CADMIUM Working Towards a Sustainable Future

ICdA International Cadmium Association

International Cadmium Association

19th Health and Safety committee meeting

Webinar, June 25th, 2021
10:00 -12:30

Agenda

AGENDA

10.00 Welcome, statement of Compliance

10.10 Revision of the occupational exposure limit values for cadmium:

- Status of the process (Noömi Lombaert)
- Negotiation at the **W**orking **P**arty on **C**hemicals (*Martin Wieske*)

10.55 Annual reporting on cadmium occupational monitoring OCdAir and OCdBio (*Mik Gilles*)

11.20 Short coffee break

11.25 The EU Green Deal and the Zero Pollution Ambition. (*Howard Winbow*)

11.45 Update on Reach and status of the Authorization process. (*Noömi Lombaert*)

12.00 Will cadmium be classified as endocrine disruptor? (*Heidi Northshield*)

12.15 Positive communication on cadmium (*Mik Gilles*)

- Website renewal
- Application sheets

12:30 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.

CMD Revision

Cadmium and its Carcinogenic Compounds

Report from RAC meetings

Upcoming WPC meeting

ECHA's OEL-setting review process

ECHA – **call for evidence** (March^{2nd}-June^{2nd} 2020)

ECHA scientific report published Sept 14th, 2020 (to become an Annex to RAC opinion)

Public consultation on ECHA's scientific report (September 14th -November 12th)

RAC commenting of first draft opinion started November 12th

RAC-55: First RAC discussion on November 30th

RAC-56: Discussion and adoption on March 8th, 2021

RAC-55, November 30th

- First draft opinion presented by the RAC rapporteurs
- Representatives at RAC-55:
  - Industry (ICdA, N Lombaert)
  - Advisory Committee for Safety and Health at Work (ACSH) - Working Party on Chemicals (WPC), representing the Employers Interest Group
    (P Levy)
- Draft opinion recommendation:

OEL (8h TWA) = 1 µg Cd/m³(inhalable fraction)

+

BLV of 1 µg Cd/g creatinine

RAC-55: outcome

Agreed by RAC

- Combination of an OEL and BLV is more effective in protecting the health of workers than using either of them alone
- General population epi studies should also be considered when discussing occupational exposure limits for Cd

NOT yet agreed by RAC: **VALUES :**

- **OEL*(8h TWA)*** = *1 µg/m^3(inhalable fraction)* was proposed
  BUT requested more justification on the air limit value and the consideration of the recently updated sublinear German AGS approach
- **BLV -** 1µg/g creatinine can be justified based on:
  - Biomonitoring data, general population from HBM4EU project: P95= 0.57µg Cd/g creatinine
  - General population studies showing effects (renal, bone, cardiovascular, decreased birth weight) at exposure levels around CdU = 1µg/g creatinine

RAC-55: industry interventions

Agreed	Combination of an OEL and BLV	
Commented: Values	**OEL**: explained the relevance of **human** lung cancer data to consider in the derivation of the air limit value	Referred back to **industry comments** made in PC demonstrating the excess cancer risk is much lower when dose response calculations are made starting from human epidemiological data.
		Industry's view is that **air level** should protect against **local** effects (**respirable** fraction). The **systemic effects** will be covered by the **BLV**
	BLV: commented on the **uncertainties** associated with the **data** from the **general population** at very low exposure levels	**Epi studies in the general population at those very low exposure levels**, should be interpreted cautiously. **Cd-U may not reflect accurately the Cd body burden** at CdU = 1µg/g creatinine
		P95 CdU = 0.57 µg/g creatinine (>HBM4EU) does not reflect the background situation in all EU regions

RAC-56, March 8th

- Final draft opinion presented by the RAC rapporteurs and discussed by RAC
- Representatives at RAC-56:
  - Industry (ICdA, N Lombaert)
  - Advisory Committee for Safety and Health at Work (ACSH) - Working Party on Chemicals (WPC), representing the Employers Interest Group
    (M Wieske)
- Some additional information was added to the final draft opinion (in comparison to first opinion) but **conclusions remained unchanged**:

OEL (8h TWA) = 1 µg Cd/m³(inhalable fraction)

+

BLV of 1 µg Cd/g creatinine

RAC-56: outcome (1)

RAC: discussions/agreements	Industry/Employer's rep comments
• RAC agrees on a combination of OEL and BLV • **an OEL value of 1µg Cd/m³ (inhalable fraction)** was proposed. The RAC rapporteurs referred to the risk of 4/10.000 at 0.9µg/m³(respirable) calculated by BAUA and to the 1µg/m³ inhalable which is already in the current CMD.	**OEL:** Strong opposition to the implementation of the inhalable fraction: • only the respirable fraction should be considered because the potential additional effect of the inhalable fraction is already covered when a BLV is imposed. This leads to 'double counting'. • the BAUA value was a respirable fraction and that the CMD value was derived in absence of a biologic limit value

RAC-56: outcome (2)

RAC: discussions/agreements	Industry/Employer's rep comments
• Based on a weight of evidence assessment, mainly based on renal, bone, and cardiovascular effects in the general population, **a BLV of 1 µg Cd/g creatinine** was proposed by the rapporteurs. • RAC discussed the uncertainties concerning setting a BLV close to the background level in certain parts of Europe. → it was agreed for the final opinion: 1) to elaborate further details on how close the values for the BLV and the background levels would be 2) to include advice that may be relevant for the monitoring of the occupational health of employees such as taking into account background levels	**BLV** • monitoring data from the general population, collected by HBM4EU, and data reported by ICdA on Cd levels of new hired workers, show that in several member states or regions, the Cd background level was demonstrably at or above the value of 1 µg Cd/g creatinine. • Uncertainties associated with the data from the general population at very low exposure levels • Industry was given an opportunity to provide additional relevant information to the Secretariat on biomonitoring. A summary of data from the ICdA biomonitoring observatory and the ICdA Guidance were duly submitted

RAC 56: Conclusion and adoption of the opinion

RAC agreed with the biological and air limit values, as proposed in the final draft opinion

RAC chair concluded:

Discussed changes to be made to the final opinion by the rapporteurs

Opinion was supported (poll showed 36 members in support)

RAC adopted its opinion (with modifications agreed at RAC-56)

OEL (8h TWA) = 1 µg Cd/m^3(inhalable fraction)

+

BLV of 1 µg Cd/g creatinine

CMD revision process: next steps

March/April: **Finalisation RAC Opinion –** **NO news yet !**

The RAC final opinion will be forwarded to the COM to be discussed with the ACSH (Advisory Committee on Safety and Health at work)

June 2021: **meeting WPC**; WPC will make a proposal to the ACSH. The ACSH will draft an Opinion to the Commission.

Cadmium not on the agenda → postponed to next WPC meeting

The Commission will do an impact assessment.

The Commission will draft a CMD amendment text for approval by EP and Council

WVMETALLE

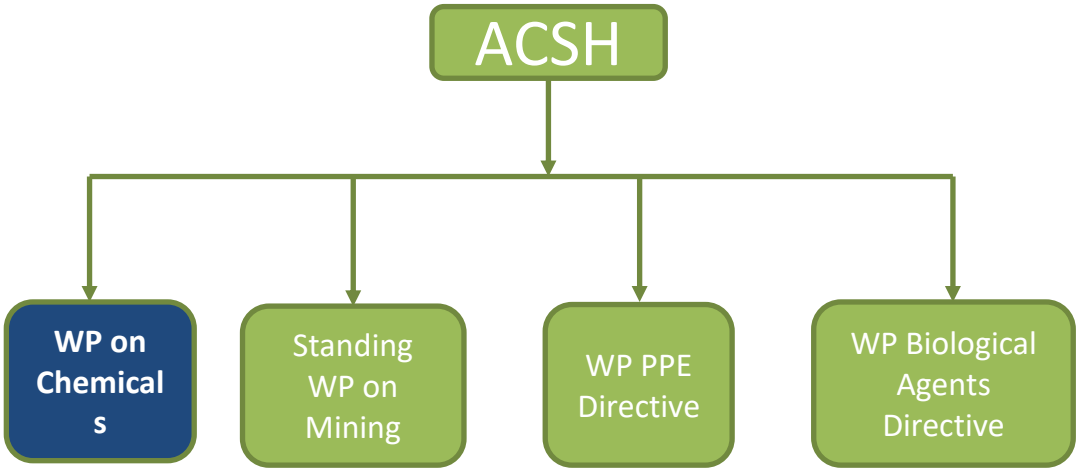
ICdA H&S Meeting, 25.06.2021

• Cadmium OELs discussion at the Working Party Chemicals (WPC)

- Dr. Martin Wieske
- WirtschaftsVereinigung Metalle e. V.
- Employers Interest Group Working Party on Chemicals

WPC: Working Party on Chemicals in the workplace

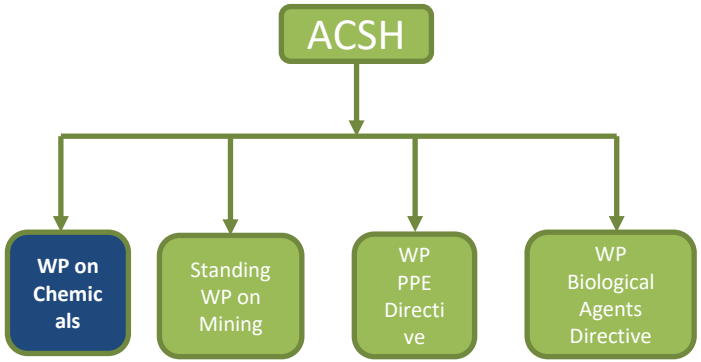
- **General setup**
- The WPC is a sub-group of the tripartite Advisory Committee on Safety and Health (ACSH)
- ACSH (and WPC) advise the European Commission on workplace health and safety



WPC

Actively engaged with and support the activities of SCOEL (RAC)

- We are the first to look on the scientific opinions and to implement them!
- We deal with occupational health and safety issues arising from the relationship between EU OSH requirements and other EU legislation and initiatives including REACH and CLP



WPC: Mandate 2021-2024

General tasks

- Advise the Commission on priority chemicals, in particular chemicals for which the setting of an OEL is recommended.
- Actively engage with and support the activities of ECHA RAC, including producing Opinions on RAC Opinions and other issues/points related to ECHA RAC activities.
- Develop activities within the framework of the CAD (98/24/EC), the CMD (2004/37/EC), the Asbestos at Work Directive (2009/148/EC) and other relevant OSH Directives and other emerging issues.
- Advise the Commission on significant development regarding approaches to chemical risk assessment and risk management at the workplace.
- Encourage the use of good occupational health and safety risk management practice regarding chemicals in other EU policy areas (e.g. REACH) which may be relevant to workers' health and safety protection.
- Deal with occupational safety and health issues arising from the "inter-relationship" between EU OSH requirements and other Union legislation on chemicals, including REACH and CLP.

WPC: Mandate 2021-24

Specific tasks (examples)

- To continue discussions on possible future approaches to developing OELs for carcinogens, including contributing to the development of a risk based approach.
- To discuss the practical implementation of the risk minimisation requirements
- To prepare an Opinion on the most effective way to regulate exposure to reprotoxic chemicals under EU OSH legislation.
- To support, contribute and monitor the external studies initiated by DG EMPL to assess the impact of future BOELs (and socio-economic feasibility).
- To encourage the use of good occupational health and safety risk management practice under REACH, including proposals for Restrictions and Authorisations or the effective use of RMOA.
- To continue to consider the specific issue of the interface between EU OSH OELs and REACH DNELs.
- To contribute to the work of EU-OSHA in preparing guidance on the use of biomonitoring at the workplace including the appropriateness of using biological guidance values (BGVs) and biological limit values (BLVs).

