

June 8th 2010

5th ICdA H&S Ctee

Objective of the Meeting

Patrick de Metz

Objective of meeting

❑ Reminder:

- The H&S Ctee was set up **primarily** to assist ICdA members with the implementation of the ICdA Guidance document
- “ICdA Guidance on the management of the risk related to chronic occupational exposure to cadmium and its compounds”

❑ Source of this initiative:

- Cd/CdO risk assessment (RA) shows a conclusion that there is a risk to workers under current management methodologies (2007)

Past (and future) H&S Ctees

- ❑ Launch of the committee, definition of the format and content
 - 1st Ctee, dated Nov 25th, 2008
- ❑ Measuring air quality
 - 2nd Ctee, dated March 10th, 2009
- ❑ Medical supervision adapted to cadmium risk
 - 3rd Ctee, dated June 16th 2009
- ❑ Individual and collective hygiene procedures
 - 4th Ctee, dated October 13th, 2010
- ❑ Detailed procedures regarding medical surveillance
 - 5th Ctee, dated June 8th: 2010
- ❑ Choosing and maintaining the right PPE
 - 6th Ctee, date provisionally set on Oct 19th 2010
- ❑ Implementing a prevention culture in our facilities
 - 7th Ctee, date to be set:

Today's meeting contents

- ❑ A follow-up of the meeting dated June 16th 2009 on the principles of medical supervision described in the ICdA Guidance
- ❑ This meeting will focus on detailed implementation issues related to the medical surveillance program

Today's meeting structure

- ❑ Review of questionnaire
- ❑ Discussion on some key points of questionnaire and ancillary points
- ❑ Selection of best implementation option when feasible
- ❑ Purpose is to leave the meeting with some practical guidance on several key implementation details

June 8th 2010

ICdA Guidance document

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Link with other legislative work

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Link with other legislative work

- ❑ Direct work with SCOEL work which has a mandate to propose:
 - OEL: sumdoc: 8hr TWA [Cd-air] = 4µg/m³ resp
 - BLV: sumdoc: [Cd-U] = 2µg Cd/g creatinine
 - Experience shows that implementing the Swedish program will get all workers with [Cd-U] < 2, after X years!
- ❑ Direct link with REACH which requires that the registration file proposes risk management measures:
 - When a health based OEL is set at EU level, it can be retained as the DNEL (for workers) for the REACH dossier
 - Producers and downstream users have to comply with RRM
- ❑ Direct link with OEL setting initiatives in Member States:
 - France (AFSSET): presentation made to convince AFSSET that we are on the right path to comply with SCOEL's proposals
 - Germany
 - Others...

