



A pragmatic risk assessment tool for assessing risks related to carcinogens

Josje Arts – Nouryon (former AkzoNobel Chemicals)

Nouryon

- **Nouryon** (former AkzoNobel Chemicals) produces a whole array of specialty chemicals
- This global company has ~10,000 employees and 90 production units worldwide
- Carcinogens are occasionally used in production processes (e.g. formaldehyde is used to produce certain chelating agents (non-classified))
- As a sustainable company we try to protect our workforce, consumers and the environment (**Priority Substances Program** – phase out or restricted use of chemicals; since 2011)
- As an (inhalation) toxicologist I am dedicated to assess risks of chemical exposure

Hazard x Exposure = Risk

Hazard assessment : 1. Classification
 2. OEL

EU-CLP Regulation:

- Acute toxicity: cat. 1, 2, 3, 4
- Irritation: cat. 1, 2A, 2B
- Sensitization: cat. 1A, 1B
- STOT SE/RE: cat. 1, 2

All based on: **POTENCY**

EU-CLP Regulation:

- CMR: cat 1A, 1B, 2

Based on: EVIDENCE

Cat. 1A: evidence in humans

Cat. 1B: strong evidence in animals

Cat. 2: limited evidence in animals

Mixtures

Cat .1A: 0.1%

Cat. 1B: 0.1%

Cat. 2: 1%

Thus: **not based on POTENCY**

Carcinogenic substances in NL

- Official list of carcinogenic substances and processes
- Based on:
 - Annex VI (cat. 1A and 1B)
 - and as concluded by the Dutch Health Council (e.g. ethanol)

Examples:

- Ethanol OEL: 260 mg/m³ (130 ppm)
- Formaldehyde OEL: 0.15 mg/m³ (0.12 ppm)

Other countries (mainly):

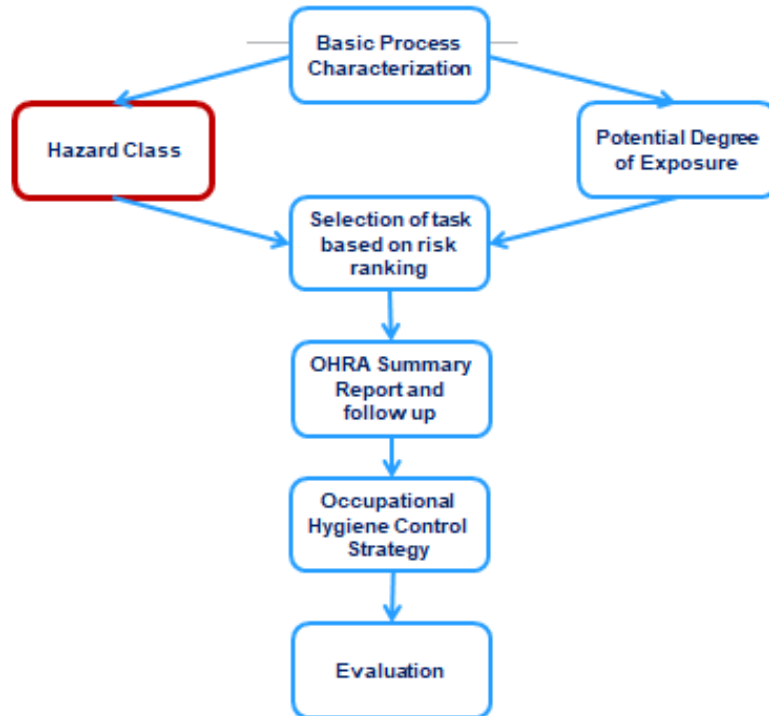
500-1000 ppm
0.3-0.5 ppm

Factor ~1000 difference in potency

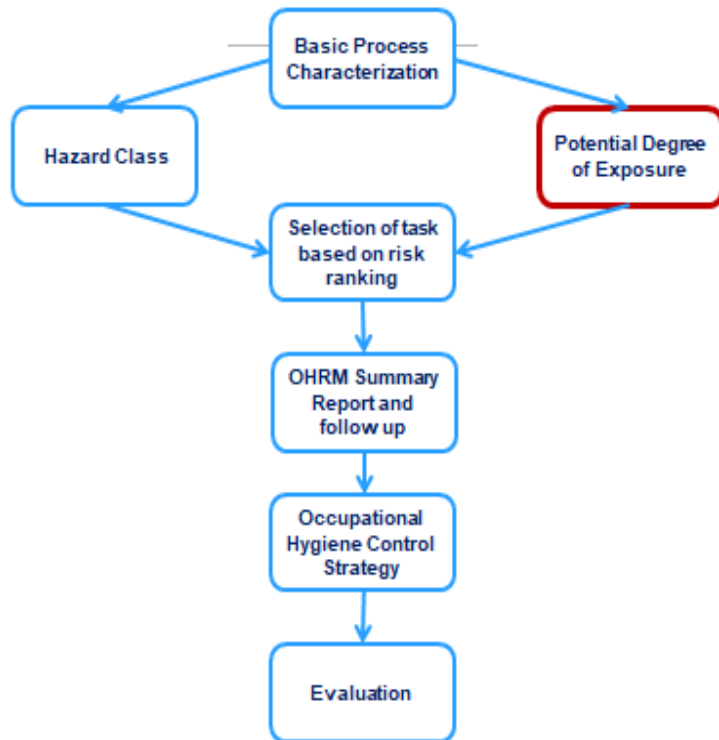
Occupational Hygiene Risk Management (OHRM)Tool

