not to have workers with CdB > 3µg/L in order to achieve the CdU target of 98% < 2µg/g in 2020.

  The following question is raised: should we lower the second action level for CdB (from 5 µg/L to 4 µg/L) of the 2013 ICdA Guidance?

- CdU:
  - Situation improved in 2016
  - The 2017 target is within reach if efforts are continued
  - For the subgroup of new hired worker, the 2020 target is within reach.
  - For the total group, the ambitious 2020 target will be missed
  - Coming from 79,7% of all workers above 2µg/g creat. in 2008, our sector has shown already excellent progress.

OCdAIR-4

Occupational Cadmium Air-monitoring Observatory

OCdAir

- Personal air sampling at the workplace
  - Fourth year of data collection
  - Decline in response
  - plant participation of in this observatory is still too low, what can we do to improve this, we suggest a dedicated workshop…?

	2013	2014	2015	2016
Plants	12	22	20	16
SEGs	67	142	131	124
Workers	994	1548	1369	1278

- Sampling procedure needs refining
  - Often too little samples per SEG: representativeness for SEG questionable
  - All measures should be of respirable fraction
  - Correction for Personal Protection Equipment during sampling

OCdAir

- ICdA guidance: Air quality should be under control to assure < 4µg Cd/m³ **respirable** air, always and for all workers
- Ongoing discussions to set a OEL for cadmium.
- In it's recent 2017 opinion, SCOEL proposes 1µg/m³ inhalable. (= +/- 0,25µg/m³ respirable)

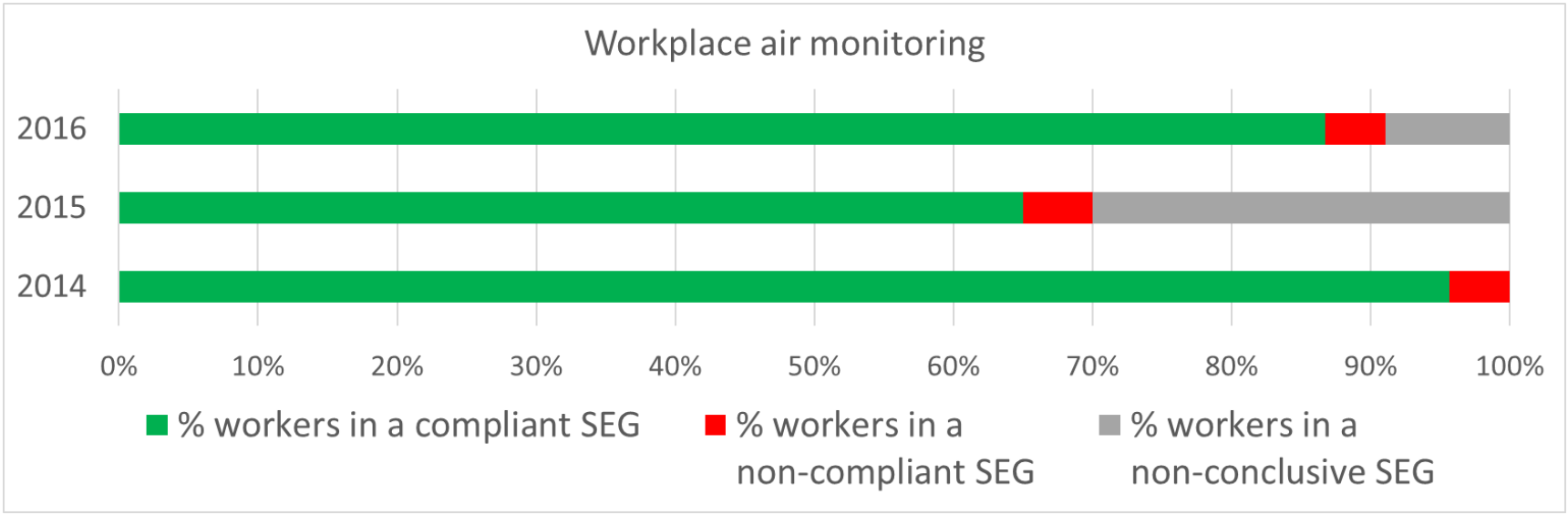
OCdAir Reporting: Geometric mean

	- OCd-AIR 2-		- OCd-AIR 3-		- OCd-AIR 4-	
	2014	2014	2015	2015	2016	2016
Range [µg/m³]	number of SEGs in this range	Number of workers	number of SEGs in this range	Number of workers	number of SEGs in this range	Number of workers
0 to 1.0	94	1148	38	753	75	915
1.1 to 2.0	26	241	10	88	22	167
2.1 to 3.0	5	35	3	40	6	22
3.1 to 4.0	8	57	1	9	1	4
4.1 to 5.0	3	18				
5.1 to 7.0	2	38	1	29	3	21
7.1 to 10.0	1	5	1	4	4	33
>10.1	3	6				
other non-compliant			7	35	1	2
non-conclusive			70	411	12	114
Total number	142	1548	131	1369	124	1278

"non-conclusive" was added in 2015 for not lognormal distribution of SEG or insufficient samples

OCdAir Reporting: Summary geo-mean

	- OCd-AIR 2-	- OCd-AIR 3-	- OCd-AIR 4-
	2014	**2015**	**2016**
% workers in a compliant SEG	96%	65%	87%
% workers in a **non-compliant** SEG	4,3%	5,0%	4,4%
% workers in a **non-conclusive** SEG	0%	30%	9%
workers above 0,25 µg/m³			64%