June 8th 2010

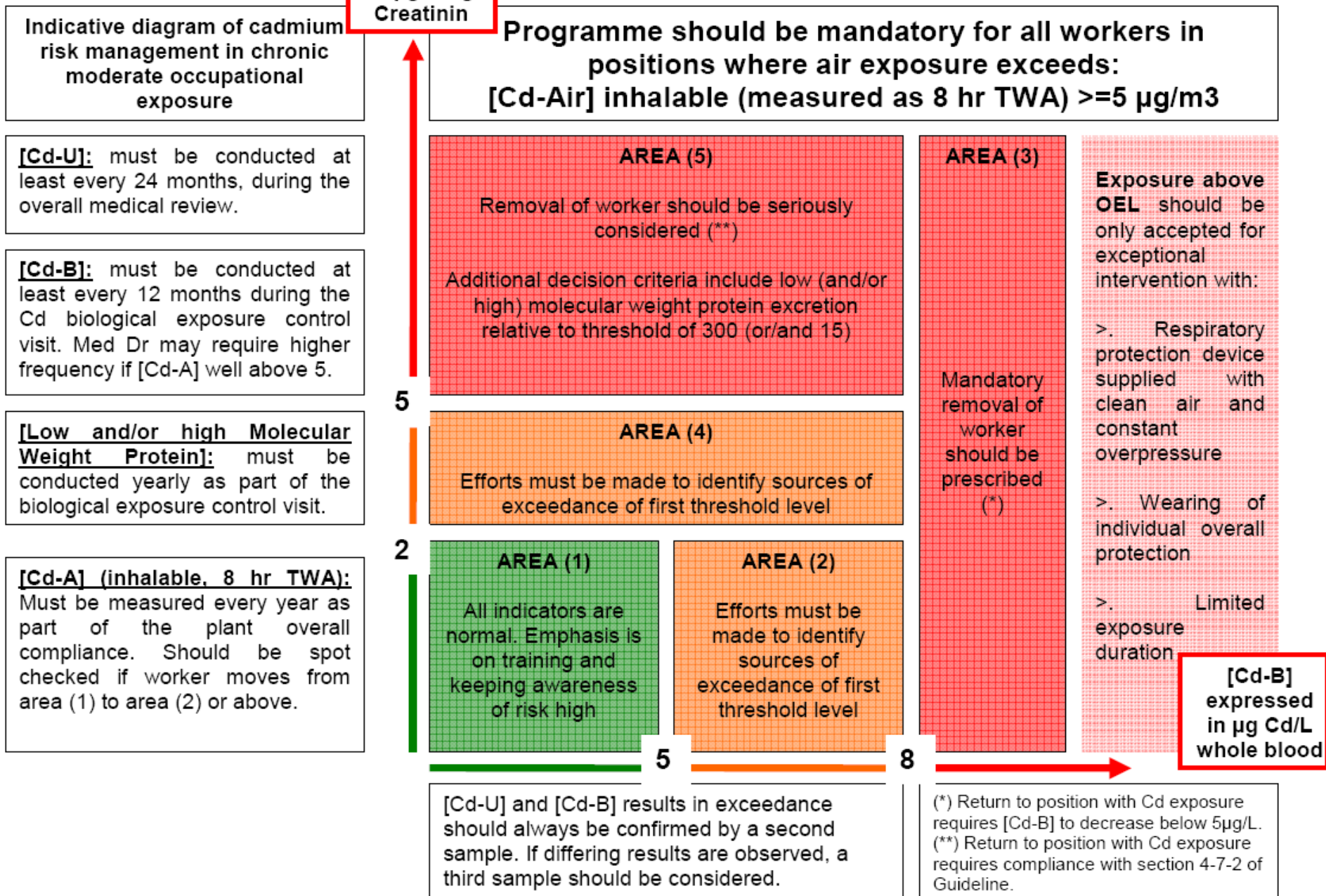
ICdA Guidance document

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*The decision diagram of
ICdA/Swedish regulation*

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TABLE 1



Health & Safety Committee

"MEDICAL SURVEILLANCE QUESTIONNAIRE-CADMIUM MONITORING" – June 2010

PLEASE DO NOT INCLUDE ANY COMMERCIALY-SENSITIVE INFORMATION IN YOUR REPLY!

No individual files will be shared between members. The questionnaire was designed so that no confidential information is asked

Company & plant details

Company: _____ Plant name and city: _____ Country: _____
 Main activity: Primary Metals ☐ Chemicals ☐ Batteries ☐ Pigments ☐ Recycling ☐ Other (please specify) _____
 Contact person for this questionnaire: _____ Telephone: _____ Fax: _____ E-mail: _____

INTRODUCTION

This questionnaire is generated to illustrate implementation details of the ICdA medical surveillance programme, which is itself based on the current Swedish regulation.

You may or may not be implementing this programme currently. Nevertheless it is the recommended programme generated by ICdA in 2006, submitted to the Commission during the Risk Reduction Strategy development process in 2007 and incorporated in the EU official risk reduction strategy as published in the OFEU (Official Journal of the EU) in June 2008.

Whether you are or are not implementing this programme, your views are welcome on the best way to implement it. So in any case your input is "of value to us".

Please find attached the decision graph supplied in the ICdA Guidance.

1. BIO-MONITORING BASICS

1.1. What is the unit you currently use to monitor Cd-U?

Non-corrected measure:

- a. ☐ µg Cd/L
- b. ☐ nmol Cd/L

Creatinin corrected measure:

- c. ☐ µg Cd/g creatinin
- d. ☐ nmol Cd/mol creatinin
- e. ☐ Other describe _____...
- f. ☐ We do no monitor Cd-U of our workers

1.2. What is the unit you currently use to monitor Cd-B?

- a. ☐ µg Cd/L
- b. ☐ nmol Cd/L
- c. ☐ Other describe _____...
- d. ☐ We do no monitor Cd-B of our workers

1.3. Which protein do you track to measure protein excretion (and efficiency of re-absorption in the kidney tubule)? Please state which marker and reason for selection:

- a. ☐ RBP
- b. ☐ α1-microglobuline
- c. ☐ β2-microglobuline
- d. ☐ Several of the above describe _____...
- e. ☐ We do no monitor protein excretion of our workers