- Started in 2011 – at that time, many substances were not REACH registered yet
- However, Dutch Labor Inspectorate wanted to have information on:
 1. An inventory of all chemicals in the workplace, including their hazards
 2. Evaluation of the risks
 3. Appropriate measures to control the risks
 4. How to safeguard the entire system
- OHRM tool accepted as good practice by the **Dutch Labor Inspectorate**

OHRM: Hazard class (HC); assigned by toxicologist



OHRM: Potential Degree of Exposure (PDE); assessed by technicians



Six determinants for inhalation exposure:




- Material Characteristics [MC]
- Manual Interaction [MI]
- Quantity Handled [QH]
- Aerosol Dispersion [AD]
- Duration of Task [DT]
- Degree of Dilution [DD]



$$\text{PDE} = [\text{MC}] + [\text{MI}] + [\text{QH}] + [\text{AD}] + [\text{DT}] + [\text{DD}]$$
$$(0-18) = (0-3) + (0-3) + (0-3) + (0-3) + (0-3) + (0-3)$$

OHRM: Risk Ranking Table

Potential Degree of Exposure (PDE)	Hazard Class (HC)				
	1	2	3	4	5**
0-4	Low	Low	Low	Low	Special attention
5-6	Low	Low	Moderate	Moderate	
7-12	Low	Moderate	Moderate	High	
13-15	Moderate	Moderate	High	High	
16-18	Moderate	High	High	High	

-  Low
-  Moderate
-  High

Hazard class (HC) – based on COSHH essentials (UK-HSE)

HC	Hazard Statements	Remarks
1	All others not otherwise listed	
2	302, 304, 312, 315, 319, 332, 335, 336, 361, 373	H335 – moderately irritating H373 – sign. effects at 10-100 mg/kg bw H361 – sign. effects > 30 mg/kg bw
3	301, 311, 314, 317, 318, 331, 335, 360, 371, 372	H317 – moderate skin sensitizer H335 – strongly irritating H372 – sign. effects at 1-10 mg/kg bw H360 – sign. effects at 3-30 mg/kg bw
4	300, 310, 317, 330, 341, <u>351</u> , 360, 362, 370, 372	H317 – strong skin sensitizer H372 – sign. effects at 0.1-1 mg/kg bw H360 – sign. effects at 0.3-3 mg/kg bw
5	334, 340, <u>350</u>	In case of CM ask for expert advice to set exposure level

Hazard class (HC) – OHRM

HC	Hazard Statements	Remarks	OEB (dust, no or slightly volatile) [mg/m3]	OEB (medium / high volatile) [ppm]
1	All others not otherwise listed		>1	>50
2	302, 304, 312, 315, 319, 332, 335, 336, 361, 373	H335 – moderately irritating H373 – sign. effects at 10-100 mg/kg bw H361 – sign. effects > 30 mg/kg bw	>0.1-1	>5-50
3	301, 311, 314, 317, 318, 331, 335, 360, 371, 372	H317 – moderate skin sensitizer H335 – strongly irritating H372 – sign. effects at 1-10 mg/kg bw H360 – sign. effects at 3-30 30 mg/kg bw	>0.01-0.1	>0.5-5
4	300, 310, 317, 330, 341, <u>351</u> , 360, 362, <u>370</u> , 372	H317 – strong skin sensitizer H372 – sign. effects at 0.1-1 mg/kg bw H360 – sign. effects at 0.3-3 mg/kg bw	>0.001-0.01	>0.05-0.5
5	334, 340, <u>350</u>	In case of CM ask for expert advice to set exposure level	≤0.001	≤0.05




Hazard class (HC) – OHRM

HC	OEB (dust, no or slightly volatile) [mg/m ³]	OEB (medium / high volatile) [ppm]
1	>1	>50
2	>0.1-1	>5-50
3	>0.01-0.1	>0.5-5
4	>0.001-0.01	>0.05-0.5
5	≤0.001	≤0.05

Ethanol (130 ppm)
Formaldehyde (0.12 ppm)

OHRM: Risk Ranking Table

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16-18	Moderate	High	High	High	

-  Low
-  Moderate
-  High

Formaldehyde
Ethanol

Conclusions / remarks

- Carcinogenic substances differ in potency; this also holds for genotoxic substances
- In case of genotoxic carcinogens, a DMEL approach is used to assess hazard class
- Exposure concentrations should be as low as possible
- To assess the real risk, a risk-based approach should be used – not only looking at hazard
- We use the OHRM tool within Nouryon globally

Thanks for your attention