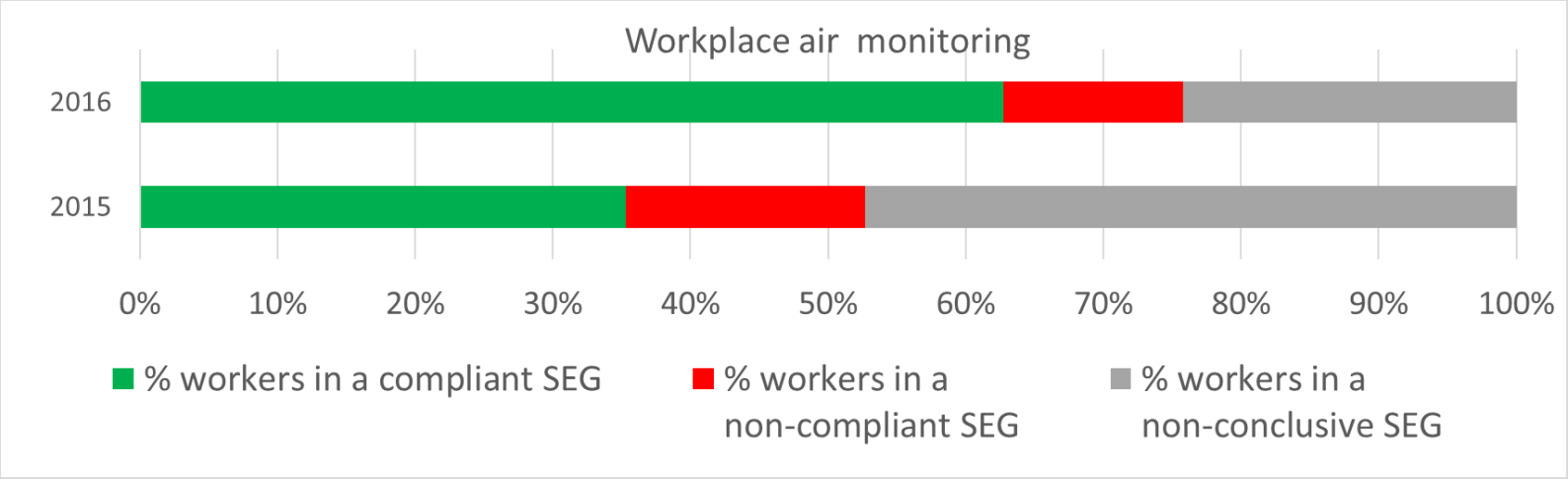


OCdAir Reporting: 90 percentile

	- OCd-AIR 3-		- OCd-AIR 4-	
	2015		2016	
Range [µg/m³]	number of SEGs in this range	Number of workers	number of SEGs in this range	Number of workers
0 to 1.0	13	267	36	269
1.1 to 2.0	9	147	18	369
2.1 to 3.0	5	21	15	116
3.1 to 4.0	4	48	7	48
4.1 to 5.0	2	8	7	54
5.1 to 7.0	2	21	3	46
7.1 to 10.0	2	49	3	19
>10.1	6	143	7	48
other non-compliant	5	17		
non-conclusive	83	648	28	309
Total number	131	1369	124	1278

OCdAir Reporting: 90 percentile

	- OCd-AIR 3-	- OCd-AIR 4-
	2015	**2016**
% workers in a compliant SEG	35%	63%
% workers in a **non-compliant** SEG	17%	13%
% workers in a **non-conclusive** SEG	47%	24%
workers above 0,25 µg/m³		89%



Cd in Air monitoring: Conclusion

- OEL at 4µg/m³ respirable: ICdA guidance – SCOEL 2010
  - Geometric mean: 4,4 % non-compliant
  - 90 percentile: 13,1 % non-compliant

- OEL at 1µg/m³ inhalable (= 0,25 µg/m³ respirable): new SCOEL opinion
  - Geometric mean: 63,8 % non-compliant
  - 90 percentile: 89,3 % non-compliant

- ICdA target for limit values
  - OEL: push for 2010 SCOEL opinion at 4 µg Cd/m³ (in combination with bio-monitoring?)
  - For long term chronic effects: geometric mean is defendable (cumulated effect over 40y)

- Combined observatory data substantiates (but would be even stronger with higher plant participation) that compliance with 4µg/m3 respirable leads to CdU
  - being maintained below 2 µg/g creat for new employees
  - being brought down progressively down below 2µg/g creat for all employees,

  therefore ensuring compliance with 2010 SCOEL recommendation (confirmed by SCOEL in 2017 as ensuring good worker protection)".

Lunch time

Status of recently started EU COM process of setting an OEL for cadmium and compounds

Are we facing the prospect of a binding OEL of **1µg/m³ inhalable**?