1.4. The ICdA Guidance states Cd-U must be measured at least every other year, do you feel:

- a. ☐ This is too low state your recommendation _____
- b. ☐ This is too high state your recommendation _____
- c. ☐ This is fine
- d. ☐ Our current Cd-U testing frequency is _____

1.5. The ICdA Guidance states Cd-B must be measured at least once a year, and possibly more depending on the situation:

1.5.1 For Cd-B, frequency should be:

- a. ☐ Between once and twice a year
- b. ☐ Between once and four times a year
- c. ☐ Other describe _____...
- d. ☐ Our current Cd-B testing frequency is _____

1.5.2 Frequency decision for Cd-B testing should be based on:

- a. ☐ Measured Cd-air level at the workplace
- b. ☐ Risk of increase of Cd-air (for any reason, such as machinery malfunction, ...) level at the workplace
- c. ☐ Level of Cd-U or Cd-B or protein excretion for the worker
- d. ☐ Other criteria which are _____

Health & Safety Committee

"MEDICAL SURVEILLANCE QUESTIONNAIRE-CADMIUM MONITORING" – June 2010

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2. REMOVAL AND RETURN TO WORK

2.1. The ICdA Guidance states there are three areas in bio-monitoring: Green (all is fine), Orange (enhanced surveillance) and Red (removal from exposure), with associated Low and High action levels of Cd-U and Cd-B (see ICdA decision table):

- a. I agree with this concept Yes. ☐ No. ☐
 b. This concept is already implemented Yes. ☐ No. ☐

2.2. What should be done when the Low Action Level is exceeded (several boxes can be checked)? (This is the moving from Green zone to Orange zone)

- a. ☐ Medical doctor to speak to worker about procedures
 b. ☐ Management to be informed and to speak to worker about procedures
 c. ☐ Management to be informed of plant area and to check Cd-air levels
 d. ☐ Other describe _____

2.3. What should be done when the High Action Level is exceeded (several boxes can be checked)? (This is the moving from Orange zone to Red zone)

- a. ☐ Nothing, associated Cd-U or Cd-B value to be retested before any decision
 b. ☐ Medical doctor to make an educated decision about Cd exposure removal
 c. ☐ Automatic removal
 d. ☐ Management to be informed and to check Cd-air levels
 e. ☐ Other describe _____

2.4. Swedish/ICdA medical surveillance programme have more flexibility for exposure removal based on Cd-U exceedance than for exposure removal based on Cd-B exceedance:

- a. I agree with this concept Yes. ☐ No. ☐
 b. What do you think the reasons should be? _____
 Identifying parameters which give flexibility to exposure removal when approaching CdU High situation:
 c. Under which conditions should CdU removal be decided if CdU has not yet reached 5?: describe _____
 d. Under which conditions should CdU removal not be undertaken even if CdU is exceeding 5?: describe _____

2.5. On which basis should 'return to work' be decided?

- a. ☐ Essentially on Cd-B level which one? _____
 b. ☐ Essentially on Cd-U level which one? _____
 c. ☐ Other describe _____

3. MEDICAL SURVEILLANCE

No recommendations are made in the ICdA Guidance regarding the following points.

Nevertheless, we would welcome the sharing of your current experience.

3.1. Are there pre-existing conditions which may make an employee (possibly someone in the hiring process) not fit for cadmium exposure?

- a. ☐ Pre-existing Cd-U above a certain level
 b. ☐ Pre-existing kidney dysfunction
 c. ☐ Heavy smoker
 d. ☐ Other describe _____
 e. Can one of these conditions lead to not hiring an outside candidate Yes. ☐ No. ☐

3.2. How do we deal with temporary workers and the medical surveillance programme?

- a. ☐ We only hire people with excellent health situation relative to Cd risk Yes. ☐ No. ☐
 b. ☐ We integrate them in the normal programme Yes. ☐ No. ☐
 c. ☐ We check them with a higher frequency as they are not familiar with this special environment Yes. ☐ No. ☐
 d. ☐ We make bio-monitoring before they leave the plant so we are sure about their status when leaving Yes. ☐ No. ☐

3.2. Remeasuring after exceeding the first CdB threshold:

3.2.1. If an employee exceeds the first CdB threshold (5µg Cd/L) at what frequency should we measure CdB? :

- ☐ Monthly ☐ Every 3 months
☐ Every 6 months ☐ Every 12 months
☐ Other describe _____