WPC: How we work

- Tripartite – employers, worker, government; five representatives of each
- Chair, vice-chair and rapporteur shared by the interest groups, rotating every 2 years
- 3 or 4 two-day meetings per year
- Sub-groups to monitor specific studies initiated by the Commission

➢ *lively discussions, but usually we agree on draft opinions going to ACSH for formal adoption (each IG can add their own comments)*

WPC: the people in the actual period

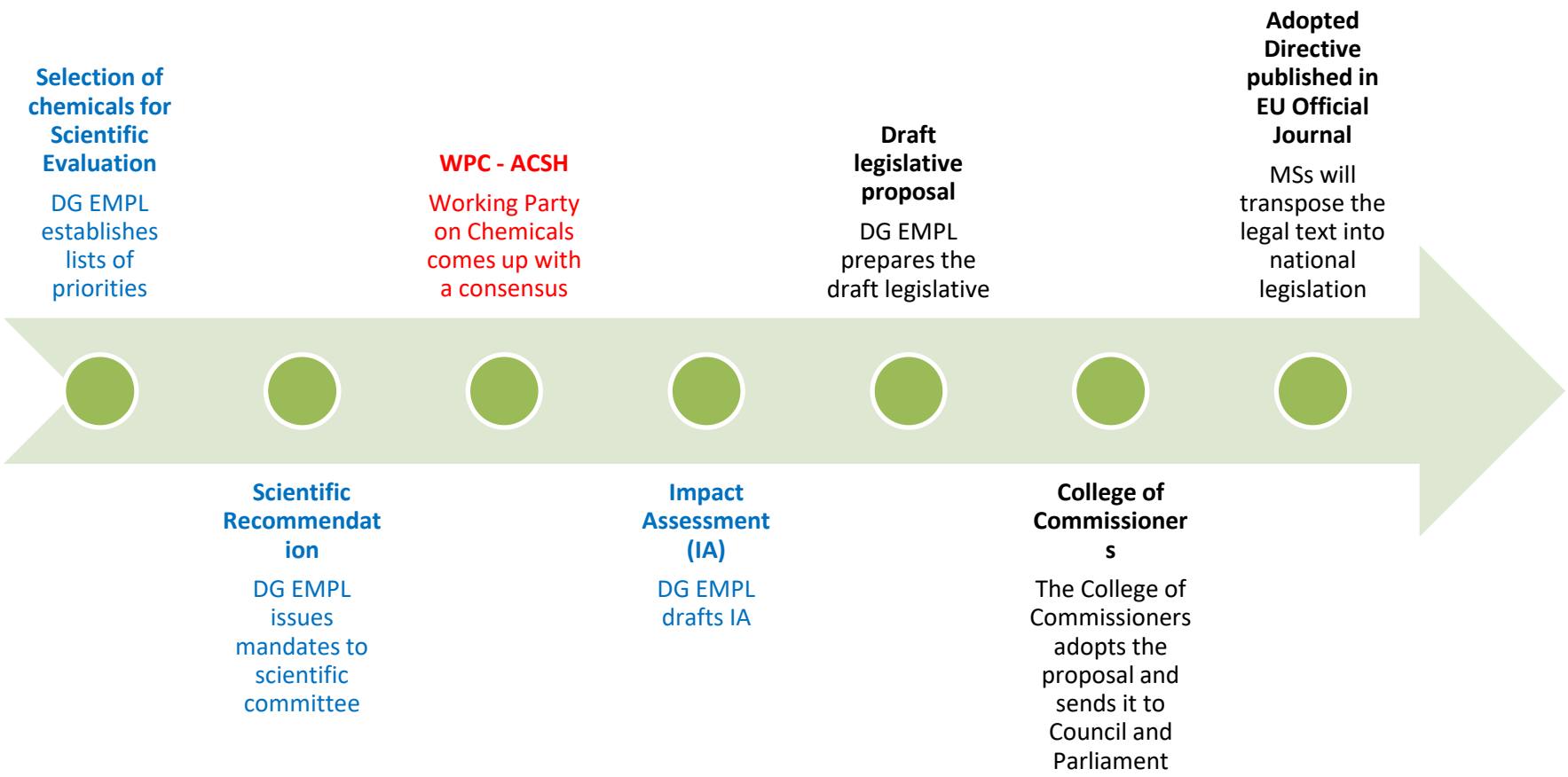
- President : SAARIKOSKI Sirkku (G)
- Vice-President : SKOVGAARD LAURITSEN Jens (E)
- Rapporteur : BARRY Frank (IRL)

- Responsible civil servant: MORRIS Alick (DG EMPL)

GOVERNMENTALS	**EMPLOYERS**	**WORKERS**
GALVEZ PEREZ Virginia (ES)	COLOMBO Maurizio (IT)	BARRY Frank (IRL)
DE SAINT-JORES Jeremy (FR)	WIESKE Martin (DE)	MUSU Tony (BE/ETUI)
MARX Romy (DE)	LEVY Patrick (FR)	STREISSLER Christoph (AT)
SAARIKOSKI Sirkku (FI)	MAYA RUBIO Isabel (ES)	VAN VEELEN Wim (NL)
Deputy member	*Deputy member*	*Deputy Member*
VAN DER AKER Ilse (NL)	SKOVGAARD LAURITSEN Jens (DK)	VAN EYCK Kris (BE)

➢ ***Contacting MS as well as national employers representatives makes sense!***

CMD: Update-Process



Cadmium in CMD 3*: basis for RAC mandating

- **Recitals:**
- (16) With regard to cadmium, it is foreseeable that it will be difficult to comply with a limit value of 0,001 mg/m³ in the short term. It is therefore appropriate to introduce a transitional period of eight years, during which the limit value 0,004 mg/m³ (inhalable fraction) should apply.
- With a view to protecting legitimate expectations and in order to avoid potential disruptions of existing practices **in Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine, the limit value of 0,004 mg/m³ should, in those Member States, be measured as respirable fraction during the transitional period**, in light of the SCOEL and ACSH opinions on cadmium and its inorganic compounds.

- * DIRECTIVE (EU) 2019/983 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019

Cadmium in CMD 3*: basis for RAC mandating

- **Recitals:**
- (17) On the basis of available valid scientific sources such as those provided by SCOEL, the RAC and relevant national bodies, the Commission should, **no later than three years after the date of entry into force of this Directive**, assess the option of amending Directive 2004/37/EC by adding provisions on a c**ombination of an airborne occupational exposure limit and a biological limit value** for cadmium and its inorganic compounds.

- (18) Setting a biological limit value for cadmium and its inorganic compounds would **protect workers against their systemic toxicity, which mainly affects the kidneys and bones**. Biological monitoring can thus contribute to the protection of workers at the workplace, but only as a means of **complementing the monitoring of the concentration of cadmium and its inorganic compounds in the air** and therefore within the breathing zone of workers. The Commission should issue practical guidelines for biological monitoring.

- * DIRECTIVE (EU) 2019/983 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019

Cadmium in CMD 3: basis for RAC mandating

- ***Article 1***
- Directive 2004/37/EC is amended as follows:

(1) In Article 18a, the following subparagraphs are added:

- '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.

BOELs and IOELVs

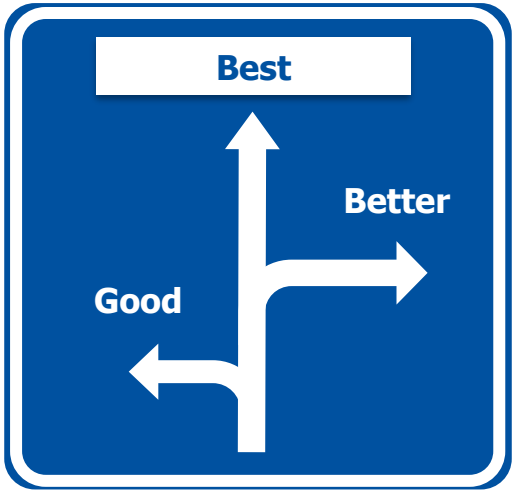
- **Binding OELs** under the Carcinogens and Mutagens Directive or the Chemical Agents Directive provide a minimum level of protection for all workers in the EU. Member States must set a corresponding binding limit that does not exceed the EU value.
  - *Impact Study needed!*

- **Indicative OELs** under the Chemical Agents Directive are health-based limits. They are established for substances for which it is possible to set a level where there is no risk to workers' health. Member States must establish a corresponding national OEL value in accordance with national legislation and practice, taking the EU value into account.
  - *Based on scientific opinion only!*

Feasibility and benefits of proposed OELs

Employers aspects

- **<u>Analysis of the socio-economic and technical feasibility for the limit values system of carcinogens in Europe</u>**
- Some experiences at WPC level from last waves for the CMD
- Monitoring the drafting of an Impact Assessment is important
- Data on costs and benefits should be available before concluding on OEL



Feasibility and benefits of proposed OELs

Employers aspects

- **<u>Analysis of the socio-economic and technical feasibility for the limit values system of carcinogens in Europe</u>**

➢ A lot of factors are to be taken into account:

- affected sectors,
- exposed workforces,
- exposure data,
- existing OELs and national specifics,
- data on ill-health cases and trends,
- benefits and costs, measurability,
- risk management measures in place…

➢ ***Close cooperation with consultants is key!***

➢ ***Delivering of exposure data is extremely helpful!***

➢ ***Be prepared to assess potential costs for low OELs!***

Cadmium: New values in Germany

- TRGS 910:

Stoffidentität			Akzeptanzkonzentration			Toleranzkonzentration			Bemer-kungen	Festle-gung/ Ände-rung Monat/ Jahr
Bezeichnung	EG-Nr.	CAS-Nr.	Vol.-Konz.	Gew.-Konz. bzw. Faser-Konz.	Hin-weise	Vol.-Konz.	Gew.-Konz. bzw. Faser-Konz.	ÜF		
Cadmium und Cd-Verbindun-gen, als Carc.1A, Carc.1B ein-gestuft	231-152-8	7440-43-9		0,9 µg/m³ (A)	b)		2µg/m³ (A)	8	(2), (4), (7), siehe TRGS 561	xx/2021

- TRGS 900:

Stoffidentität			Arbeitsplatzgrenzwert		Spitzenbegren-zung		Änderung/
Bezeichnung	EG-Nr.	CAS-Nr.	ml/m³ (ppm)	mg/m³	Überschrei-tungsfaktor	Bemerkungen	Monat/ Jahr
Cadmium und anorganische Cadmium Ver-bindungen	231-152-8	7440-43-9		0,002 (E)	8 (II)	AGS, X, 10, 38	xx/21

CHANGE IN TRGS 910 (RISK BASED APPROACH):

- R-Dust: Toleranzkoncentration 2 µg/m³
  ERB non-linear
  better situation also for AC

CHANGE IN TRGS 900 (HEALTH BASED APPROACH):

- I-Staub: AGW at 2 µg/m³

➢ ***Concluded on in AGS May 2021!***

25.06.2021

THANKS!

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Cadmium monitoring

Cadmium Occupational Monitoring

2

Cadmium Occupational monitoring

OBSERVATORIES:
Monitoring Cd exposure of workers

- OCdAIR-8: results, analysis, discussion
  - Presentation of reported data from members
  - Conclusions
- OCdBIO-13: results, analysis, conclusions
  - Presentation of reported data from members: CdU, CdB, and post-2000 hires subgroup
  - Conclusions
- Way forward

OCdAIR-8

Occupational Cadmium Air-monitoring Observatory

Preliminary reporting
2020 monitoring results

OCdAir-8

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

	2013	2014	2015	2016	2017	2018	2019	2020
Plants	12	22	20	16	30	25	31	33
SEGs	67	142	131	124	162	165	204	316
Workers	994	1548	1369	1278	2249	1857	3499	3662

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

Compliance check

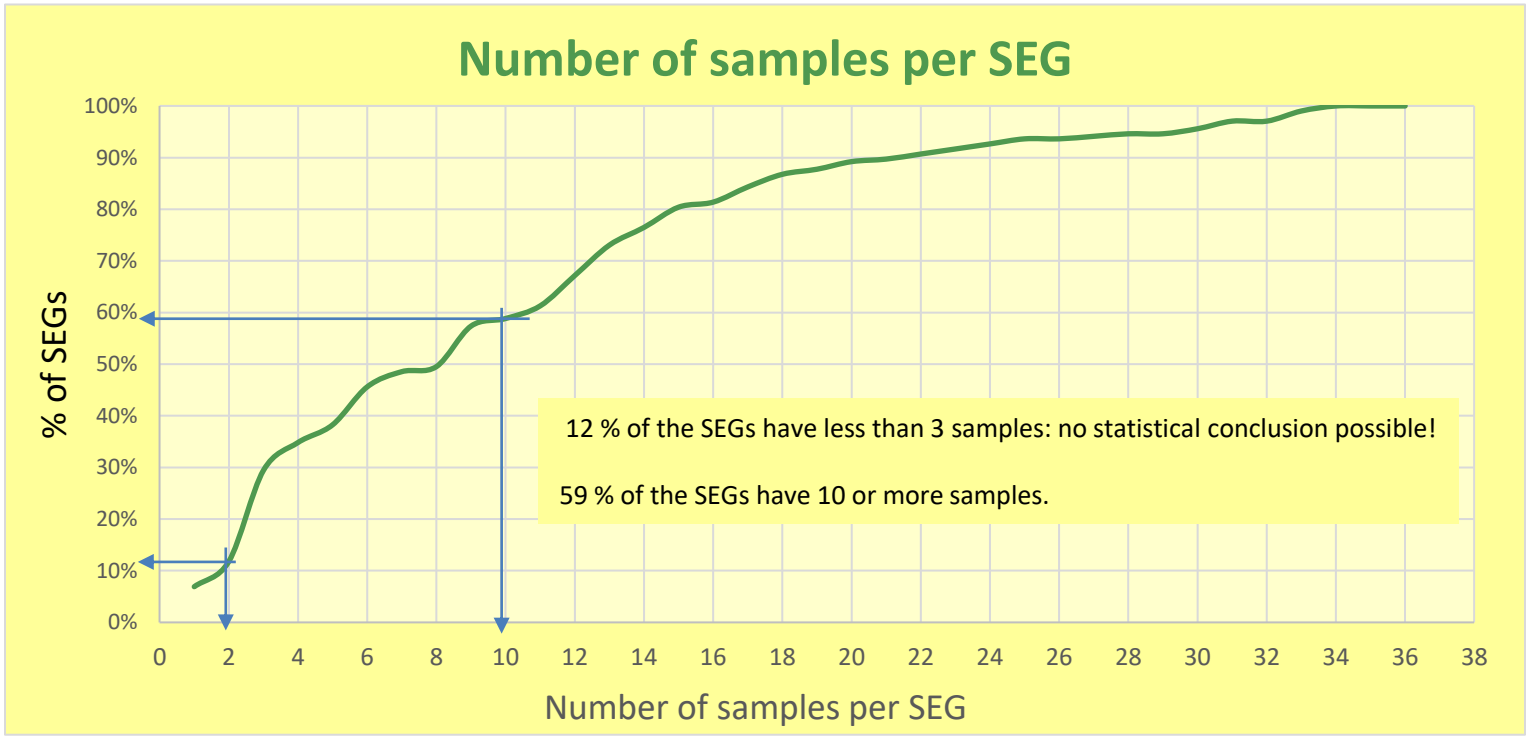
- The OEL has been derived from a 40 year cumulative exposure at which no adverse health effect occurs after 40 years.
- It is based on the fact that Cd accumulates and only after long time will reach body levels that are harmful.
- How is this assessed in practice?
  - The **geomean** value would be 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.
  - For REACH dossiers, the 90 percentile is often looked at.
  - Few inspectors seem to ask for a **sampling frequency**.
- We will present results according to different criteria to show how if affects compliance.