P. de Metz

EU cadmium exposure limits

Situation as of end of 2016 (1)

- **Recommendation from the Scientific Committee on Occupational Exposure Limits for cadmium and its inorganic compounds**
  SCOEL/SUM/136
  February 2010

- 8 hour TWA : 0.004 mg/m³ (respirable fraction)
  STEL (15 min) : -
  Notation : -
  BLV : 2 µg Cd/g creatinine
  SCOEL carcinogen group : C *(genotoxic carcinogen for which a practical threshold is supported and a health –based OEL is proposed)*

- These values (OEL and BLV) are taken forward in the ICdA 2013 Guidance

EU cadmium exposure limits

Situation as of end of 2016 (1)

- **2µg/g creat (CdU):** protective against systemic effect of Cd exposure (kidney, bone)

- **4µg/m3 (respirable) :** protective against local respiratory effects of Cd exposure

- experimental studies have reported the induction of tumours in rats exposed to low concentrations of Cd (12.5 µg/m³).
- in humans, no sufficiently valid epidemiological data exist to perform a working-life risk assessment for the cancer risk when exposure is to Cd alone. When an increased risk was observed, co-exposures did appear to play a central role
- the mechanism of the carcinogenic activity of Cd is not exactly known, but involves, at least in part, genotoxic events mediated by indirect mechanisms for which a threshold can be identified (Category C, Bolt and Huici-Montagud, 2008)
- a threshold of 1000 µg/m³x years (or 25 µg/m³ during 40 years) has been reported for genotoxic effects in workers exposed to Cd by inhalation
- there is also some epidemiological evidence that Cd does not seem to induce an excess of lung cancers at exposure levels sufficient to cause renal and respiratory toxicity (Sorahan and Esmen, 2004).

Human data have shown that changes in residual volume of the lung occur for a cumulative exposure to CdO fumes of 500 µg Cd/m³*years, corresponding to 40 years exposure at a level of 12.5 µg Cd/m³ (LOAEL). Applying a default extrapolation factor of 3 (LOAEL to NOAEL,Leung, 2002) leads to a value of 4 µg Cd/m³.

An OEL of 4 µg/m³ (respirable fraction), based on non-cancer respiratory effects, is therefore recommended to protect workers against local respiratory effects of Cd exposure.

EU cadmium exposure limits

DG EMPLOY program as of 10/01/2017

EUROPEAN COMMISSION

Brussels, 10.1.2017
COM(2017) 12 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy

{SWD(2017) 9 final}
{SWD(2017) 10 final}

ANNEX 1

List of occupational safety and health actions

Action		Actors	By when
Fighting occupational cancer and dealing with dangerous chemicals			
1	Second amendment of the Carcinogens Directive	European Commission	Early 2017
2	Third amendment of the Carcinogens Directive	European Commission	Early 2018
3	Fourth list of indicative limit values in the Chemical Agents directive	European Commission	Early 2017
4	Database on occupational exposure for some hazardous chemicals	European Commission	Early 2017
5	Healthy Workplaces Campaign on dangerous substances	European Agency for Safety and Health at Work	2018-2019

Legislation to improve protection against dangerous and fight occupational cancer

- Second amendment of the Carcinogens and Mutagens Directive
- Subsequent amendments of the Carcinogens and Mutagens Directive are foreseen concerning substances such as formaldehyde, beryllium, cadmium, chromium VI compounds and nickel compounds. Work has started with a view to presenting a new Commission proposal envisaged for early 2018
- In parallel, work will continue on enhancing the relevance and effectiveness of the Chemical Agents Directive by revising existing and establishing further occupational (indicative) exposure limit values and biological limit values in 2017 and 2018.

EU cadmium exposure limits

New SCOEL Opinion of 08/02/2017

SCOEL/OPIN/336
Cadmium and its
inorganic compounds

Opinion from
Scientific Committee on Occupa

An 8h-TWA (8h time-weighted average) of 4 µg/m³ (respirable fraction), based on non-cancer respiratory effects, can therefore be considered as being protective for workers against local respiratory effects of Cd exposure. Such a 8h-TWA value of 4 µg Cd/m^3 (as derived by SCOEL in 2010) must be seen in close conjunction with the derived BLV, as both refer to and are protective for different toxicity endpoints of relevance (local and systemic). Thus, implementation of both elements of the OEL- TWA and BLV- are of critical importance.

However, an isolated OEL (8-h TWA) of 4 µg/m^3 (not linked with a BLV) would not appear being equally protective against the systemic nephrotoxixity of Cd. Evaluations by both WHO (2000) and the German AGS (*Ausschuß für Gefahrstoffe*; BAuA 2014) of published data (primarily by Thun et al 1991) have pointed, for nephrotoxicity, to a cumulative (life-time) lowest-effect exposure of 100-400 µg/m^3 x years. For working-life exposure of 40 years, this equals an LOAEC range of 2.5 – 10 µg/m^3. AGS (BAuA 2014) has deduced that nephrotoxic effects could arise in about 1% of the workforce after 40 years of airborne exposure to 4 µg Cd/m^3. Accordingly, an OEL (8h-TWA, not connected with biological monitoring) for Cd and its inorganic compounds should be 1 µg/m^3.

In this case, an **OEL (8h TWA) of 1 µg Cd/m^3 (inhalable fraction)** can be proposed.

This value of 1µg/m3 is NOT to protect local (lung cancer) BUT for systemic (kidney…) effects!

EU cadmium exposure limits

WPC (Working Party on Chemicals) compromise approved in ACSH (Advisory Ctee on Safety and Health at work)

TWO APPROACHES:

- **Approach ONE:** based on new SCOEL opinion
- **Approach TWO:** based on old SCOEL recommendation

Two approaches were agreed by all three interest groups;

Approach one:

1 µg/m^3 (inhalable fraction, 8h TWA), with a transition period of 7 years (to end no later than 2027) at 4 µg/m^3 (inhalable fraction, 8h TWA).

