SEA case study: Human Health
The impact of chromium (VI) on occupational disease burden

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Workshop on health and environmental impacts in the context of socio-economic analysis under REACH, 11.03.2010
Outline

- Project background and objectives
- Overview on case studies
- Chromium (VI) – case study on occupational disease burden
- Conclusions
- Questions to discuss
Project background and objectives

- UBA: Only little experience with SEA or the development of Risk Reduction Strategies (RRS) under Existing Substance Regulation (ESR)

- Project started in October 2008

- **Objectives**: to test methodologies of related SEA guidance with a special focus on environmental and health impacts in order to
  - identify limitations and problems of SEA methodologies
  - develop solutions and recommendations to support best practices in SEA
  - learn about SEA (process)
Project background and objectives

- **Scope**: four sample cases, applying different methodologies contained in the guidance

- **Advisory group**: small group with representatives of competent authorities, industry, NGOs, employers’ insurance association

- **Progress to date**: commenting on draft case study reports finished, draft summary report in preparation
Overview on case studies

- **Chromium (VI)**: quantification of health effects and monetary valuation of benefits of proposed Occupational Exposure Limit (OEL)

- **Nonylphenols**: quantification of environmental impacts and monetary valuation of the benefits of marketing and use restriction

- **Pentabromodiphenylethers (PBDEs)**: use of multi-criteria methods (scoring and weighting) to carry out an assessment of alternatives

- **Short chain chlorinated paraffins (SCCPs)**: simulating a dossier prepared by a company seeking authorisation
Case study on Chromium (VI) – Overview

Restriction scenario:
OEL: 0.01 mg/m³ (8-hr TWA)
+
Improved use of personal protective equipment (PPE)

Review of RAR, RRS Literature Data bases

Quantification of impacts
→ lung cancer
→ dermatitis
→ asthma

valuation of impacts
Case study on Chromium (VI) – Overview

Restriction scenario:
OEL: 0.01 mg/m³ (8-hr TWA) +
Improved use of personal protective equipment (PPE)

Review of RAR, RRS Literature Data bases

Quantification of impacts
→ lung cancer
→ dermatitis
→ asthma

Focus on quantification of impacts

valuation of impacts
Chromium (VI) – Background

- Risk Assessment Report (RAR) was published in 2005 covering five different Cr(VI) compounds (chromium trioxide, sodium chromate, sodium dichromate, ammonium dichromate and potassium dichromate)

- Rapporteur: UK

- RAR identified significant concerns to health in workers with a need for risk reduction for all exposure scenarios considered

- Human Health RRS was completed in 2007

- Commission recommended the setting of harmonised EU-wide OELs
Human health concerns included

- Respiratory tract sensory irritation
- Eye and skin irritation
- Acute toxicity owing to short-term peak inhalation exposure
- skin sensitization,
- occupational asthma,
- reproductive toxicity (fertility and developmental toxicity) as a consequence of repeated inhalation exposure, and
- mutagenicity and carcinogenicity.
## Uses

<table>
<thead>
<tr>
<th>Compound</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chromate</td>
<td>Manufacture of other chromium compounds</td>
</tr>
<tr>
<td>Sodium dichromate</td>
<td>Manufacture of other chromium compounds, Manufacture of wood preservative products, Vitamin K manufacture, Mordant in dyeing, Wax manufacture, Metal finishing</td>
</tr>
<tr>
<td>Chromium trioxide</td>
<td>Metal finishing, Manufacture of wood preservation products, Catalyst manufacture, Chromium dioxide manufacture, Pigment manufacture, Magnetic media</td>
</tr>
<tr>
<td>Potassium dichromate</td>
<td>Pigment manufacture, Manufacture of wood preservation products, Dye manufacture, Catalyst manufacture, Chromium metal manufacture, Colouring agent in ceramics</td>
</tr>
<tr>
<td>Ammonium dichromate</td>
<td>Magnetic tape manufacture, Catalyst manufacture, Mordant in dyeing, Pigment manufacture</td>
</tr>
</tbody>
</table>

RAR: 42 kt
Highlight most significant uses (according to RRS)
Trend information
Karen Thiele, 08/03/2010
Number of workers exposed – data available

- **RRS**: about 50,000 workers
  - detailed information: subdivided to different industries/activities and related to Cr(VI) exposure levels (reasonable worst case)
  - Still: involves a lot of assumptions

- **CAREX data base**: more than 400,000 (dermal) and 550,000 (inhalative) workers in high exposure industries sectors
  - rough estimate: all workers of a relevant industry sector potentially are exposed
  - No information on exposure levels
Restriction scenario: Setting of OEL