Health & Safety Committee

"MEDICAL SURVEILLANCE QUESTIONNAIRE-CADMIUM MONITORING" – June 2010

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3.3. Remeasuring after exceeding the second CdB threshold:

3.3.1. If an employee exceeds the second CdB threshold (8µg Cd/L) at what frequency should we measure CdB? :

- | | |
|---|--|
| <input type="checkbox"/> Monthly | <input type="checkbox"/> Every 3 months |
| <input type="checkbox"/> Every 6 months | <input type="checkbox"/> Every 12 months |
| <input type="checkbox"/> Other describe _____ | |

3.4. Return to work:

3.4.1. What criteria should be evaluated before returning an employee to work after medical removal? :

- | | |
|---|---|
| <input type="checkbox"/> CdU < 5 | <input type="checkbox"/> CdB < 5 |
| <input type="checkbox"/> βMG-U or RBP-U < 300 | <input type="checkbox"/> Complete blood count |
| <input type="checkbox"/> Urinalysis | <input type="checkbox"/> Pulmonary function tests |
| <input type="checkbox"/> Medical History and conditions | <input type="checkbox"/> Work history |
| <input type="checkbox"/> Smokers | <input type="checkbox"/> Other describe _____ |

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ICdA Guidance document

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Some key implementation points

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Plan



□ General rules

- Zones, markers and correction
- Frequency
- Communication
- Entering the program
- Changing zone
- Removal from exposure
- Bio-monitoring while removed from exposure
- Returning to work

General rules

❑ Concepts:

- Three zones -- two zones?
- Cd-U only – Cd-B (as advanced marker) and Cd-U (as cumulative marker)?

❑ Measurements:

- Cd-U uncorrected – Cd-U corrected for creatinine (proxy for dilution or urine in water)?

❑ Frequency:

- Cd-U yearly (or more) -- every other year (or less)?
- Cd-B yearly -- or more depending on measure of risk at workplace?

❑ Biomarker communication to worker (if all good):

- By medical doctor -- by nurse?

Entering the program

- Determination of fitness before assigning to work:
 - Which tests?
 - Which conditions?
 - Impact of smoking status
 - If new employee: can this lead to a “no hire” decision?
- Higher [Cd-B] frequency for newcomers?
 - Issues and benefits?

Changing zone

- ❑ Only if action level is exceeded

Or

- ❑ If speed of CdB (or CdU) change from earlier result is abnormal

Changing zone

- When Green to Orange change:
 - Second measure or immediate communication?
 - Communication to worker by Dr. -- Nurse?
 - Communication to management of area -- of ID?
 - Dr. to remind worker of risk and prevention measures?
 - Management to check area compliance?
 - Management to remind worker of risk and prevention measures?

Changing zone

- When Orange to Red Change (1):
 - Second measure or immediate communication?
 - Communication to worker by Dr. -- Nurse?
 - Communication to management of ID?
 - Dr. to remind worker of risk and prevention measures?
 - Management to check area compliance?
 - Management to remind worker of risk and prevention measures?

Changing zone: removal from exposure

- When Orange to Red change (2):
 - If Cd-B exceedance:
 - ✓ Removal mandatory or recommended?
 - ✓ second measurement or immediate removal?
 - If Cd-U exceedance:
 - ✓ Removal mandatory or recommended?
 - ✓ If recommended, on what basis can a worker stay exposed?
 - ✓ second measurement or immediate removal?

Bio-monitoring while removed from exposure



Return to work



June 8th 2010

Second OCdBIO (2009 data)

*Occupational Cadmium Bio-
monitoring observatory*

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Second OCdBIO (data 2009)

□ Reminder:

- Anonymous data sent to ICdA as trustee,
- Data aggregated across all respondents and shared with Pr Bernard,
- Pr Bernard to conduct a review and present us with results in the next H&S Ctee with an assessment.

□ Changes over last year:

- Additional column specifying the number of workers medically removed from Cd exposure for each Cd-U category,
- No other changes.



- Second OCdBIO - Occupational Cadmium Bio-monitoring Observatory

Period covered: 2009

DATE :
COMPANY / GROUP :
SITE :
CONTACT PERSON :
TELEPHONE :
EMAIL :

LABORATORY NAME :

Recommendations

1. All workers having been controlled for Cd in 2009 are included in the study,
2. For those plants where Cd-U is not taken every year, please include 2008 (if Cd-U taken every other year) or 2008 and 2007 (if Cd-U taken every third year),
3. Indicate clearly below whether the urine-data for which creatinine is outside the 0.3 µg/L to 3.0 µg/L range are excluded (outside of this range, creatinine correction is incorrect)
4. In case of several measurements, report the latest one,
5. Indicate on top of this sheet the name of the laboratory performing the analysis.