Approach two:

To combine an airborne OEL with the biological monitoring value proposed by SCOEL which could be used as a mean of demonstrating control of workers' exposure in those Member States where biomonitoring is carried out. This would be based on complying with both the SCOEL biomonitoring value of 2 µg Cd/g creatinine in urine and the 8 hour TWA of 4 µg/m^3 as recommended by SCOEL/ OPIN/336 (page 10 paragraph 2, adopted 8th of February 2017).

The ACSH agrees that both approaches present adequate technical means of protecting workers' health. The ACSH requests the Commission to investigate whether the combined biomonitoring and TWA OEL approach could be included in the CMD as a directly related provision in accordance with CMD Article 16.

The ACSH strongly recommends the Commission to adopt as soon as possible binding occupational exposure limit value for this substance under Directive 2004/37/EC.

EU cadmium exposure limits

Is approach ONE feasible?

1. Current air quality levels as demonstrated by OCdAIR-4

2. Discussions with experts
   - Example of French OEL on Cr VI
   - Went from 50µg/m3 (indicative) to 1µg/m3 (binding)!

3. Your view?

What can ICdA and its members do to avoid the setting of an unrealistic OEL?

P. de Metz

EU cadmium exposure limit

Next step: Commission impact assessment

EUROPEAN COMMISSION

DIRECTORATE-GENERAL

Directorate Employment, Social Affairs & Inclusion
Unit B.3

CALL FOR TENDERS

N° VT/2017/005

STUDY ON

Collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

2.4. Substances subject to the contract

The following substances are subject to the contract:

- Cadmium and inorganic compounds as far as under the scope of the CMD
- Beryllium and inorganic compounds as far as under the scope of the CMD
- Arsenic acid and its salts as far as under the scope of the CMD
- Formaldehyde, CAS No 50-00-0
- Chromium (VI) compounds as far as under the scope of the CMD (under the condition that the value currently proposed by the Commission is not reduced significantly, e.g. by an order of magnitude, during Council and EP negotiations)
- 4,4'-Methylene-bis(2-chloroaniline) (MOCA), CAS No 101-14-4

EU cadmium exposure limit

Impact assessment - Baseline scenario

- **Task 2:** supply an overview of:
  - Carcinogenicity and mutagenicity information, supplemented by an overview of other occupational diseases
  - Existing OELs and their nature in the EU and in the main economic competitors
  - Risk management measures in place to comply with CMD requirements to minimize exposure
  - Voluntary industry initiatives to reduce exposure
  - Available standard monitoring methodologies/tools used
  - Assessment of the existence of intermediate (as defined by REACH) uses
  - Example of best practice following hierarchy of measures to comply with specified OELs
  - Market analysis (number of firms, typical size), main economic sectors
  - Estimation of number of workers exposed and exposure levels
  - Estimate how many cancer cases and deaths are currently due to past exposure
  - Determine how the situation is likely to evolve if no OELs are established

EU cadmium exposure limit

Impact assessment – Assessing the **costs** of different scenarios

- **Task 3:** identify and assess costs associated with several scenarios:
  - Enterprises:
    - Substantive compliance costs (CAPEX and OPEX)
    - Administrative costs
    - Indirect costs (passed on to companies through the price of inputs)
    - Particular emphasis on SMEs
    - Identification of sectors that are expected to incur significant costs, allowing for the analysis of the impact on sectoral competitiveness
  - Administration/government
    - Administrative burden and other costs for EU MS with surveillance and enforcement of existing OELs and costs due to changes of OELs

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Impact assessment – Assessing the **benefits** of different scenarios

- **Task 4:** identify and assess benefits associated with several scenarios:
  - Workers and families
    - Avoided cancer cases and other adverse effects
    - Moral pain and suffering
    - Loss of present and future income
    - Avoided private and indirect medical and rehab costs
    - …
  - Employers:
    - Higher labor productivity
    - Reduced administrative and legal costs
    - Reduction in sick payments
    - …
  - Administration/government:
    - Savings on social protection expenditure
    - Savings in state benefits
    - Avoided tax revenue loss
    - Avoided administrative and legal costs

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Impact assessment – **Cost/benefit** analysis

- **Task 8:** cost-benefit analysis and cost effectiveness analysis
  - **Changes should be assessed relative to the baseline scenario** (cancer cases and DALY: Disability Adjusted Life Years)
  - A continuous model for the assessment of the costs and benefits is preferred
  - Determining whether the relationship is linear of exponential
  - In which proportion costs and benefit change as a result of incremental change to the OEL value

- **Scenarios:**
  - 1 - Baseline: no new measures at EU level
  - 2: EU OEL at the level of the maximum MS limit value
  - 3: EU OEL at the level of the minimum MS limit value
  - 4: EU OEL at the median or the mean of MS OELs
  - 5: EU OEL set at the relevant SCOEL scientific assessment

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Cost/benefit analysis

BENEFITS:

- Reduced occurrence of high proteinuria (vs baseline)
  Multiplied by unit cost (unknown at this time)

- Reduced occurrence of lung cancer (vs baseline)
  Multiplied by unit cost (estimated 3M€/occurrence)

COSTS:

- CAPEX
- OPEX

EXAMPLE	BENEFITS	COSTS	CONCLUSION
Scenario 1	Description of baseline situation		
Scenario 2	5 M€	2 M€	Possible for industry!
Scenario 3	8 M€	5 M€	Recommended!
Scenario 4	10 M€	10 M€	Unclear
Scenario 5	11 M€	20 M€	Advised against!