OCdAir-8

- 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.
- RAC draft proposal:
  - Biomonitoring AND < 1µg 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



Cd exposure in SEGs : geomean value

- In 5 SEGs the Cd concentration in air is too high! One SEG with with 15 workers is at >10 µg Cd/m³ (but measured as inhalable).
- In 8% 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**	**2020**
<4 µg Cd/m³ respirable	52	107	150	143	176	193
non-conclusive	70	12	4	20	18	18
4 <=> 7	1	3	6	2	3	4
7 <=> 10	1	4				
> 10			2		1	1
other non-compliant	7	1				
total	131	127	162	165	198	216

Geomean	% of SEGs in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	40%	84%	93%	87%	89%	89%
non-conclusive	53%	9%	2%	12%	9%	8%
4 <=> 7	1%	2%	4%	1%	2%	2%
7 <=> 10	1%	3%	0%	0%	0%	0%
> 10	0%	0%	1%	0%	1%	0%
other non-compliant	5%	1%	0%	0%	0%	0%
total	100%	100%	100%	100%	100%	100%
<10 µg Cd/m³ respirable	95%	99%	99%	100%	99%	100%

Workers exposure: geomean value

- For 101 workers (6%), all samples are below 4µg Cd/m³ but insufficient samples to conclude (we ask for at least 3 samples per SEG)
- 51 workers (1,4%) are exposed to a too high Cd concentration
- 15 workers have an exposure > 10 µg Cd/m³

Geomean	number of workers in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	890	1195	2169	1711	3241	3510
non-conclusive	411	114	28	126	99	101
4 <=> 7	29	21	48	20	21	36
7 <=> 10	4	33				
> 10			4		18	15
other non-compliant	35	2				
total	1369	1365	2249	1857	3379	3662
<10 µg Cd/m³ respirable	1334	1363	2245	1857	3361	3647

Geomean	% of workers in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	65%	88%	96%	92%	96%	96%
non-conclusive	30%	8%	1%	7%	3%	3%
4 <=> 7	2%	2%	2%	1%	1%	1%
7 <=> 10	0%	2%	0%	0%	0%	0%
> 10	0%	0%	0%	0%	1%	0%
other non-compliant	3%	0%	0%	0%	0%	0%
total	100%	100%	100%	100%	100%	100%

Cd exposure in SEGs : 90 percentile

- In 29 SEGs (13%) the Cd concentration in air is too high!
- In 65 SEGs (30%), there are insufficient samples to assess the exposure.
- In 10 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**	**2020**
<4 µg Cd/m³ respirable	31	79	100	99	124	122
non-conclusive	83	28	40	47	52	65
4 <=> 7	4	10	10	11	11	13
7 <=> 10	2	3	5	6	7	5
> 10	6	7	7	2	4	10
other non-compliant	5					1
total	131	131	162	165	198	216

90 percentile	% of SEGs in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	24%	60%	62%	60%	63%	56%
non-conclusive	63%	21%	25%	28%	26%	30%
4 <=> 7	3%	8%	6%	7%	6%	6%
7 <=> 10	2%	2%	3%	4%	4%	2%
> 10	5%	5%	4%	1%	2%	5%
other non-compliant	4%	0%	0%	0%	0%	0%
total	100%	97%	100%	100%	100%	100%

Workers exposure: 90 percentile

- For 693 workers (19%), all samples are below 4µg/µg m³ but insufficient samples for statistical assessment.
- 436 workers (12%) are exposed to a too high Cd concentration
- 135 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**	**2020**
<4 µg Cd/m³ respirable	483	975	1672	1207	2579	2533
non-conclusive	648	309	441	405	513	693
4 <=> 7	29	100	56	178	68	242
7 <=> 10	49	19	40	52	183	44
> 10	143	48	40	15	36	135
other non-compliant	17					15
total	1369	1451	2249	1857	3379	3662

90 percentile	% of workers in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	35%	67%	74%	65%	76%	69%
non-conclusive	47%	21%	20%	22%	15%	19%
4 <=> 7	2%	7%	2%	10%	2%	7%
7 <=> 10	4%	1%	2%	3%	5%	1%
> 10	10%	3%	2%	1%	1%	4%
other non-compliant	1%	0%	0%	0%	0%	0%
total	100%	100%	100%	100%	100%	100%

Cd exposure in SEGs : EN689

- 51% of all SEGs are compliant with EN689
- In 34 SEGs (15%) the Cd concentration in air is too high!
- In 71 SEGs (33%), there are insufficient samples to assess the exposure.
- In 15 SEGs (7%), 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**	**2020**
<4 µg Cd/m³ respirable	12	35	78	74	109	111
non-conclusive	102	66	54	60	59	71
4 <=> 7		6	10	9	9	9
7 <=> 10		3	5	9	7	3
> 10	1	6	15	8	9	15
other non-compliant	16	11		5	5	7
total	131	127	162	165	198	216

EN689	% of SEGs in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	9%	28%	48%	45%	55%	51%
non-conclusive	78%	52%	33%	36%	30%	33%
4 <=> 7	0%	5%	6%	5%	5%	4%
7 <=> 10	0%	2%	3%	5%	4%	1%
> 10	1%	5%	9%	5%	5%	7%
other non-compliant	12%	9%	0%	3%	3%	3%
total	100%	100%	100%	100%	100%	100%

Workers exposure: EN689

- For 708 workers (19%), all samples are below 4µg/µg m³ but insufficient samples for statistical assessment, or don't have a log normal distribution.
- 478 workers (13%) are exposed to a too high Cd concentration
- 311 workers (8%) have (occasionally) an exposure > 10 µg Cd /m³

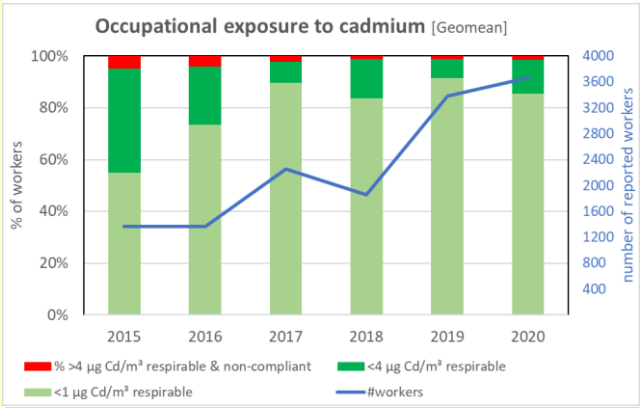
EN689	number of workers in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	257	568	1441	852	2393	2476
non-conclusive	904	597	517	521	553	708
4 <=> 7		95	158	147	124	65
7 <=> 10		22	41	99	67	19
> 10	18	104	92	166	184	311
other non-compliant	190	65		72	58	83
total	1369	1451	2249	1857	3379	3662

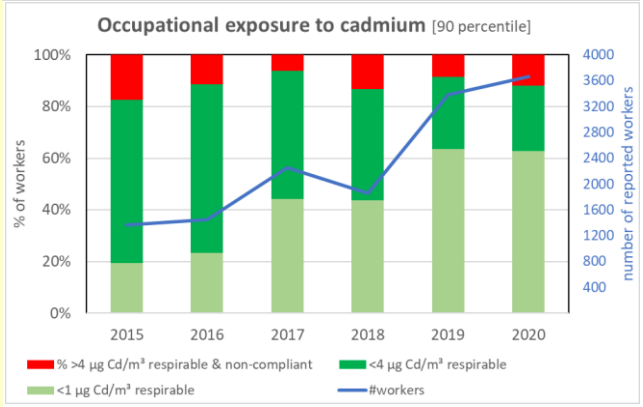
EN689	% of workers in this range					
Range [µg/m³] respirable	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
<4 µg Cd/m³ respirable	19%	39%	64%	46%	71%	68%
non-conclusive	66%	41%	23%	28%	16%	19%
4 <=> 7	0%	7%	7%	8%	4%	2%
7 <=> 10	0%	2%	2%	5%	2%	1%
> 10	1%	7%	4%	9%	5%	8%
other non-compliant	14%	4%	0%	4%	2%	2%
total	100%	100%	100%	100%	100%	100%

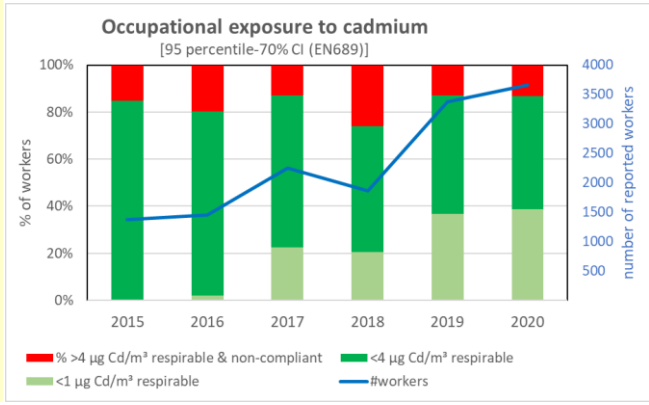
Summary on air quality

- When applying the most realistic assessment criterium (geomean), performance is excellent, with only 5 SEGs and 51 workers in exceedance of the 4µg Cd/m³ respirable limit workers value.
- Obviously, more efforts are needed to address the high exposure in these 5 SEGS.
- When assessed according to EN689, 15% of all SEGS and 13% of all workers exceed the limit value.
- More sampling is required in 33% of the SEGs to allow a conclusive assessment of the exposure.

Remark: When, according to the draft RAC opinion, 1µg Cd/m³ <u>inhalable</u> fraction needs to be considered, more than 60% of SEGs will not be compliant.







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 13 years follow-up!
  - A strong coverage of EU industrial sites: in 2020 we received reporting from 4621 workers on 36 sites!!!

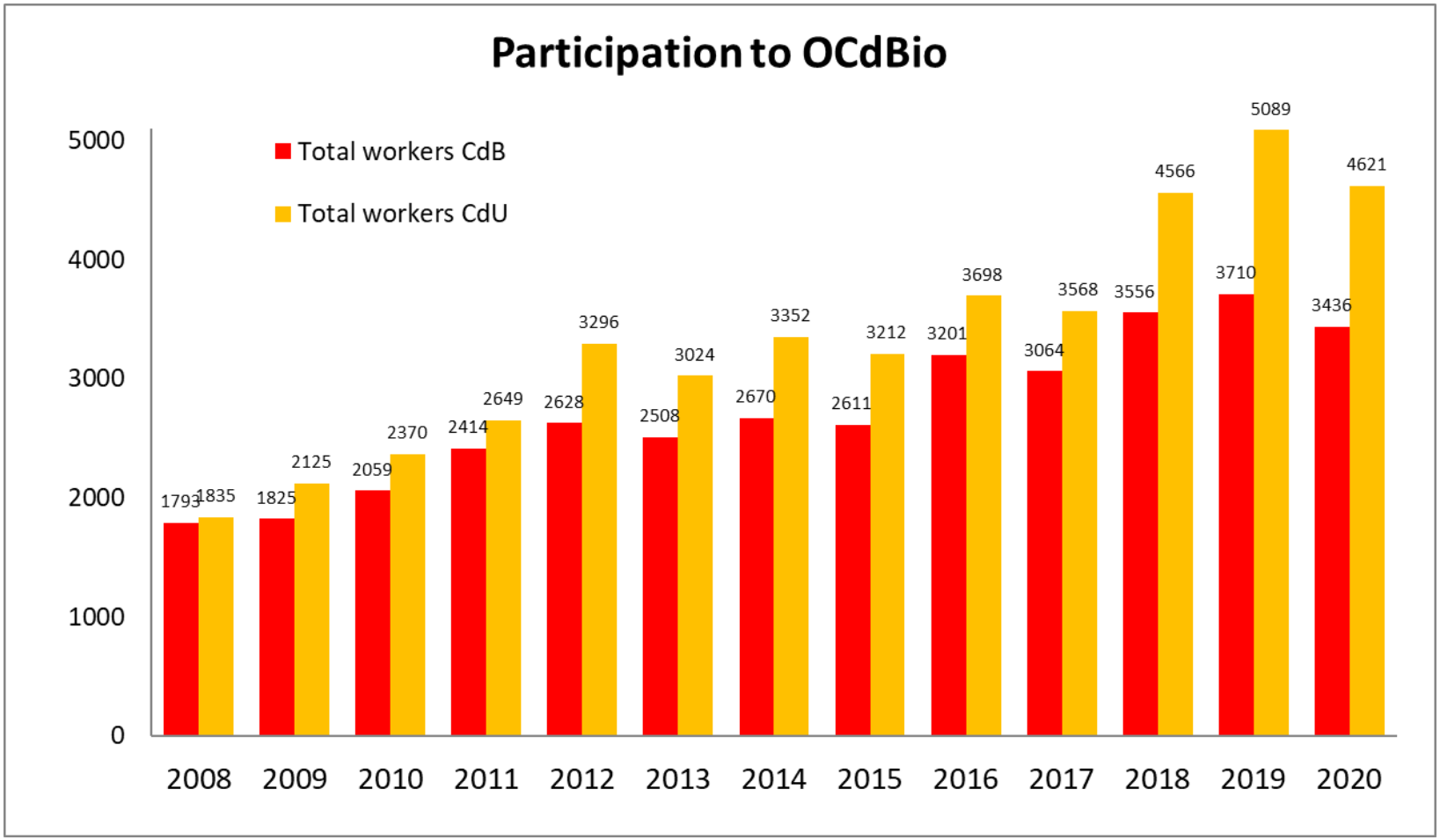
Selected biomarkers of exposure

- 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 <u>not covered</u> by this indicator!!! => OEL (air) required.