• No ‘safe’ OEL possible owing to genotoxic potential of Cr(VI) → exposure should be as low as possible

• Existing OELs ranged from 0.02 to 0.1 mg/m³ (8-hr TWA)

• RRS suggested that it would be possible to limit inhalation exposure to Cr (VI) compounds to 0.01 mg/m³ (8-hr TWA) by adherence to good control practices

• Enforced use of personal protective equipment to reduce dermal exposure as much as possible
Quantification of impacts – lung cancer

**Approach:** Estimate the number of excess cancer cases avoided

**Data basis:**

- ✓ Number of workers exposed
  - → data from RRS

- ✓ Current exposure level
  - → reasonable worst case estimates taken from RRS/RAR

- ✓ Estimates on excess lifetime lung cancer risk at different exposure levels
  - → Use of linear extrapolation data developed by the Scientific Committee on Occupational Exposure Limits (SCOEL)
Quantification of impacts – lung cancer

Baseline scenario

- Number of workers exposed: 50,625
- Reasonable worst case exposure: e.g. 0.025 mg/m³
- Excess rate of lifetime lung cancer risk: e.g. 2-14 per 1000 workers

NOW: excess cases

Restriction scenario

- Number of workers exposed: 50,625
- OEL: 0.01 mg/m³
- Excess rate of lifetime lung cancer risk: 1-6 per 1000 workers

With OEL: excess cases

(potential) cancer cases avoided with the restriction

55 – 446 cases
Quantification of impacts – asthma

**Approach:** Estimate the number of excess incidences avoided

**Data basis:**

- **Number of workers exposed**
  - 553,588 workers in high exposure industries (CAREX)

- **Incidence data for occupational asthma**
  - General workforce: 1.3 - 1.8 incidences per 100,000 workers per year (Eurostat)
  - High Cr(VI) exposure industries: 4.38 (mean)/ 2 (median) per 100,000 workers per year (HSE)
  - Potential underestimation may be considerable

- **No Cr (VI) specific incidence data → need for several assumptions**
Quantification of impacts – asthma

Baseline scenario

Number of workers in high Cr(VI) industries
553,588

Excess incidence rate of asthma
e.g. $4.38 - 1.8 = 2.58$

Assumption:
10 % attributable to Cr(VI)

**NOW**: excess cases
e.g. 1.43 per year

(potential) asthma cases avoided e.g. 0.86 cases per year

Restriction scenario

Number of workers in high Cr(VI) industries
553,588

Excess incidence rate of asthma
e.g. $4.38 - 1.8 = 2.58$

Assumption:
10 % attributable to Cr(VI)

Assumption:
60 % reduction by OEL

**With OEL**: excess cases
e.g. 0.57 per year
Approach: Estimate the number of excess incidences avoided

Data basis:

- Number of workers exposed
  → 422,286 workers in high exposure industries (CAREX)

- Incidence data for dermatitis
  - general workforce: <3 - 8.6 incidences per 10,000 workers per year (Eurostat, Dickel et al., FIOH), assumption: 3 incidences per 10,000 workers per year
  - high Cr(VI) exposure industries: 8.26 (mean)/ 7.9 (median) per 10,000 workers per year (Dickel et al.), assumption: 8 incidences per 10,000 workers per year
  - potential underestimation may be considerable

- Degree of Cr (VI) sensitisation
  → 9.1 - 91.5 % (literature data), assumption: 50 % of dermatitis cases attributable to Cr (VI)
Quantification of impacts – dermatitis

Baseline scenario

Number of workers in high Cr(VI) industries
422,286

Excess incidence rate of dermatitis
e.g. 8 - 3 = 5 per 10,000

Assumption: 50 % attributable to Cr(VI)

NOW: excess cases
e.g. 106 per year

(potential) dermatitis cases avoided e.g. 63 cases per year

Restriction scenario

Number of workers in high Cr(VI) industries
422,286

Excess incidence rate of dermatitis
e.g. 8 - 3 = 5

Assumption:
50 % attributable to Cr(VI)

Assumption:
60 % reduction by OEL

With OEL: excess cases
e.g. 43 per year
Conclusions

• possible to estimate the occupational health impact based on RA and literature data

• Often not possible to develop a robust estimate of health impacts due to lack of data

• Data based on documented occupational disease cases → underestimation of real impacts?

• A lot of assumptions (expert judgement) involved
Some questions to discuss

- When is it worthwhile to try to quantify health impacts? When does the quantification provide useful information for the decision-making?
- What is the minimum data set to make a robust estimate?
- How can qualitative data be used best to complement quantitative estimates?
Thank you

And also....

Meg Postle and Phil Holmes, RPA
Dirk Jepsen and Olaf Wirth, Ökopol

Questions?