EU cadmium exposure limit

Cost/benefit analysis – Scope of issue

- How many workers need to be protected? The ICdA response:
  - "3200 workers are under biomonitoring and are reported to OCdBIO, this represents 90% of exposed workers in the EU"
  - We recognize the Cd surface treatment industry is not participating!
  - However, only 16 plants and 1300 workers are reported in OCdAIR

- Typical consultant analysis:
  - Based on past impact assessments: OSHA data could be used :https://www.osha.gov/SLTC/cadmium/
  - Who is exposed to cadmium?

    OSHA estimates that 300,000 workers are exposed to cadmium in the United States. Worker exposure to cadmium can occur in all industry sectors but mostly in manufacturing and construction. Workers may be exposed during smelting and refining of metals, and manufacturing batteries, plastics, coatings, and solar panels. The expanding Ni-Cd battery recycling industry is a concern for cadmium exposure. Electroplating, metal machining, welding and painting are operations associated with cadmium exposure. Workers involved in landfill operations, the recycling of electronic parts, or the recycling of plastics may be exposed to cadmium. Compost workers and waste collectors are also potentially exposed to dust which may contain cadmium. The incineration of municipal waste is another source of cadmium exposure.
  - Data supplied through "open government" show US exposure is very low or nil

- Need:
  - to gather data on Cd exposure in these plants (air value or biomonitoring values)
  - To assess size of workforce in surface treatment exposed to cadmium

EU cadmium exposure limit

Cost/benefit analysis: ELEVATED PROTEINURIA

- We need to demonstrate occurrence is controlled

- Method 1: show 'quasi-compliance' with the 2010 SCOEL recommendation: **CdU<2**
  - Industry guidance in place since 2006, industry target is to reach 98% below 2
  - Number of workers above 2µg/g creat shows a well established decreasing trend
  - Down to 259, from a high of 434 in 2010
  - 259 represents 8.2% (from a high of 20.3%), of which 215 are between 2 and 5µg/g creat

- Method 2: challenge (somewhat) the 2010 SCOEL recommendation (use Chaumont et al. 2010):
  - BMDL5 (Beta2M) = 3.0 => No increase of occurrence of elevated proteinuria if CdU below 3
  - Only 121 workers (3.8%) have CdU>3 (v. 260 in 2008)

- But: if consultant retains the 2017 SCOEL Opinion: **1 µg/m3 inhalable**:
  - Industry is clearly far above this limit, however there is no indication of high occurrence elevated proteinuria (show data recorded in Chaumont study)
  - Conversely, what would the costs be to place industry in full compliance with 1 µg/m3 inhalable?

EU cadmium exposure limit

Cost/benefit analysis: LUNG CANCER

- Cost of cancer is approx 3M€/occurrence

- Method: show 'quasi-compliance' with SCOEL 2010 recommendation: **CdAIR < 4µg/m3 (respirable)**
  - Industry guidance in place since 2010, industry target is full compliance
  - Current status is 63% in strict compliance + 24% in soft compliance = 87%
  - However OCdAIR only covers 16 facilities and 1300 workers
  - Need to drastically expand coverage of OCdAIR-5 is critical

- But: if consultant retains AGS/BAUA dose-response relationship: **toleranz-risiko 4/1000: 1.6µg/m3 (respirable)**
  - This would be problematic: industry coverage is weak AND we are only striving for 3 times that value (3*1.6 = 4.8)
  - Reported exposure occurrence is approx. 5
  - We need to develop costs to get to different air quality targets so as to be able to answer the consultant on the cost side of his work
  - Suggested targets:
    - Our current ICdA guidance target: compliance with 4 µg/m3 respirable (using the 90th percentile methodology)
    - Reaching compliance with the German toleranz risiko level of 1.6 µg/m3 respirable (using the 90th percentile …
    - Consideration of the economical/technical feasability of going below 1.6

EU cadmium exposure limit

Industry response to upcoming impact assessment

8th October

- **Gather OELs/BLVs in place in main competing countries:**
  - USA
  - Japan, South Korea, and China
  - Others …?

- **Generate (third party?) costs estimates to place your plant in compliance with:**
  - **4.0 µg/m3 respirable** which is the ICdA Guidance level and the mandatory REACH DNEL
  - **1.6 µg/m3 respirable** required if the German approach is retained for cancer occurrence assessment modelling (quite likely to be raised)
  - Your view regarding the feasibility of reaching **1.0 inhalable** (broadly eq. to 0.25 µg/m3 respirable)
  - We need to cover the following sectors: **Cd production** - **Specialty compounds manuf** - **PV panels** - **Batteries manufacturing** - **Connectors manufacturing** - **Pigments manufacturing** - **Cd waste recycling**

- **Enhance coverage of OCdAIR-5 and deliver data for October 8th, 2017 (data of 2017!)**
  - Only 16 plants and 1300 workers (vs 28 plants and 3200 workers for CdU)
  - Compliance with 4µg/m3 is not great: 63% (+24%) with 90th percentile methodology!