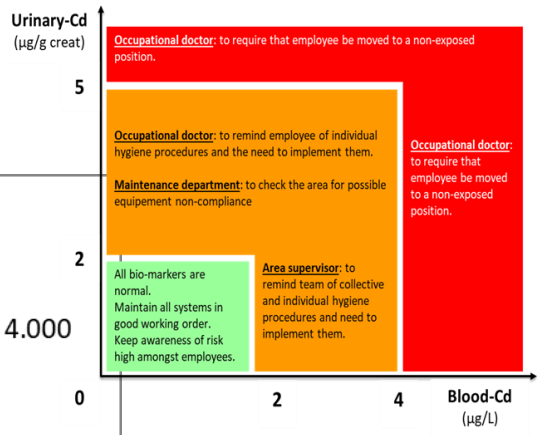
Number of reported workers

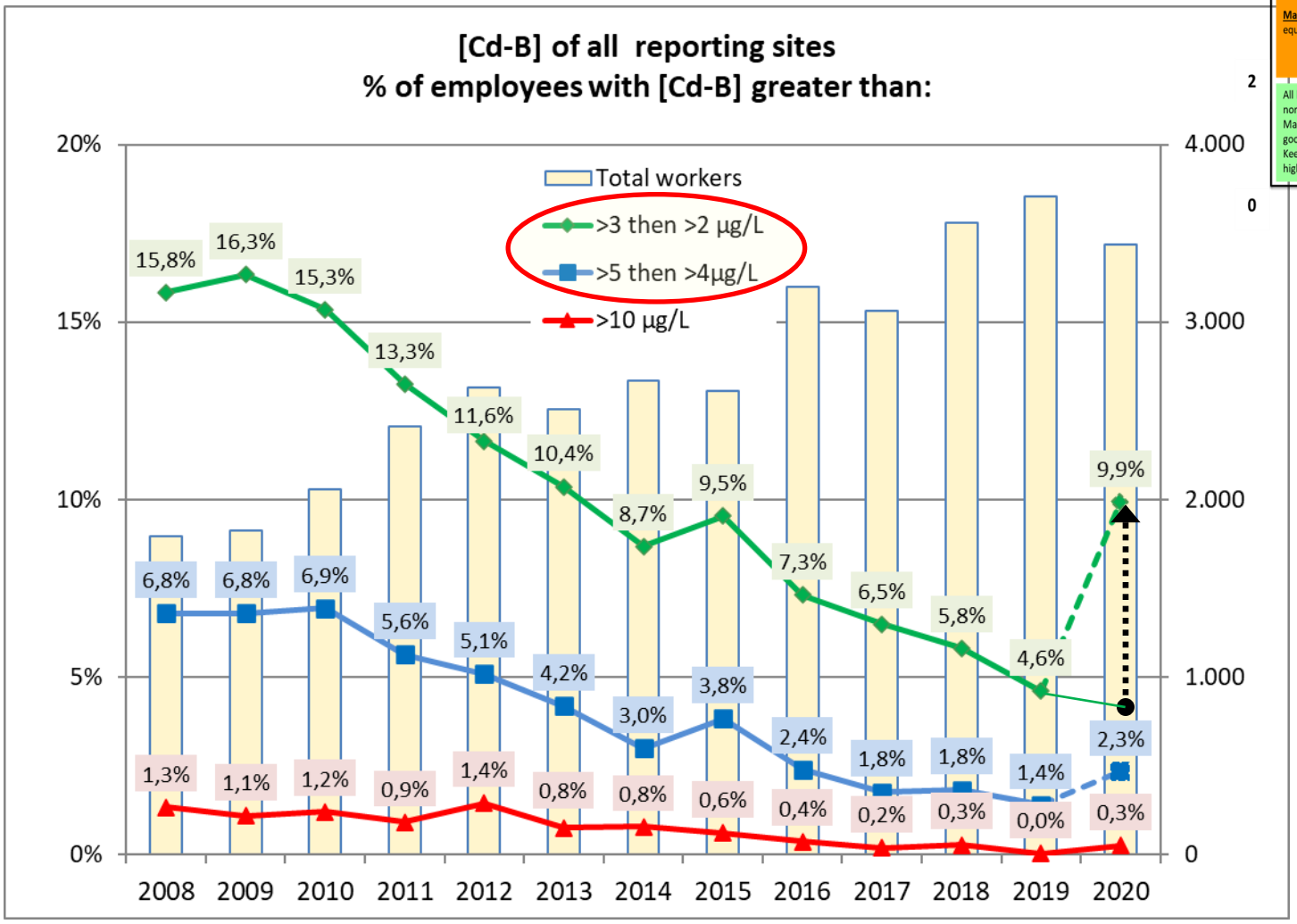


- Strong response but sometimes difficult to get the information from the doctor due to work overload during Covid crisis

CdB distribution - all sites in % -

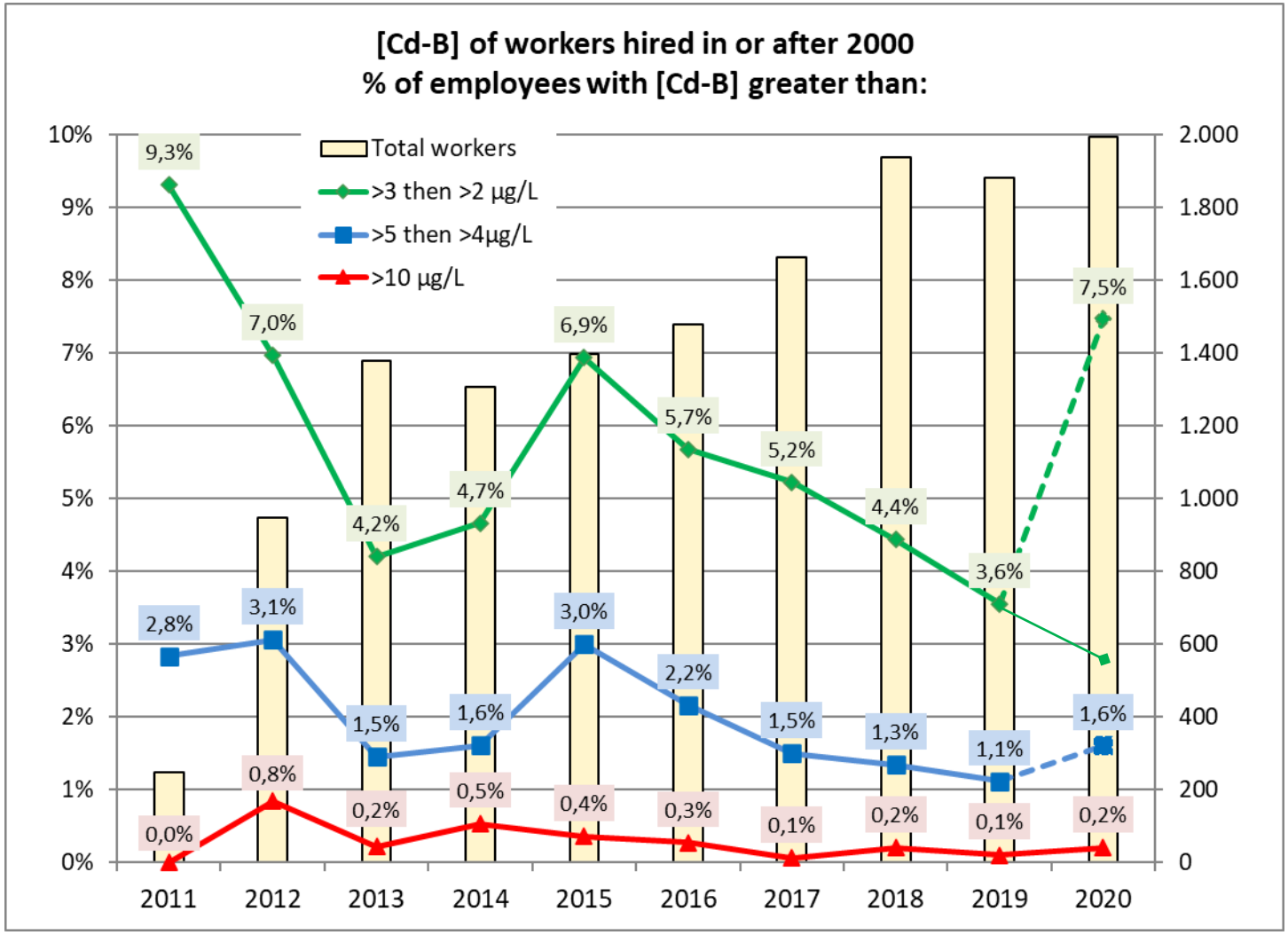
Target values reset in line with ICdA Guidance





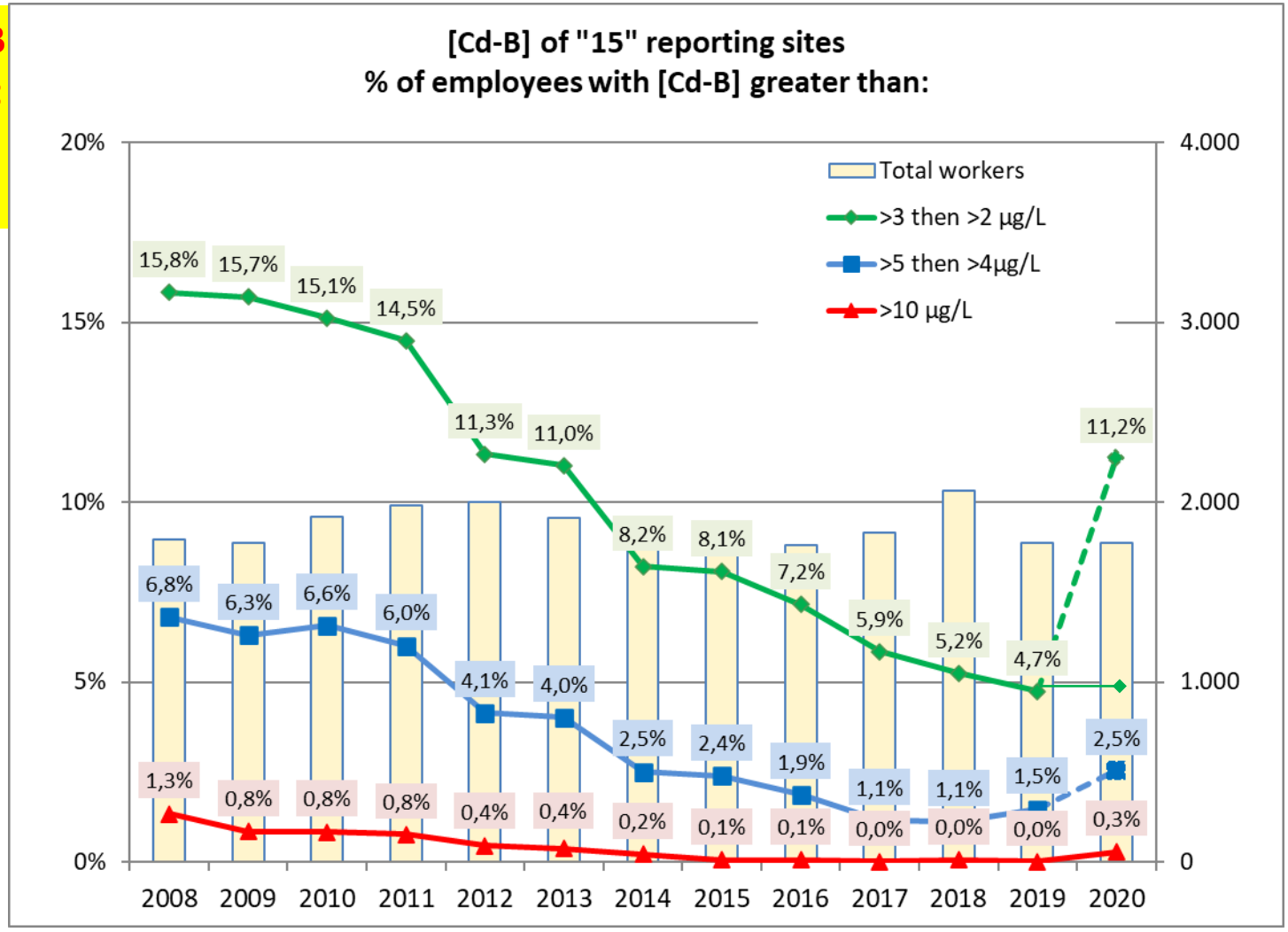
from 2020, the green and blue lines represent workers with CdB >2µg Cd/L and with CdB >4µ Cd/L.
Previous target values were 3µg/L and 5 µg/L.
Hence the upwards jump in 2020. Without this change in criteria, the 2020 results would be very similar to 2019

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



CdB distribution original “15”

Some recent high CdB values were sampled: incidents with Cd exposure still happen

