Health impact assessment of policy measures for chemicals in non-food consumer products

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Content

- Introduction
- Some methodology items
- Example
- Concluding remarks
Question
Ministry of Health, Sports and Welfare

• Do an inventory research on studies on health gain as a result of exposure to chemicals from consumer products

• Focus on hazardous substances (CMRS- substances)

• Calculate for some cases (substances in non-food consumer products) using literature data or models the health gain or decrease in health loss for the consumer as a result of the policy of chemicals in consumer products.
HIA chemicals in consumer products

- Performed together with TNO Quality of Life
- Supporting committee:
  - Dutch Food and Product Safety Authority (VWA)
  - Ministry of Health, Welfare and Sport
  - different other departments within RIVM
- Started in 2005, final report finished in 2008
HIA chemicals in consumer products

Criteria in the choice of the case studies:

- existing or future policy measures
- different domains (toys, textiles, cosmetics, Do-it-yourself products, ....)
- hazard properties (CMRS)
- acute/chronic
- availability of information on toxicology and exposure
<table>
<thead>
<tr>
<th>compound</th>
<th>product</th>
<th>toxicology</th>
</tr>
</thead>
<tbody>
<tr>
<td>acrylamide</td>
<td>cosmetics</td>
<td>carcinogenicity, neurotoxicity</td>
</tr>
<tr>
<td>azo dyes</td>
<td>textiles</td>
<td>carcinogenicity</td>
</tr>
<tr>
<td></td>
<td>tattoos</td>
<td></td>
</tr>
<tr>
<td>dichloromethane</td>
<td>DIY</td>
<td>acute neurotoxicity</td>
</tr>
<tr>
<td>formaldehyde</td>
<td>chipboard</td>
<td>carcinogenicity</td>
</tr>
<tr>
<td></td>
<td>cosmetics</td>
<td>sensitization</td>
</tr>
<tr>
<td></td>
<td>textiles</td>
<td>sensitization</td>
</tr>
<tr>
<td>lamp oil</td>
<td>household</td>
<td>acute poisoning</td>
</tr>
<tr>
<td>nickel</td>
<td>jewellery</td>
<td>sensitization</td>
</tr>
<tr>
<td>nitrosamines</td>
<td>teats/soothers</td>
<td>carcinogenicity</td>
</tr>
<tr>
<td></td>
<td>cosmetics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>balloons</td>
<td></td>
</tr>
<tr>
<td>toluene</td>
<td>DIY</td>
<td>acute neurotoxicity</td>
</tr>
<tr>
<td></td>
<td>DIY</td>
<td>acute neurotoxicity</td>
</tr>
</tbody>
</table>
sources

compound

toxicity/health effects

effect level

exposure

target population

realistic and average estimate

effect of the measure

difference in exposure

difference in margin of safety

difference in incidence of effect/disease

difference in health impact
Methodology HIA

Start with establishing scenario 1 ("business as usual" or baseline) and scenario 2 (situation after measure)

Different steps comparable with RA

• exposure assessment (realistic, average)
• health effect assessment
  - derivation of effect level
• comparison, resulting in incidence of effect
• calculation to DALY?
<table>
<thead>
<tr>
<th></th>
<th><strong>Risk Assessment</strong></th>
<th><strong>Health Impact Assessment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exposure</strong></td>
<td>worst case estimate</td>
<td>realistic estimate</td>
</tr>
<tr>
<td></td>
<td>person based</td>
<td>population based</td>
</tr>
<tr>
<td><strong>Toxicity</strong></td>
<td>define a No-Observed-Adverse-Effect-Level for the critical effect</td>
<td>look for an actual occurrence of an effect</td>
</tr>
<tr>
<td></td>
<td>focus on parameters indicative for toxicity</td>
<td>focus on clinical manifest disease</td>
</tr>
<tr>
<td></td>
<td>extrapolation to a safe level (protection for any adverse effect)</td>
<td>extrapolation of effects in animals to effects in humans</td>
</tr>
<tr>
<td></td>
<td>assessment factors accepted in consumer protection paradigm</td>
<td>assessment factors do not provide a realistic extrapolation</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>risk or no concern</td>
<td>?</td>
</tr>
<tr>
<td></td>
<td>PROTECTIVE</td>
<td>PREDICTIVE</td>
</tr>
</tbody>
</table>
Measures for health impact

Single outcome measures:
- mortality
- morbidity

Integrated health measures (mortality and non-fatal health)
- DALY
- QALY
- ALE
- HYE

Economically oriented measures
- WTP
- WTA
DALY-concept

- Global burden of disease (WHO)
- Disability-adjusted-life years (DALY)
  - The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability (WHO).

- DALY = YLL + YLD
  - Years of Life Lost
  - Years Lived with Disability
    - = incidence * duration (or prevalence) * disability weight

Murray CJL, Lopez AD (eds.).
Example of DALY calculation

Population of 3 persons

- **Person 1:** traffic accident, dies at age 20
  - YLL = 80 - 20 = 60, YLD = 0
  - DALY = 60

- **Person 2:** rheumatoid arthritis at age 50, dies at age 80
  - YLD = 30 * 0.5 = 15, YLL = 0
  - DALY = 15

- **Person 3:** diabetes at age 30, dies at age 60
  - YLL = 80 - 60 = 20, YLD = 30 * 0.2 = 6
  - DALY = 26

- This total population lost 60 + 15 + 26 = 101 DALYs
Case studies
Case study lamp oil