- **Generate OCdBIO-10 by October 8th, 2017**
  - Purpose is to show further progress is made => reduction of workforce with CdU>2

Discussion

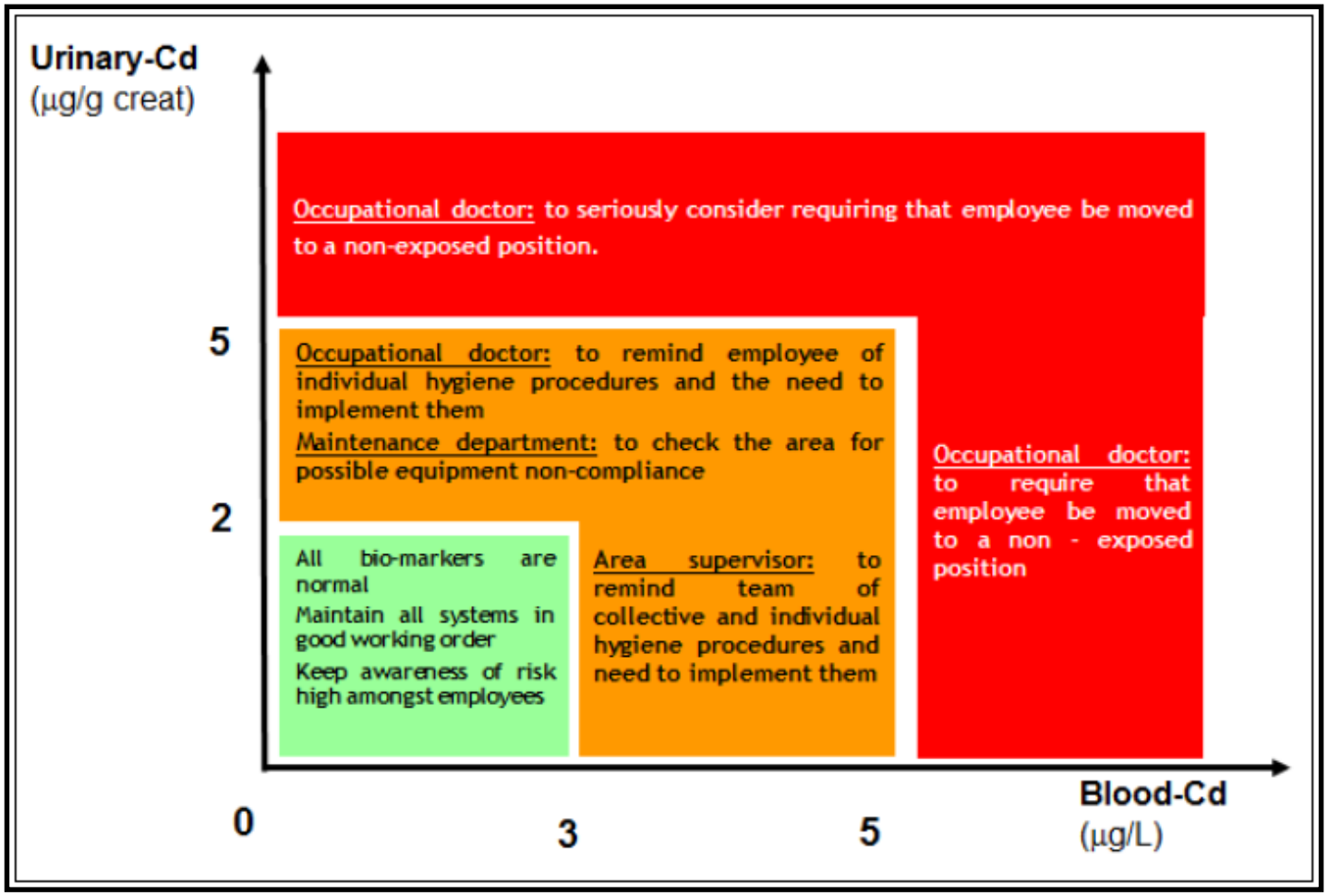
review of the ICdA Guidance document

Situation good but not excellent

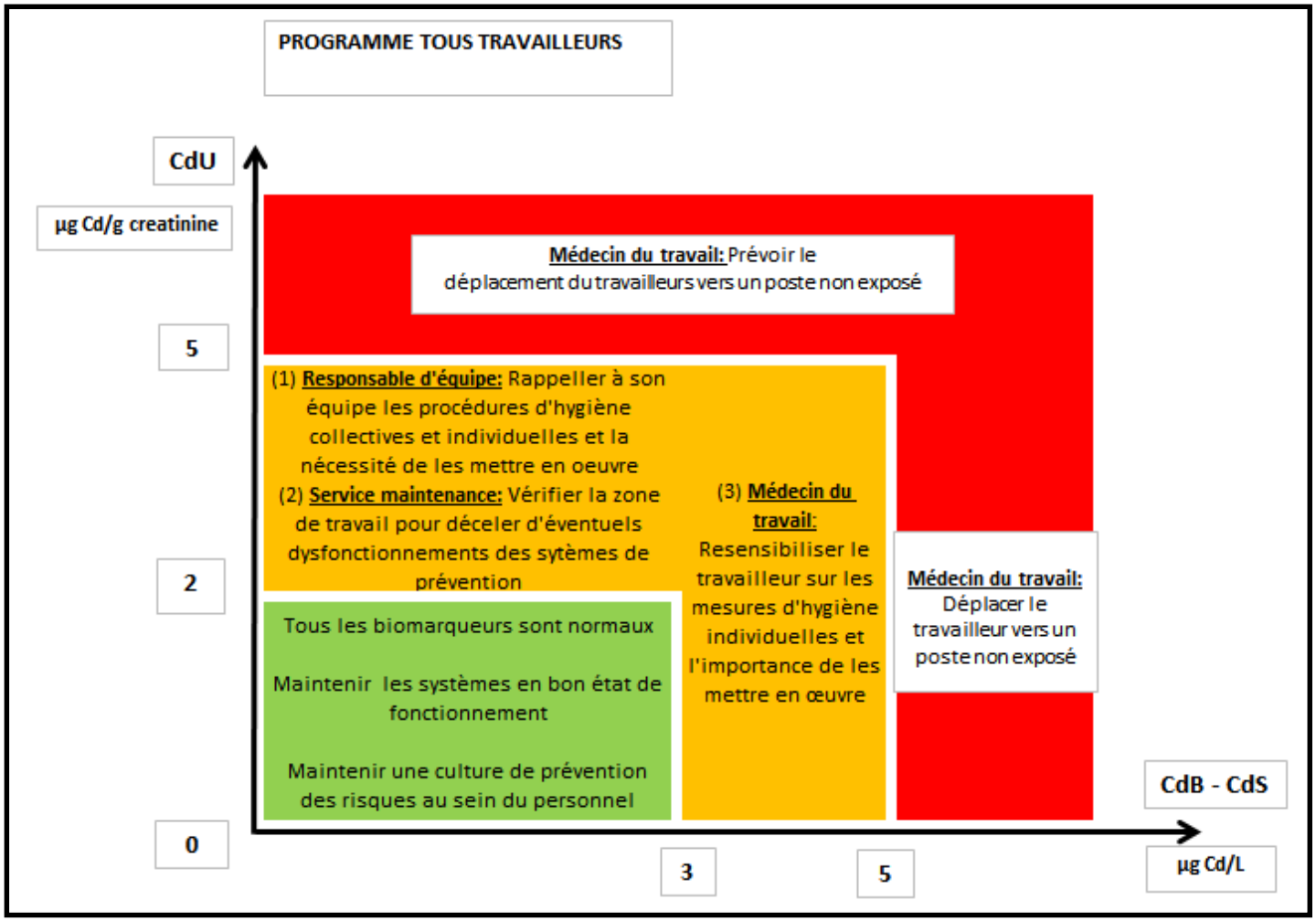
- OCdAIR shows:
  - Reporting is not as extensive as OCdBIO
  - Compliance with DNEL is weak
  - Action: promote reporting tool

- OCdBIO shows:
  - Progress has been steady
  - Progress will be slower
  - Progress could stall
  - Action: assess ICdA guidance for fitness

ICdA guidance document (2013) decision diagram_English



ICdA guidance document (2013) decision diagram_French



Industry Goal