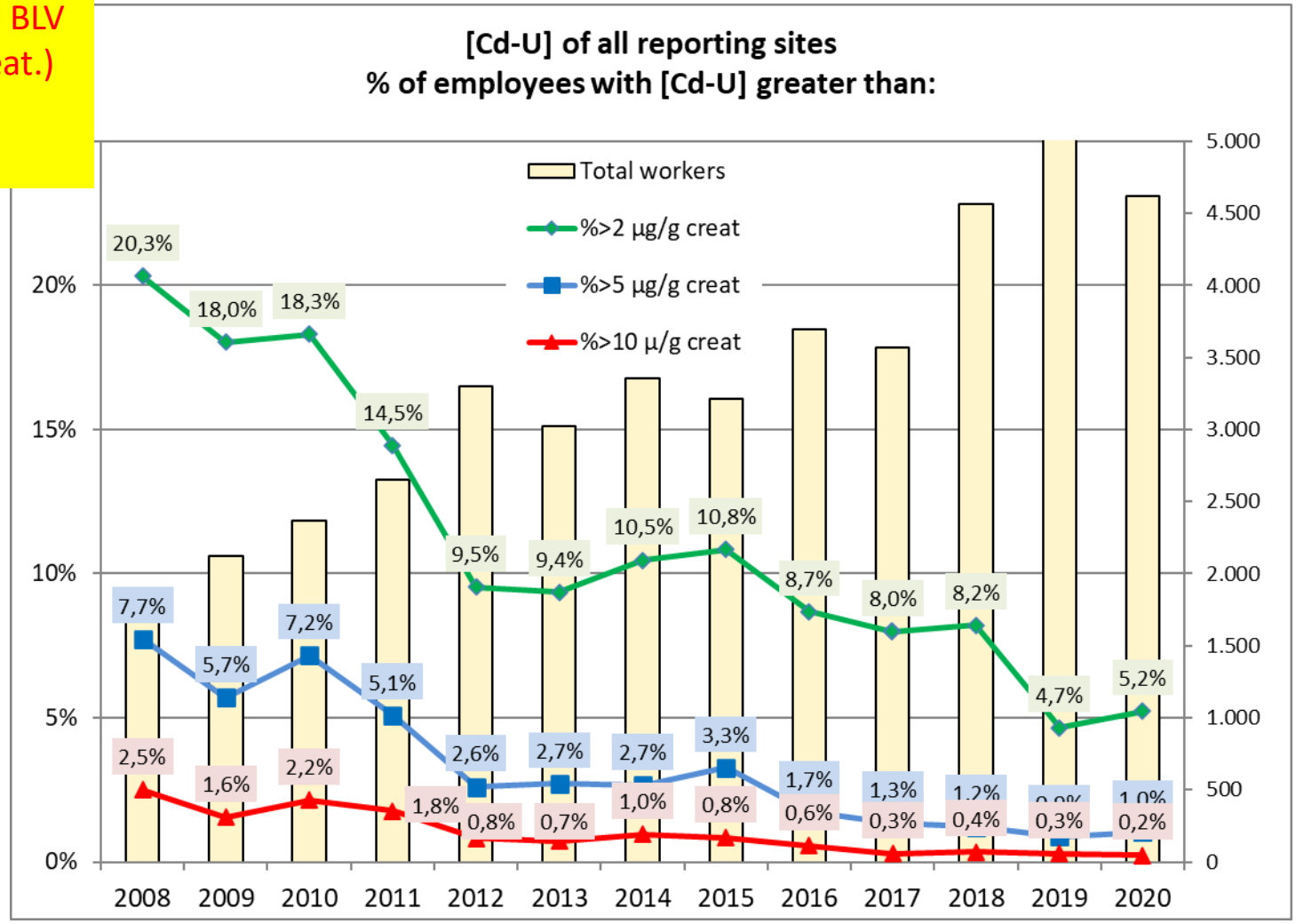


Cd in Blood: conclusion

- Further progress was made: Exposure of workers was reduced in 2020
- But we need increase our ambition…
  - Still too many workers have too high level of exposure to keep (or bring) them below the target of 2µg Cd/g creatinine, which may become a CMD limit.
  - 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.

- Reduction of cadmium body burden flattens.
- 5,2% of workers above proposed BLV (CdU>2 µg/g creat.)

CdU distribution
- all sites in % -

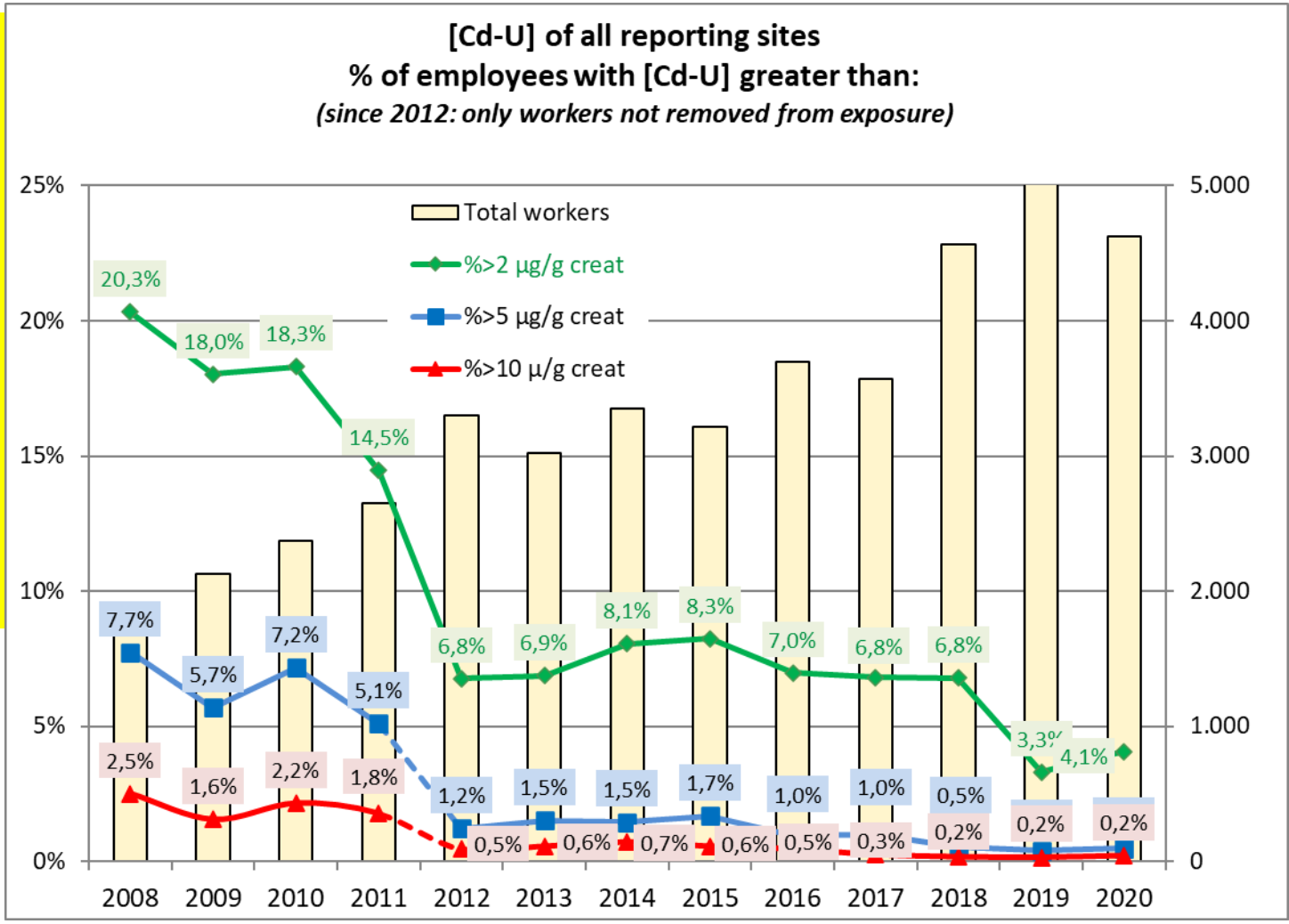


CdU distribution

- all sites in % - (removed workers excluded)

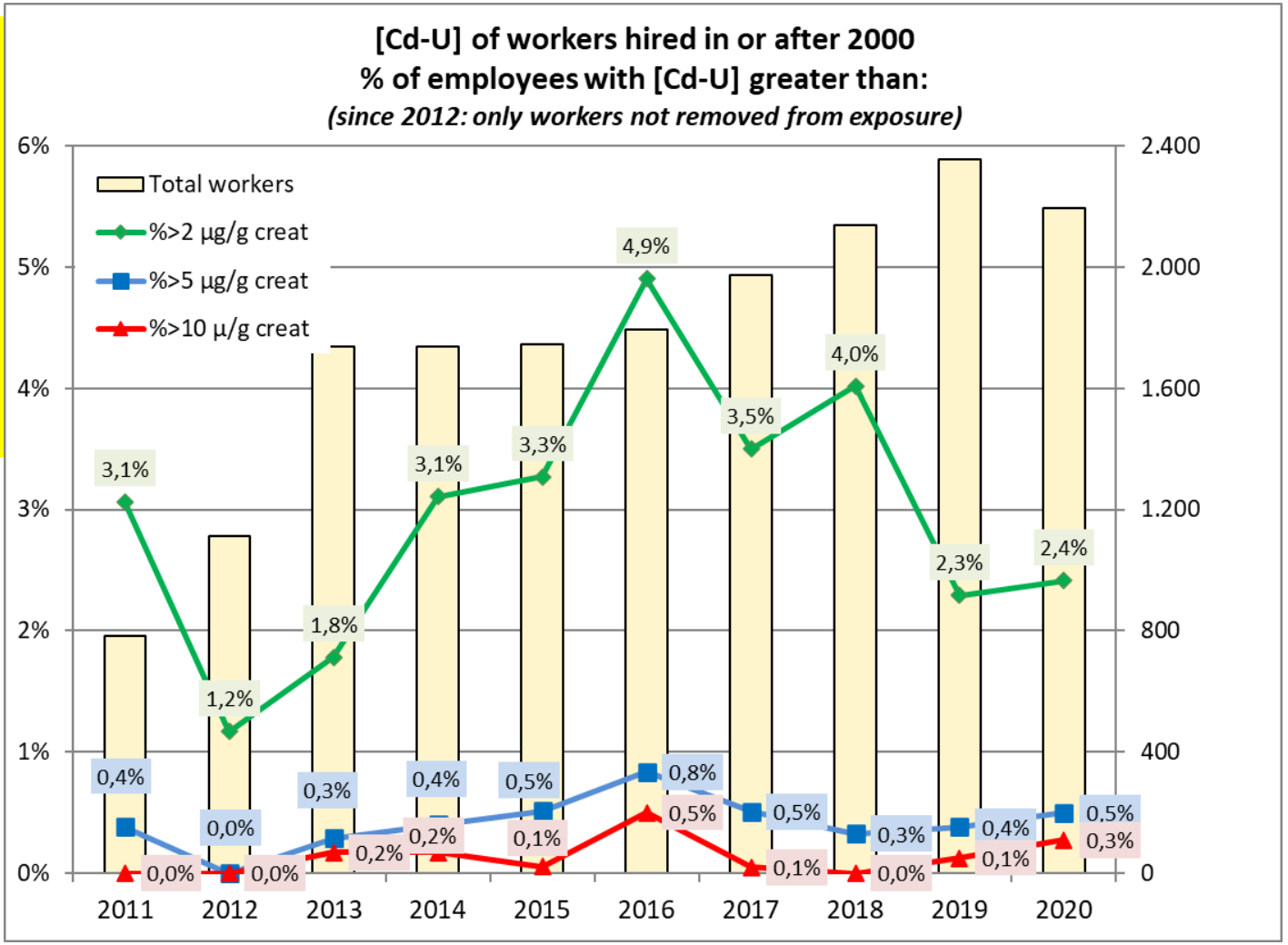
- 4,1 % of workers above proposed BLV (CdU >2 µg/g creat.)
- 22 workers with CdU >5µg/g creat. are not removed, including 10 above 10µg/g creat.

Concerned companies should check how they can address this.



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

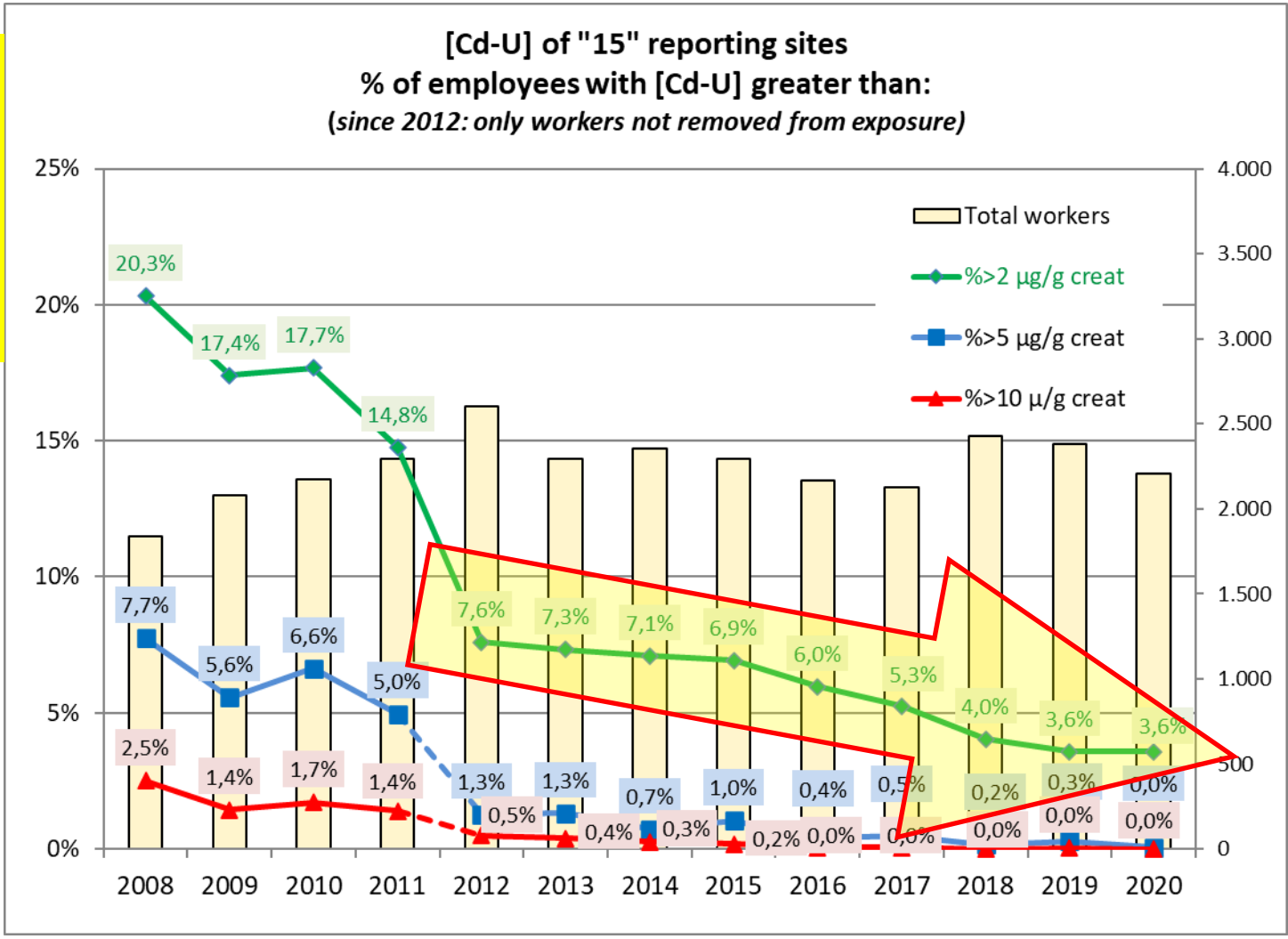
- Situation stabilized!
- Also here we see 11 workers above 5µg/g creat. and 6 above 10 µg which are not removed



CdU distribution

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

- Decreasing trend continues!
- Excellent response to ICdA Guidance to remove workers above 5µg/g creat.