Cd in Blood µg/L whole blood	Number of workers
0.00-2.00	
2.01-3.00	
3.01-5.00	
5.01-7.00	
7.01-8.00	
8.01-10.00	
>10.00	
Total workers	

Cd in Urine µg/g creatinine	Number of workers	Of which number of workers medically removed from Cd exposure
0.00-1.00		
1.01-2.00		
2.01-3.00		
3.01-5.00		
5.01-7.00		
7.01-10.00		
>10.00		
Total workers		

With regard to the urinary cadmium which should be standardized relative to creatinine concentration in order to correct for possible dilution, please confirm that you have used a screening test on the urinary creatinine value: **YES / NO**

If your answer to the above question is positive, please indicate if this screening test is (please circle the right answer):

1. the screening suggested on p 22 of the ICdA Guidance, which is: [urinary creatinine] > 0.5 g/L?
2. the screening proposed by Pr Bernard, which is: [urinary creatinine] > 0.3 g/L **AND** [urinary creatinine] < 3 g/L
3. another screening test, please describe:

Please send the completed questionnaire, as soon as possible, and before June 25th to:

ccanoo@cadmium.org

The data received will be treated confidentially and only forwarded for assessment as aggregated values

CONFIDENTIAL – ICdA Trustee function

Occupational Limit Values for Cadmium

Development in Germany

The AGS

Committee on Hazardous Substances (AGS)

- Based on § 21 Hazardous Substances Ordinance
- Tripartite Committee advising **Federal Ministry of Labour and Social Affairs**
 - OSH-measures (incl. classification and labelling)
- 21 members
(representatives of social partners, enforcing authorities, statutory insurance and others)
- Two meetings each year

The AGS

Committee on Hazardous Substances (AGS)

Composition of the AGS

- 5 Representatives of Industry
- 5 Representatives of Employees (Unions)
- 3 Representatives of the Obligatory Insurance
- 3 Representatives of the Federal States
- 5 Independant Experts

Members appointed by the Federal Minister of Labour and Social Affairs.

The AGS

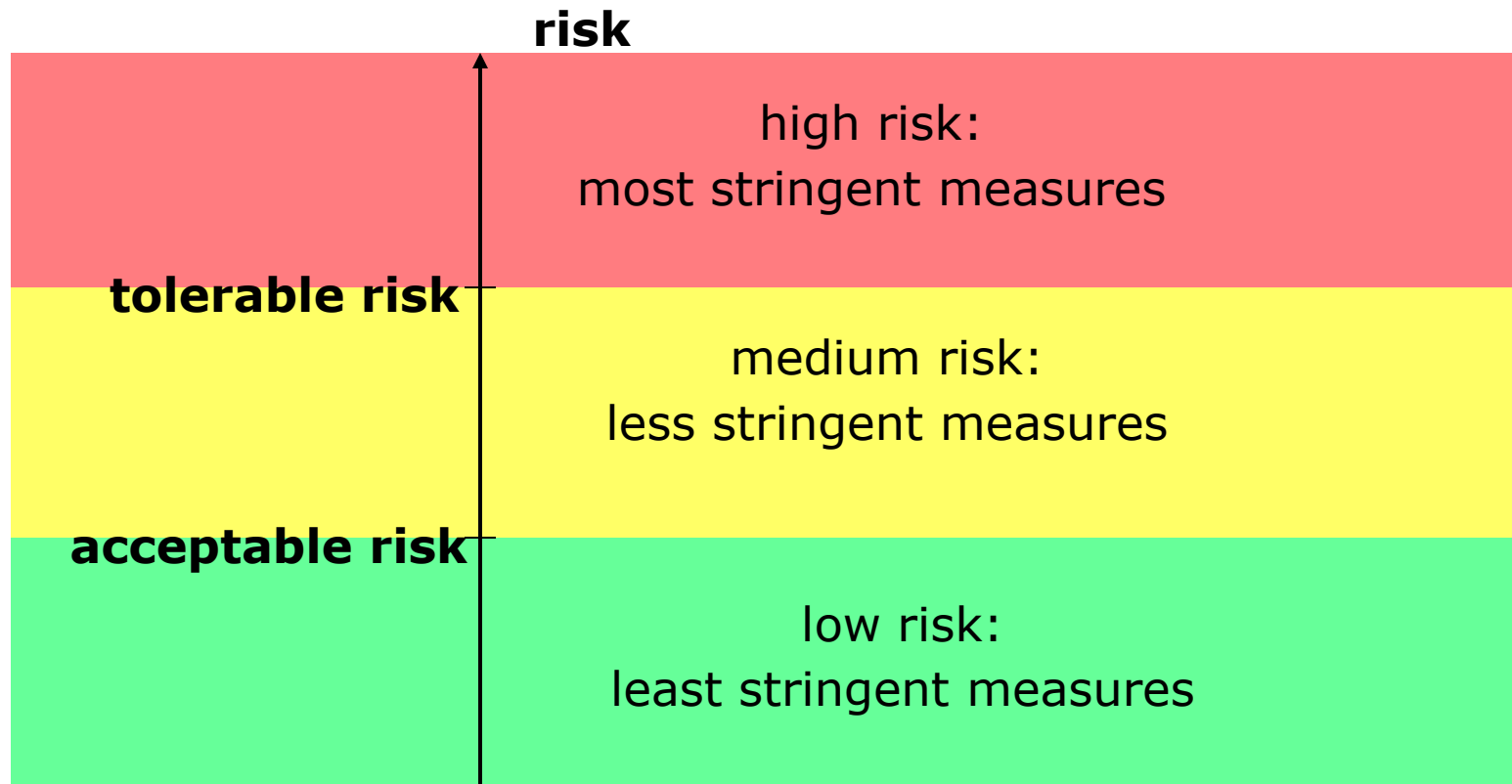
Committee on Hazardous Substances (AGS)