- **2017:**
  - Minimum 95% of exposed workers under biomonitoring comply with CdU <2µg/g creat
- **2020:**
  - Minimum 98% of exposed workers under biomonitoring comply with CdU <2µg/g creat
- **Issue:**
  - Fully adequate protection of recently hired workers (2000 and after) is questionable, as elevated CdU fraction for this population is above 2%

Possible ways forward

- **Introduce an enhanced program**
  - Focused on the main “action biomarker”: CdB
  - Do not change action levels of CdU, this is more of a “result biomarker”

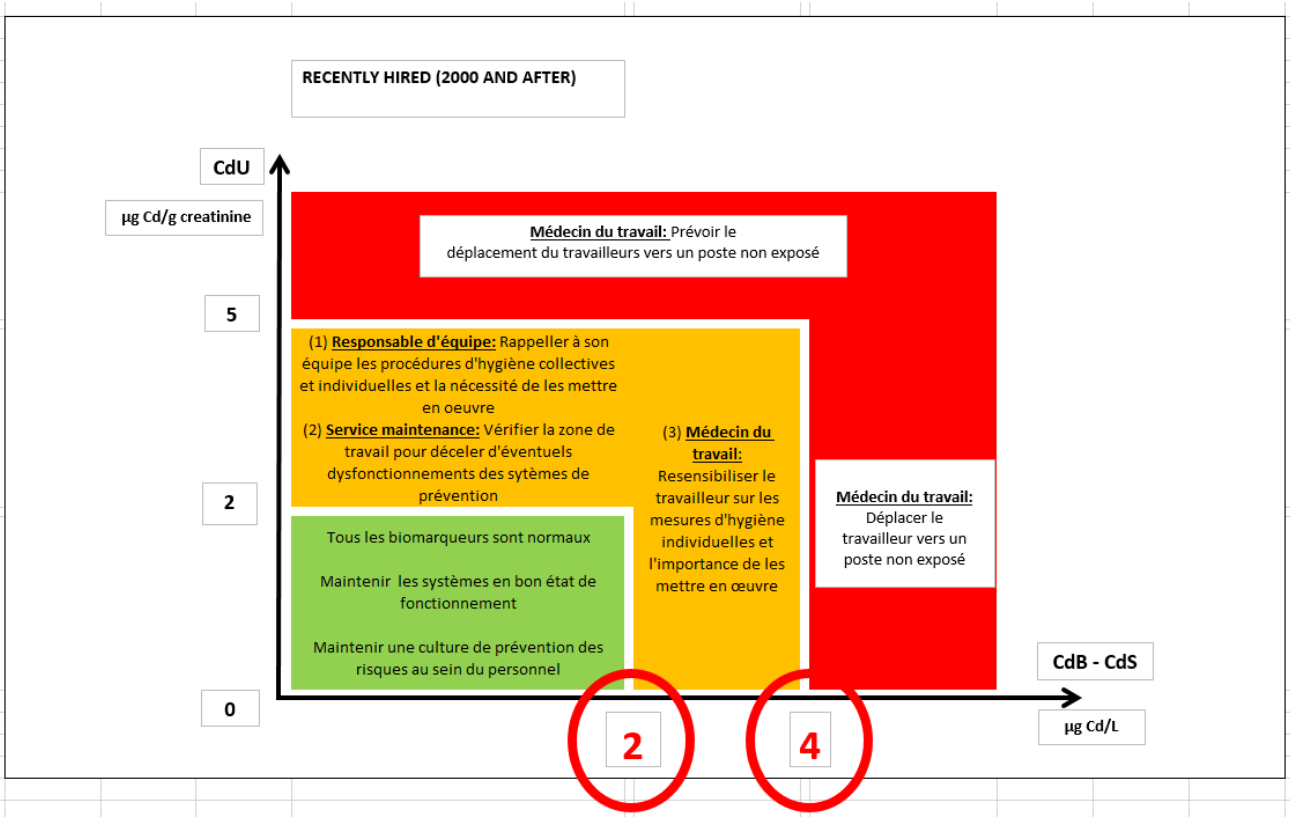
- **Differentiate between ‘old timer’ and ‘recently hired’**
  - Reduce action levels in a differentiated manner for CdB