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)
  - 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 body burden of some workers is too high to bring them below 2µg Cd/g creatinine 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.
    - Today, 7,5% of these workers are above a CdB of 2µg/L and 1,6% are above 4µg/l!

- CdU:
  - Last years' decrease of workers in the segment 2-5 µg Cd/g creat. confirmed!
  - 22 workers (0,4%) with CdU> 5 µg Cd/g creat. are not removed from exposure => check assessment procedures with doctor.
  - 242 workers have > 2µg Cd/g creat and 120 of them above 3µg.
    Today 60 workers are removed from exposure.
    - Should a very stiff compliance with CdU>2 be regulated, this would mean that an additional 182 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.

take 5 minutes for a

Coffee break

Changing Regulatory Landscape..
The EU Green Deal

Focus here on:

Zero Pollution Ambition


Mobilising research and fostering innovation
Transforming the EU's economy for a sustainable future
Increasing the EU's Climate ambition for 2030 and 2050
A zero pollution ambition for a toxic-free environment
Supplying clean, affordable and secure energy
The European Green Deal
Preserving and restoring ecosystems and biodiversity
Mobilising industry for a clean and circular economy
From 'Farm to Fork': a fair, healthy and environmentally friendly food system
Building and renovating in an energy and resource efficient way
Accelerating the shift to sustainable and smart mobility
Financing the transition
Leave no one behind (Just Transition)
The EU as a global leader
A European Climate Pact

‘Towards a Zero Pollution ambition for a toxic-free environment’

The European Green Deal

Create a **toxic-free environment**: more action required to prevent pollution from being generated & measure to clean

Natural functions of ground & surface water must be restored

How?

Introduce new legislation or amend existing regulations

1. **Chemicals strategy for sustainability**
2. **Zero Pollution action plan for water, air and soil**
3. **Revision of Industrial Emissions Directive**

Surfing on waves…

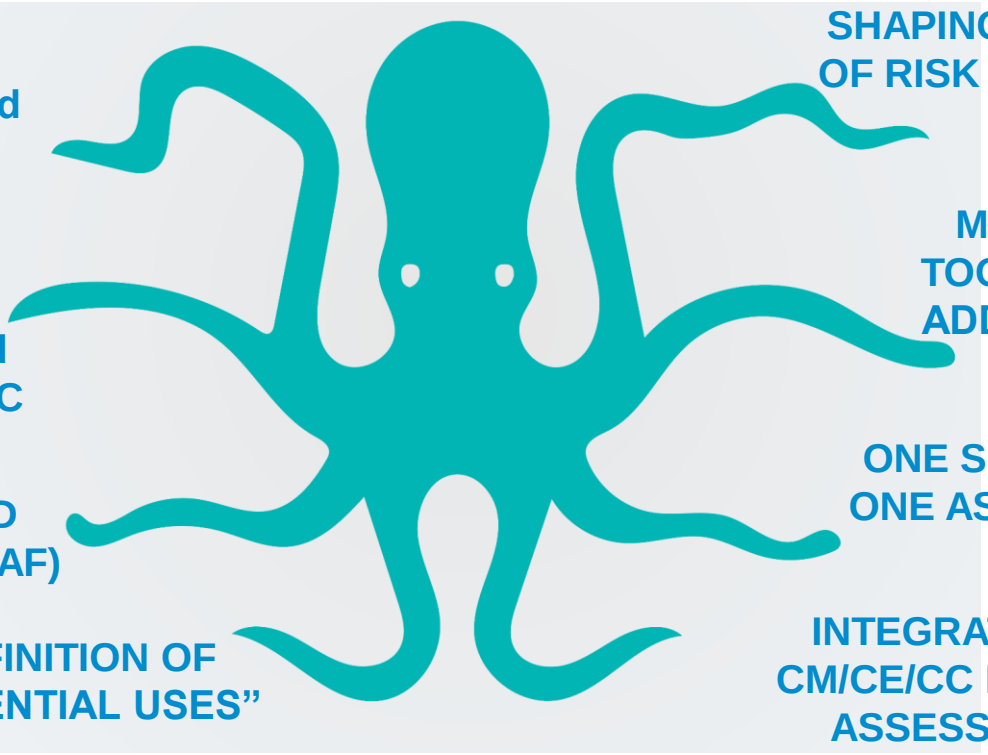
ZERO POLLUTION ACTION PLAN (ZPAP)

CHEMICALS STRATEGY FOR SUSTAINABILITY (CSS)

REVISION OF INDUSTRIAL EMISSIONS DIRECTIVE (IED)

Commission

The CSS has far reaching tentacles with several new concepts..



Q: How to react and organise?
A: Identify Actions = 57! And prioritise by traffic light system

#	Actions foreseen by COM	EU legislation	Indicative timing	Impact on metals	Potential for advocacy	Resources needed	Additional comments	Overall importance
7	Introduce legal requirements on the presence of substances of concern in products, including PFAS, through the initiative on sustainable products	Sustainable products initiative	2021-2022	• Enormous potential impact: Besides SVHC eligible metals, almost all metals would be covered. • Seems especially problematic for Cu and Zn? Al alloys containing Pb?	• Any actions proposed on this category of substances have potential to significantly impact the metals industry (linked with the EU's raw materials agenda). • Any attempts to minimise or eliminate such a group of SoCs in recycling loops would oppose the EU's priorities to develop recycling infrastructure for batteries, electronics waste, base metals and other priority waste streams. Safe recycling should instead be the EU's priority.	COM) • An industry impact assessment could be made on why a SoC category is needed before the EU proposes any market limitations, including the actual risks of exposure. • **Urgent action:** need to address this issue in the public consultation on the IIA of sustainable products initiative available here. Deadline is 02/11/2020. • **Urgent action:** need concrete data on certain metals affected by the definition. • Identify scenarios SoC vs.(non-)essential uses .	defined in the CSS as substances having a chronic effect for human health or the environment (REACH Candidate list + CLP Annex VI) but also those which hamper recycling for safe and high quality secondary raw materials. • Although the problematic definition remains, the language on how SoCs will be dealt with has been softened. It is now about minimising them in consumer products. • Ecolabel shows that such an approach may not be proportionate.	
8	Initiatives and funding to promote the development of green and smart technologies, advanced materials, and innovative business models for the low-carbon and low environmental impact industrial production and use of chemicals		As of 2021	• Company-specific issue	• None foreseen at this stage.		• Is there a link with taxonomy (under the sustainable finance portfolio)?	
9	Access to risk finance, in particular for SMEs and start-ups		As of 2021	• Company-specific issue	• None foreseen at this stage.		• SMEunited to be in the lead in any case.	
10	Make amendments to the EU legislation on industrial emissions to promote the use of safer chemicals by EU industry	Industrial emissions Directive	2021	• All sectors including metals.		• Industrial Emissions TF: may require support from external consultant.	• Climate considerations? • Link with E-PRTR, IIA IED: more centralisation / monitoring of data through digitalisation • Link with HAZBREF.	

For metals, further refinement

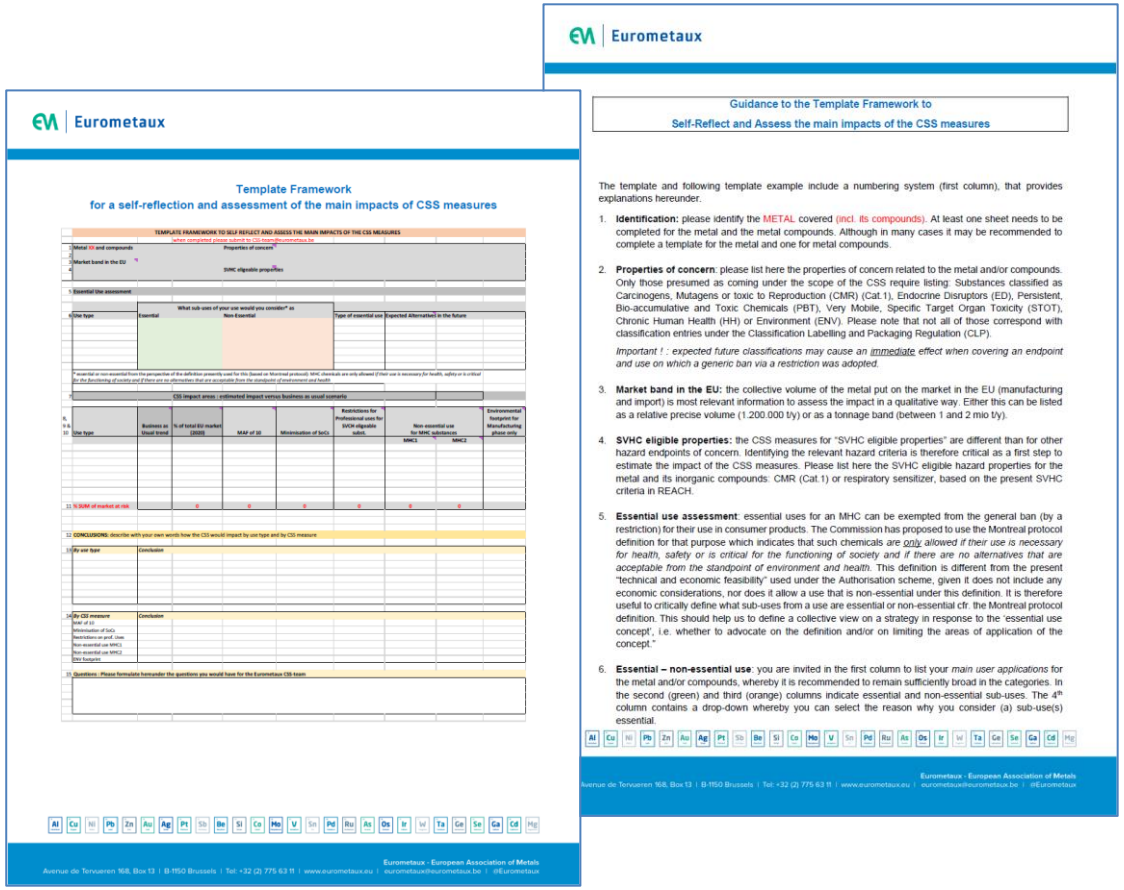
=> top new priority issues identified:

1. **‘Substances of Concern (SoC)’:**
   - **New concept, not fully defined.**
2. **‘Essential Uses (EU)’:**
   - **New concept, not fully defined.**
3. **‘Mixture Assessment Factor (MAF)’:**
   - **Re-emerging topic.**

Action: How to Assess these potential impacts

EM Survey on different impacts of new concepts:

- Guidance
- Survey excel
- Example
- Explanatory document on new concepts in CSS
- Collate multi-metal database



Eurometaux

Template Framework
for a self-reflection and assessment of the main impacts of CSS measures

Eurometaux

Guidance to the Template Framework to
Self-Reflect and Assess the main impacts of the CSS measures

The template and following template example include a numbering system (first column), that provides explanations hereunder.

1. **Identification:** please identify the METAL covered (incl. its compounds). At least one sheet needs to be completed for the metal and the metal compounds. Although in many cases it may be recommended to complete a template for the metal and one for metal compounds.
2. **Properties of concern**: please list here the properties of concern related to the metal and/or compounds. Only those presumed as coming under the scope of the CSS require listing: Substances classified as Carcinogens, Mutagens or toxic to Reproduction (CMR) (Cat.1), Endocrine Disruptors (ED), Persistent, Bio-accumulative and Toxic Chemicals (PBT), Very Mobile, Specific Target Organ Toxicity (STOT), Chronic Human Health (HH) or Environment (ENV). Please note that not all of those correspond with classification entries under the Classification Labelling and Packaging Regulation (CLP).