Legislation

Plans started in 1997
Legislation in Europe 2000 (Directive 76/769/EC)

Ban on lamp oil containing colouring or perfume
Case study lamp oil

Health effects
From investigation of National Poisons Information Centre (NVIC, 1996)
165 cases, 109 inquiries filled in

- Nausea: 11%
- Vomiting: 18%
- Persistent coughing: 48%
- Shortness of breath: 7%
- Pneumonitis: 8%, 10-23%*, 48%**
- Fever: 11%
- Drowsiness: 17%

BgVV, 1997*, 2001**
Case study lamp oil

**EuroQol-methode**
Six dimension are scored from 1 to 3
- mobility
- self care
- daily activities
- pain / discomfort
- anxiety / depression
- cognition
All scores 1 → disability weight 0
All scores 3 → disability weight 1
Each score above 1 adds 0.08 (1/12) to the total score
**EuroQoL**

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Score</th>
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</thead>
<tbody>
<tr>
<td>mobility</td>
<td>1</td>
</tr>
<tr>
<td>self-care</td>
<td>2</td>
</tr>
<tr>
<td>usual activities</td>
<td>2</td>
</tr>
<tr>
<td>pain / discomfort</td>
<td>2</td>
</tr>
<tr>
<td>anxiety / depression</td>
<td>1</td>
</tr>
<tr>
<td>cognition</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total score</strong></td>
<td><strong>0.33</strong></td>
</tr>
</tbody>
</table>
Case study lamp oil

nausea/vomiting/ persistent coughing/ shortness of breath/ drowsiness together:
acute effects
via EuroQol weighing factor (on mobility, self care, usual activities, pain, anxiety, cognition) 122212 dus 0.33
1 day

pneumonitis
Weighing factor 0.1 voor pneumonia
over a year (from Public Health Forecast, 1997)
Case study lamp oil

N=167 (decrease in number of cases per year after policy measure) in the Netherlands

nausea/vomiting/ persistent coughing/ shortness of breath/ drowsiness together:
found in 48% of the cases
→ 80 x 0.33 x 1/365 = 0.07 DALYs

pneumonitis
found in 8% of the cases
→ 13 x 0.1 = 1.3 DALYs

Total 1.4 DALY’s
Case study lamp oil

Remarks:
- underreporting?
- NL data
  - in Germany somewhat higher reportings
  - German data more serious effects
  - and 2 child fatalities in 2004 (is + 140 DALY)
- Method of DALY calculation (more permanent damage not taken into account)
Case study lamp oil

In comparison with other policy measures (up to 100 or 3000 DALYs) not much health gain

However, risk perception!!
Other case studies

• Euroqol method might be useful in cases with more acute endpoints

• Not possible for endpoints such as liver, kidney and reproductive toxicity

• Carcinogenicity
  assumption: every case results in an early death and years of disease of average 8 DALY for each cancer case (based on 65% of all cancers)
<table>
<thead>
<tr>
<th>Substance</th>
<th>Product</th>
<th>Tox</th>
<th>DALY</th>
<th>uncertainty</th>
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</thead>
<tbody>
<tr>
<td>Acrylamide</td>
<td>Cosmetics</td>
<td>Carc</td>
<td>300</td>
<td>high</td>
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<tr>
<td>Azo dyes</td>
<td>Textiles</td>
<td>Carc</td>
<td>1500-3700</td>
<td>high</td>
</tr>
<tr>
<td></td>
<td>Tattoos</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Dichloromethane</td>
<td>DIY</td>
<td>Acute</td>
<td>100</td>
<td>middle</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Chipboard</td>
<td>Carc</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cosmetics</td>
<td>Sens</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Textiles</td>
<td>Sens</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Lamp oil</td>
<td>Household</td>
<td>Acute</td>
<td>1</td>
<td>low</td>
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<tr>
<td>Nickel</td>
<td>Jewelry</td>
<td>Sens</td>
<td>3000</td>
<td>middle</td>
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<td>4200*</td>
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<tr>
<td>Nitrosamines</td>
<td>Soothers</td>
<td>Carc</td>
<td>0.2-800</td>
<td>high</td>
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<td></td>
<td></td>
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<td>20-65000</td>
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<td></td>
<td>Cosmetics</td>
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<td>negligible</td>
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<td>Balloons</td>
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<tr>
<td>Toluene</td>
<td>DIY</td>
<td>Repro</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute</td>
<td>12</td>
<td>middle</td>
</tr>
<tr>
<td>VOC</td>
<td>DIY</td>
<td>Acute</td>
<td>90</td>
<td>very high</td>
</tr>
</tbody>
</table>
Conclusions exposure

• many assumptions
  - sometimes data available on concentrations in products and air
  - almost always assumptions on use frequency, exposure duration, migration from products, dermal absorption, …

• realistic and average exposure estimate (peak exposure)

• sensitivity in population

• distribution in population
Conclusions

- Effect level (instead of no-effect level)
- Extrapolation
  - animal to human
  - toxic effect to disease
  - 10 x 10 in RA, but in this case?
- Carcinogenicity
  - linear extrapolation?
  - relevance animal tumours for humans?
  - assumption: every case results in an early death and years of disease of average 8 DALY for each cancer case (based on 65% of all cancers)
- Acute tox  Euroqol method used
Conclusions

• Extrapolation

• Establishing target population
  for users of textiles, cosmetics, paint, cleaners, .......

• Indication for this one year (no discounting, life tables, age of onset, .....)

DALY

SIR
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Questions?