Hired on or after 2000
current state of reflection

- **If recently hired (on or after 2000)**

- **Reduced action levels for CdB:**
  - First action level: **from 3 to 2**
  - Second action level: **from 5 to 4**

- **Expected benefit:** better control over CdU increase

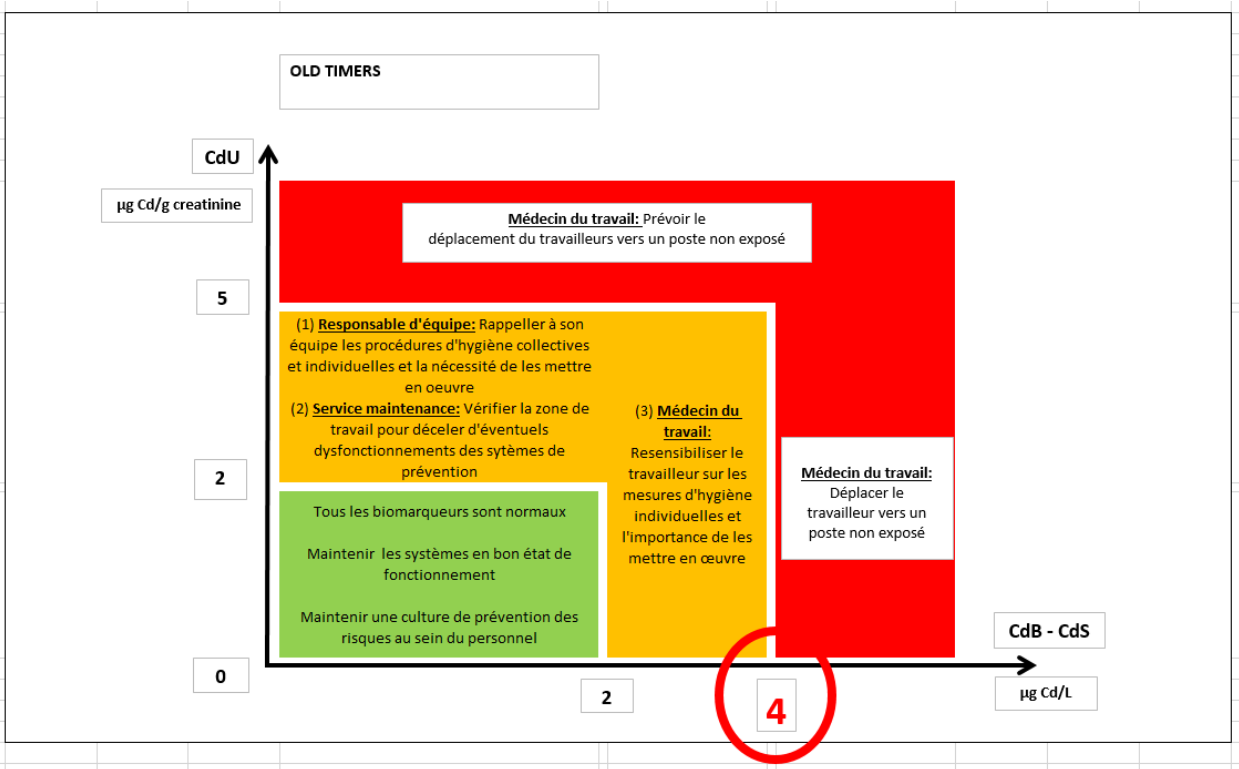


Hired before 2000
Current state of reflection

- **If “old timer” with company (hired before 2000)**

- **<u>Reduced second action level for CdB</u>**: **from 5 to 4**

- Expected benefit: better control over CdU decrease



Discussion

- Employees hired before 2000
  - Pros
  - Cons
- Employees hired on or after 2000
  - Pros
  - Cons
- Possible schedule
  - Adoption in 2017
  - For implementation in 2018

THE END

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