   Important ! : expected future classifications may cause an immediate effect when covering an endpoint and use on which a generic ban via a restriction was adopted.
3. **Market band in the EU:** the collective volume of the metal put on the market in the EU (manufacturing and import) is most relevant information to assess the impact in a qualitative way. Either this can be listed as a relative precise volume (1.200.000 t/y) or as a tonnage band (between 1 and 2 mio t/y).
4. **SVHC eligible properties:** the CSS measures for "SVHC eligible properties" are different than for other hazard endpoints of concern. Identifying the relevant hazard criteria is therefore critical as a first step to estimate the impact of the CSS measures. Please list here the SVHC eligible hazard properties for the metal and its inorganic compounds: CMR (Cat.1) or respiratory sensitizer, based on the present SVHC criteria in REACH.
5. **Essential use assessment**: essential uses for an MHC can be exempted from the general ban (by a restriction) for their use in consumer products. The Commission has proposed to use the Montreal protocol definition for that purpose which indicates that such chemicals are *only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health*. This definition is different from the present "technical and economic feasibility" used under the Authorisation scheme, given it does not include any economic considerations, nor does it allow a use that is non-essential under this definition. It is therefore useful to critically define what sub-uses from a use are essential or non-essential cfr. the Montreal protocol definition. This should help us to define a collective view on a strategy in response to the 'essential use concept', i.e. whether to advocate on the definition and/or on limiting the areas of application of the concept."
6. **Essential – non-essential use**: you are invited in the first column to list your *main user applications* for the metal and/or compounds, whereby it is recommended to remain sufficiently broad in the categories. In the second (green) and third (orange) columns indicate essential and non-essential sub-uses. The 4th column contains a drop-down whereby you can select the reason why you consider (a) sub-use(s) essential.

Action: Assessment of impacts

TEMPLATE FRAMEWORK TO SELF REFLECT AND ASSESS THE MAIN IMPACTS OF THE CSS MEASURES

when completed please submit to CSS-team@eurometaux.be

1	Metal: Cd and Cd Compounds		Properties of concern	generally (see full list below - tba) Acute Tox. 2, Muta. 2, Carc. 1B, STOT RE 1, Aquatic Acute 1, Aquatic Chronic 1, Repr. 2
2				CdTe Aquatic Chronic 2
3	Market band in the EU	3,000t		Cd pigments - no classification
4			SVHC eligeable properties	CMR

Howard Winbow:
However Cd pigments are not classified so the concept of Essential Use should not apply. Unless some form of Grouping is used.

5 Essential Use assessment

6	Use type	What sub-uses of your use would you consider* as Essential	Non-Essential	Critical for functioning of Society	Expected Alternatives in the future
	in photovoltaics	All for green solar energy conversion	When lifecylce environmental footprint is of no importannce	Climate Change, Energy Security, Circular Ec	Silicon/Polymer systems
	in ceramics and glass	For inherent properties eg forming, colour, opacity, s	For decorative aspects only	Functioning of Society	Other inorganics with no/lower hazard
	in pigments	For restoration of masterpieces, safety applications, for high temperature coating processes	For decorative/modern day pallet only	Functioning of Society, safety	Other inorganics/organics with no/lower hazard
	in alloys	For mechanical, electric or lowering temp of use	For decorative aspects only	Significant extend service life - Sust/Green deal, Safety	
	in rechargeable batteries	All for inherent properties eg electrical performance, safety and reliability, also under more	consumer goods	Digital/Electrical, Green. Functioning of Soci	Much research is ongoing in batteries but today not clear when a product with same robustness will appear
	in coatings	components in extreme environments eg aerospace, offshore, nuclear	civilian non -aeronautic applications	Functioning of Society, Safety	Validation of other coatings is slow due to lengthy validation process in aeronautic safety applications.
	In X-ray and IR detectors	unique properties for detectors	Uses where enhanced capabilities of these detectors are not required.	Functioning of Society, Safety	Alternatives are developped and used for several applications. Cd based detectors are used in those applcations were broaderspectrum and sensitivity is required. No

* essential or non-essential from the perspective of the definition presently used for this (based on Montreal protocol): MHC chemicals are only allowed *if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health*

Action: Assessment of impacts

7	CSS impact areas : estimated impact versus business as usual scenario								
8, 9 & 10	Use type	Business as Usual trend	% of total EU market (2020)	MAF of 10	Minimisation of SoCs	Restrictions for Professional uses for SVCH eligeable subst.	Non-essential use for MHC substances		Environmental footprint for Manufacturing phase only
	in photovoltaics	+	0.2	10%	100%				+++
	in ceramics and glass	-	0.6	100%	50%				+/-
	in pigments	-	11.5	100%	20%				-
	in alloys	+/-	2.5	100%	60%				+
	in rechargeable batteries	-	84.5	100%	100%				+/-
	in coatings	+/-	0.7	75%	10%				+
	In X-ray and IR detectors	+/-	0.01	10%	100%				+/-
11	% SUM of market at risk		100.01	100	89	2	0	0	

Howard Winbow: but Cd not generally available once incorporated into the article.

Howard Winbow: Pigments should be out of scope, unless some form of grouping is used.

Howard Winbow: almost no professiosnl uses for Cd, but pigments were subject to a failed Artist Paint Restriction attempt in 2014 which could be raisd again.

Action: Assessment of impacts

12	CONCLUSIONS: describe with your own words how the CSS would impact by use type and by CSS measure	
13	*By use type*	*Conclusion*
	in ceramics and glass in alloys in paints and coatings in batteries, PV, detectors and other EEE	Uses are, in the main, considered essential. Main threat would be the use of MAF (see below), possible SoC substitution issues relating to Cd concentrated in local ENV, and existing Member state/local interpretations of acceptable Cd in the environment re WfD, EQS, Drinking Water Quality. Risk of relocation of manufacturing/purchasing outside of EU = unethical export of EU pollution without control.
14	*By CSS measure*	*Conclusion*
	MAF of 10	Very difficult for the Cd industry as a whole to be able to cope with a MAF of 10 or 5. Our calcualtions show that even a MAF of 2 or 3 would give many RCRs above 1. Demonstrating safe use under REACH will therefore not be possible for production and most uses. If such a measure was also applied on the EQS under the Water framework Directive, the vast majority of EU water bodies could be considered at risk, because of the natural Background which is generally higher than the EQS/10 or EQS/5. As with REACH RCRs, even a MAF of 2 or 3 would be problematic, because of the small margin between background and PNEC/EQS. As a result, Cd production (from Zinc) in the EU would be challenging, which would affect the whole supply chain downstream, and could force reliance on import from outside the EU.
	Minimisation of SoCs	As above, some specific areas could be targeted - namely local concentration of Cd arising from microplastics. Ceramic/glass use more at risk from manufacture than the final article.
	Restrictions on prof. Uses	
	Non-essential use MHC1	
	Non-essential use MHC2	
	ENV footprint	
15	Questions : Please formulate hereunder the questions you would have for the Eurometaux CSS-team	
	Since the main concern identified is the MAF, we focus our comments and questions on this here, referencing the recent Arche summary report on impact assesssment:	
	The report concludes that "an Assessment Factor of 5 or more would affect to a large extent both the workers and the environmental scenarios with little option for improvement of the hazard assessment part." We think there is a risk with presenting a number in the conclusion in this way: it could be used by the regulators as a benchmark from the industry itself - 10 is a problem but a MAF of 5 or a bit lower is OK. As seen in the calculations, while such a MAF may be OK for some substances, a holistic multi metal advocacy approach should aim to protect all substances including the most challenging cases. Conversely of course these are often the most data-rich substances. The graphs presented by Arche showing % impact at different MAFs should not be translated into a compromise of 'sacrificing' a number of substances that could not meet certain MAF values.	
	The assessment correctly notes the small potential for refinement of the RCR at the effect level. However, it suggests that some improvement is possible at the exposure level, e.g. by using more monitoring data. Please note that this generalization is again not relevant for Zn and Cd, since we already rely mainly on monitoring.	
	The use of the added risk is mentioned as a possible solution. Please note that under the Water framework directive, the added risk approach is abandoned for metals using a bioavailability correction…	
	The stepwise approach for refining the assessment mentions a specific sectorial approach as an alternative. This is valid: we know very well how to do mixture tox assessment for the metals. However, while doing metals mixture assessment, we still don't address the effect of non-metallic substances…the big unknown in the regulators heads. Where is the hard evidence for this overall mixture tox, assumed by the regulators. We should challenge that assumption in the first place.	
	Level 4 of the same scheme introduces the ecological, biodiversity–based approach. This approach is surely valid, and may provide a solution. However, it is not sure that regulators will be ready to follow the ecological track, since it goes completely against the current methodology of PNEC/EQS setting, surely when, like in the cadmium case, the ecology demonstrates that the EQS are overly conservative.	
	For SOC the main issue for Cd chemicals is if grouping is used for 'Cd and Cd compounds', as we have seen in other proposals on eg CMD, REACH Restriction proposals. This would negatively affect applications like CdTe and Cd pigments.	

Mixture Assessment Factors MAFs:

why a problem for cadmium and other metals?

In REACH, 'safe use' is demonstrated by Risk Characterization Ratios, RCRs being <1

- RCRs are used to cover all end-points, populations, exposure routes and time scales, both environmental and human.
- RCRs are derived by comparing exposure levels to suitable predicted no-effect concentrations (PNECs) or derived no-effect levels (DNELs).

For the environmental end-points, this is the ratio of predicted environmental concentration (PEC) to PNEC:

$$RCR = \frac{PEC}{PNEC} \text{ or } \frac{Exposure}{DNEL}$$

- In a simplistic approach to deal with potential 'cocktail effect' of substances together in a given environment, the MAF would simply be applied to this ratio.

- Many RCRs for metals in HH or ENV are currently between 0.1-1.0. How many would go >1 with different MAFs applied?...

MAFs – Multi-metal impact for HH and ENV end points

Table 1: Number of CS exceeding a RCR of 1 at given MAF values

	Worker CS	Consumer CS	MvE CS	All Populations
Total number of CS	*4186*	*188*	*698*	*5072*
MAF value				
1	0 (0 %)	0 (0 %)	0 (0 %)	0 (0 %)
2	557 (13 %)	3 (2 %)	17 (2 %)	577 (11 %)
3	982 (23 %)	10 (5 %)	23 (3 %)	1015 (20 %)
5	1592 (38 %)	21 (11 %)	27 (4 %)	1640 (32 %)
10	2232 (53%)	32 (17 %)	35 (5 %)	2299 (45 %)

	Freshwater ES at risk	Soil ES at risk	Combined
No MAF	0 %	0 %	0 %
MAF = 2	19 %	20%	29 %
MAF = 3	39 %	35 %	47 %
MAF = 5	52 %	41 %	63 %
MAF = 10	65 %	57 %	76 %

Summary of top new priority issues identified:

1. **‘Substances of Concern (SoC)’: New concept, not fully defined.**
   - For Cd – to be watched but already several are SVHC.
2. **‘Essential Uses (EU)’: New concept, not fully defined.**
   - For Cd, to be watched but many Uses are covered by Restrictions with Essential Uses niche applications remaining**.**
3. **‘Mixture Assessment Factor (MAF)’: re-emerging topic.**
   - Approach to combined toxicity will be critical for many substances… technical and political advocacy needed..

... plus Endocrine Disruptors (EDs)

- Appears in 5 action areas, including to include in REACH, CLP, SDSs!
- More in later slides.

Zero Pollution Action Plan - scope

Prevent and reduce pollution to waters and oceans and facilitate remediation

Prevent and reduce air and noise pollution

Prevent and reduce soil pollution and facilitate remediation

European Commission



Non-exhaustive list of impact assessments or evaluations announced or planned under the Zero Pollution Action Plan to be delivered between 2021-2023

- Ambient Air Quality Directive
- Water Framework and Directive (incl. Priority Substances / Groundwater)
- Urban Wastewater Directive
- Sewage Sludge Directive
- Bathing Water Directive
- Marine Strategy Framework Directive
- Industrial Emissions Directive (IED) & EPRTR
- Review of the Energy Taxation Directive
- Review of the Alternative Fuels
- Infrastructure Directive
- Implementing and delegated acts for the Taxonomy Regulation

Update on REACH

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

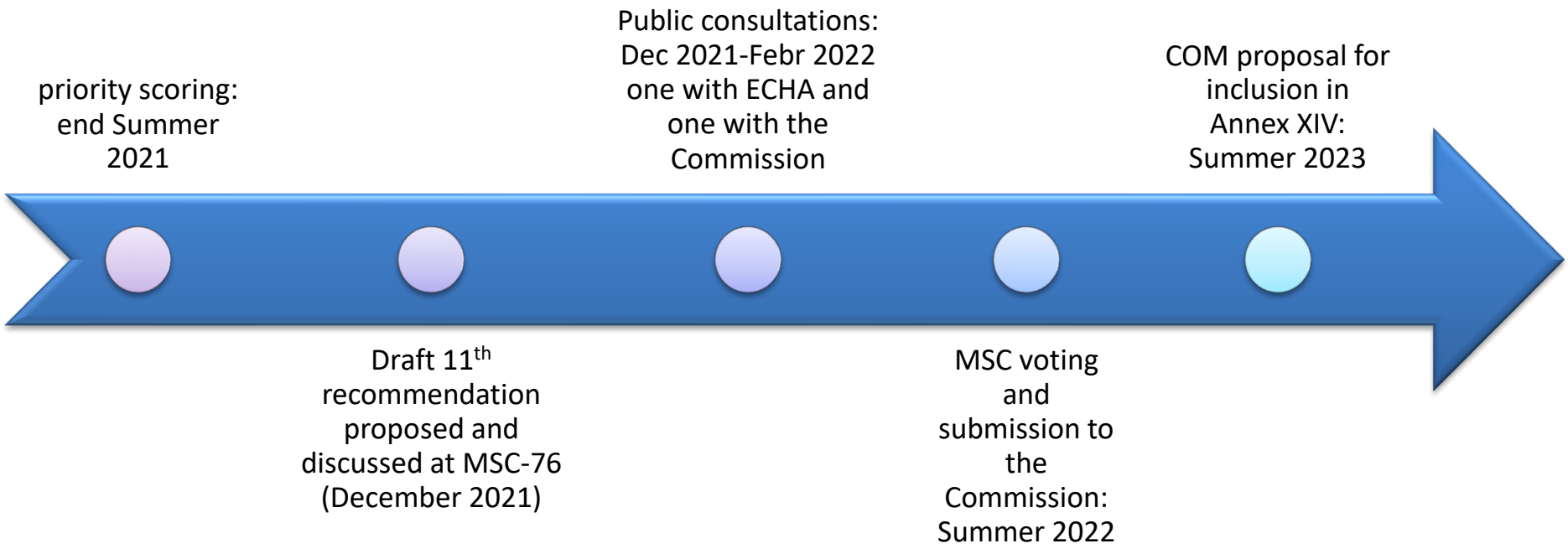
Update on REACH

Authorization procedure

Cadmium substances

Authorization
Draft recommendation listing: 11th list

Cd-substances (notably $Cd(OH)_2$, CdO & Cd) might be nominated in the 11th recommendation-list of ECHA



Update on REACH

Update of REACh files (MISA)

Exposure scenarios are not reflecting the reduced cadmium exposure!