- **3 subcommittees** assisted by **working groups**
 - Hazard management (I)
 - Protection measures (II)
 - Hazard risk assessment (III)
- in addition
subcommittee occupational medicine (together with the committee for biological agents - ABAS)
- **Project groups**

New OEL System for Carcinogens

- **introduction of three risk bands** (in comparison to two risk bands under the old system)
- **definition of a substance-independent set of control measures; each individual type of measure graded according to the three risk bands**
- **derivation of two substance-independent risk limits** (“acceptable risk” and “tolerable risk”)
- **as basis for two substance-specific concentration values per carcinogen**

New OEL System for Carcinogens



New OEL System for Carcinogens

Framing conditions for derivation of risk-based limits

- ▶ assumption of continuous exposure during whole working-life (i.e. 8 hours/day, 240 days/year, 40 years)

upper risk-based limit (“tolerable risk”)

- ▶ 4 : 1,000

lower risk-based limit (“acceptable risk”)

- ▶ 4 : 100,000 (starting 2018 at the latest)
- ▶ 4 : 10,000 (for a transitional period of at least until 2013, at most until 2018)

New OEL System for Carcinogens

■ Obligations for actual exposure above “tolerable concentration”

- ▶ lowering of actual exposure below “tolerable concentration” within three years
- ▶ deriving an action plan
- ▶ informing of enforcement agency; yet no permission needed within those three years
- ▶ additional control measures.

■ Obligations for actual exposure below “acceptable concentration”

- ▶ (basic) occupational hygiene
- ▶ minimization of actual exposure not obligatory, but left to agreements at company level instead

Status Discussion on Cadmium

Proposed values for Cadmium in UA III:

	Cd in Air (respirable Part)	Cd in Urine
"Point of Departure": BMD10, lunge cancer, rat (Cadmiumchloride), Takenaka et al., (1983)	40 µg/m ³	
4:1.000 (Tolerable Risk)	1.6 µg/m ³	<= 2 µg/g Creatinine
4:10.000 (Akzeptable Risk until 2013)	160 ng/m ³	<< 2 µg/g Creatinine
4:100.000 (Akzeptable Risk after 2013, latest 2018)	16 ng/m ³	

Proposal is discussed in the working group „Metals“ of subcommittee III

Status Discussion on Cadmium

Statement of Our Representative in UA III:

- Proposal is based on one study only
- Methodological weakness of the derivation of the values
- Concentration in air is not the most reliable values at so low concentrations. Proposal to focus more on biological values
- Proposal to use the ICdA risk management strategy as an alternative
- **No decision about new values before the deadline of REACh registration of Cadmium.**