Exposure assessment and risk characterisation:

- It was agreed with ECHA to revise the exposure scenarios of the Cd substances with highest tonnages: the Cd, CdO and $Cd(OH)_2$ dossiers first
  - Dossiers submitted on November 30th 2020
- EBRC have started working on the remaining compounds
  - checking on already collected data
  - further questionnaires may follow if needed
- EBRC is coordinating with ARCHE for the environment part
- Aim to finish work by Q3

Endocrine disruptors

- Will cadmium be classified as endocrine disruptor?

Regulatory background

- Revision of CLP and REACH regulations:
  - Revision of CLP hazard criteria: (Q4 2021?)

  Draft proposals for the introduction of hazard classes for endocrine disruptors in the CLP regulation

  - Category 1: Known or presumed endocrine disruptors (ED HH 1 and ED ENV 1)
  - Category 2: Suspected endocrine disruptors (ED HH 2 and ED ENV 2)

  - Revision of REACH: (Q1 2022?)

  Information requirements to include endocrine disrupting properties

- CASG ED sub-group
  - Last meeting on 22 March 2021
  - Opportunity to comment on the REACH and CLP draft proposals in April 2021

Preliminary literature screening for HH

- Evidence of ED activity for Cd (mainly *in vitro* and i.p. studies)
- **No solid evidence** from *in vivo* / epi studies

- Cadmium-induced toxicity by *various mechanisms:* ROS production, competition with other metal ions, etc.
- Mechanisms and specific pathways of cadmium toxicity are intertwined
- Plausible that other mechanisms play a **more prominent role** at environmentally relevant exposure conditions

In-depth systematic literature review and ED testing will probably be required

Cadmium probably concerned

Three conditions for ED identification:

a) evidence of endocrine activity. ✓ (mainly *in vitro*, i.p.)

b) evidence of an adverse effect. ✓ (mainly *in vitro*, i.p.)

c) biologically plausible link between ED activity and adverse effect. ✗ Difficult to determine

("endocrine MoA")

→ confounding with repro effects, how to distinguish?

Focus limited to EATS modalities : Estrogen, Androgen, Steroid(-ogenesis) and Thyroid

Impact of ED classification

Increased costs

- Systematic literature review (HH & env)
- Additional ED testing

If classified

- Substance added to SVHC list: however, Cadmium metal, nitrate, hydroxide, carbonate, sulfate, fluoride, chloride, sulfide and oxide are already on it
- Additional labelling: ED specific hazard statement
- Mentioned on SDS

Level 1	Existing data/in silico modelling
Level 2	In vitro assays (endocrine mechanisms and pathways)
Level 3	In vivo assays (endocrine mechanisms and pathways)
Level 4	In vivo assays (adverse effects on relevant endocrine endpoints)
Level 5	In vivo assays (further testing of relevant endocrine endpoints)

Label elements of endocrine disrupting properties for the environment

Classification	Category 1	Category 2
Symbol/pictogram		
Signal Word	Danger	Warning
Hazard Statement	EUHXXX: May cause endocrine-related adverse effects on the environment	EUHXXX: Suspected of causing endocrine-related adverse effects on the environment
Precautionary Statement Prevention	P273	P273
Precautionary Statement Response	P391	P391
Precautionary Statement Storage		
Precautionary Statement Disposal	P501	P501

Label elements of endocrine disrupting properties for human health

Classification	Category 1	Category 2
Symbol/pictogram		
Signal Word	Danger	Warning
Hazard Statement	EUHXXX: May cause endocrine-related adverse effects on human health	EUHXXX: Suspected of causing endocrine-related adverse effects on human health
Precautionary Statement Prevention	P201 P202 P260	P201 P202 P260
	P263 P264 P270 P280	P263 P264 P270 P280
Precautionary Statement Response	P308 + P313	P308 + P313
Precautionary Statement Storage	P405	P405
Precautionary Statement Disposal	P501	P501

IZA/ICdA actions so far

- Provided comments on REACH and CLP draft proposals to EM (submitted to EC)
- Following the developments and documents published by the members, experts, and stakeholders of the (CARACAL) sub-group on Endocrine Disruptors.
- Initial literature survey on ED effects of Cd
- In contact with consultants who could perform a systematic review should it be required.
- In contact with labs (Charles River NL) should additional ED testing be required.

Next steps provide comments during public consultation, impact assessment, etc.

Indicative timings

CLP review

- Inception Impact Assessment (roadmap) for 4 weeks stakeholder consultation –April 2021
- Public stakeholder consultation for 12 weeks is planned in all EU languages –Q2 2021.
- Supporting actions –Q1 2021 to Q3
- Impact Assessment – Q42021
- Drafting proposal for revision of CLP : 2022

REACH review

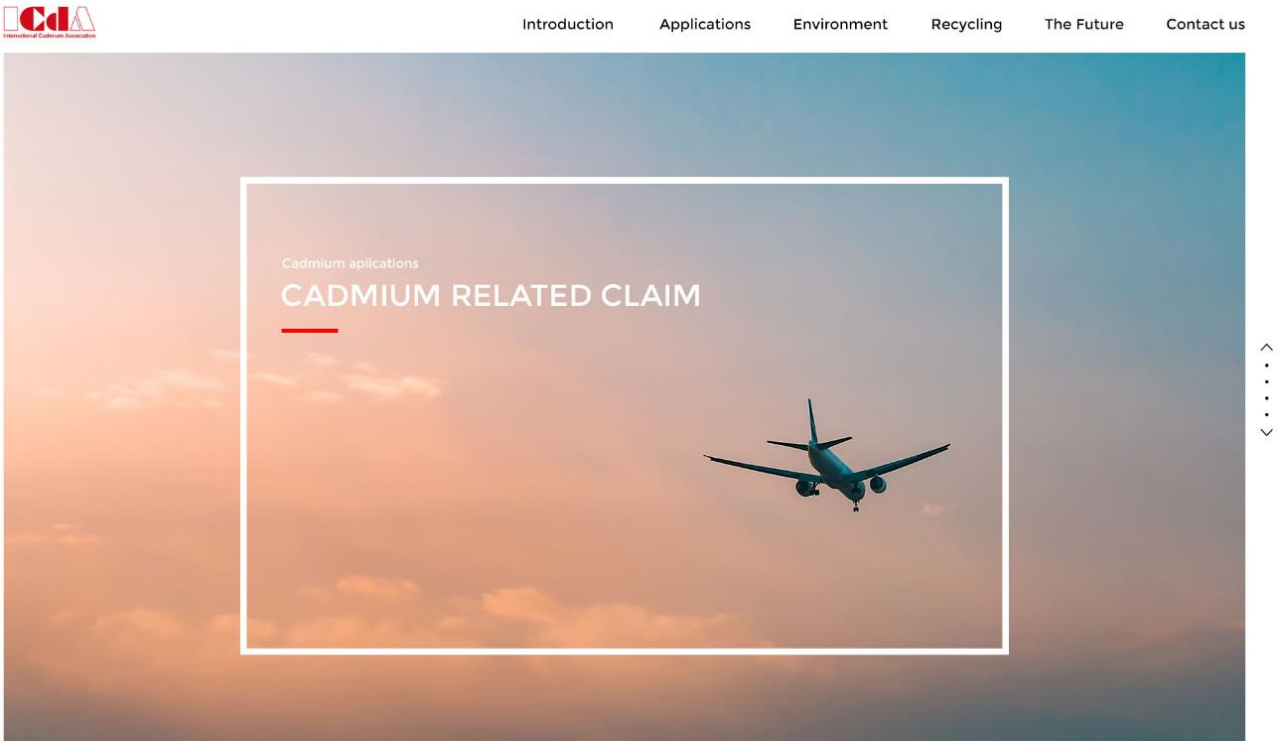
- Inception Impact Assessment (roadmap) for 4 weeks stakeholder consultation – April-May 2021
- Supporting actions and studies – Q1 2021 to Q1 2022
- Impact Assessment – Autumn 2021 to Summer 2022
- Open public consultation for 3 months – January-March 2022
- Drafting proposal for revision of REACH – 2022
- Commission adoption of proposal – end 2022

Positive communication on cadmium

- Website renewal
- Application sheets

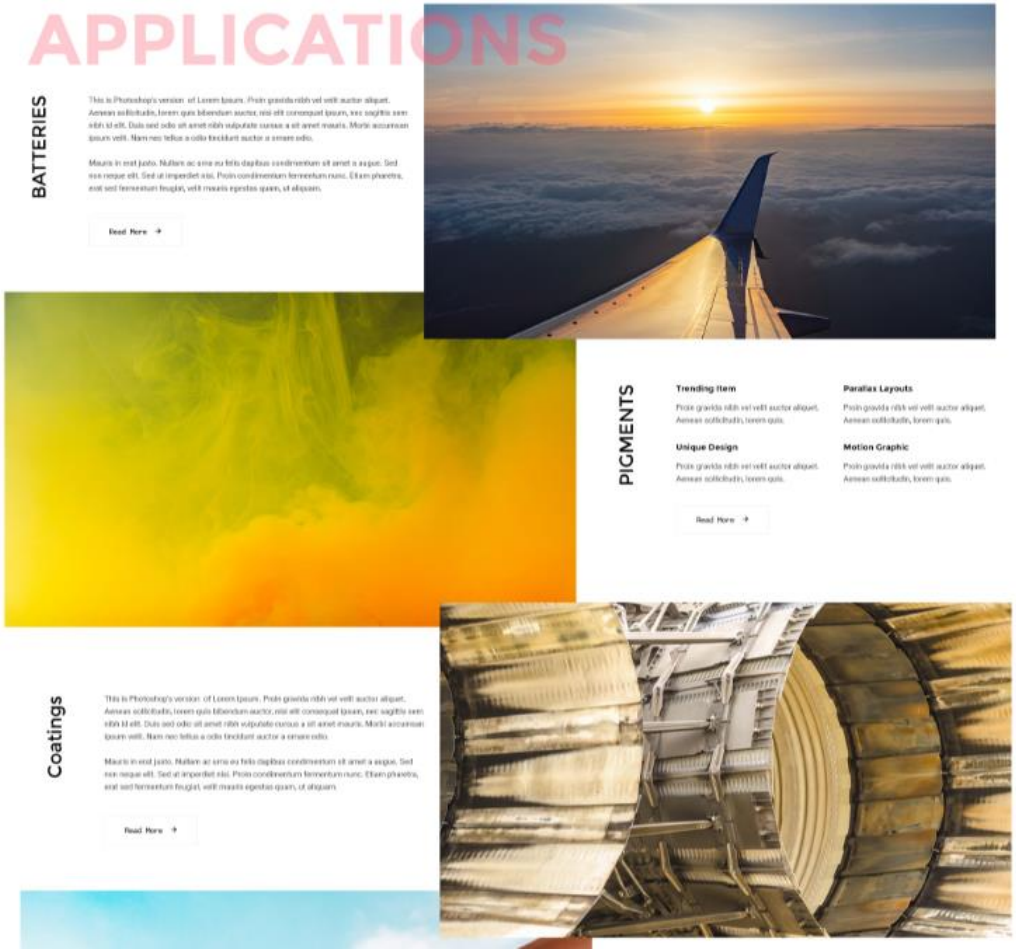
6

ICdA website renewal



- Introduction page with horizontal table of content on top.
- Focus on positive aspects of applications.
- Members pages will be copied from old website but with little attention for esthetical redesign.

ICdA website renewal



- Scrolling intro page from where the different applications can be opened.
- Appealing images for each application.
- Drafting NiCd battery sheet ongoing with copywriter.
- Once approved, same style will be applied to the other application sheets.
- Review and approval of each application sheet by members

Application sheets

- NiCd batteries
- Pigments
- CdTe PV cells
- Cd coatings
- Cd alloys
- IR detectors

- A two-pager per application
  - Unique properties
  - Benefits to society
  - Safe manufacturing and use
  - End of life recycling
- Members are invited to share appealing images for their applications.
- Published on website
- Members can make printout leaflets for their business

Before going home…

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