Toxicovigilance of Poisonings and Product Documentation in Germany

Axel Hahn
Hazard Identification and Risk Assessment

**Hazard Identification**

**Exposure Assessment**
- Release of Substances
- Entry from Environment
- Identification of exposed Persons
- Exposure in Relation to Path

**Dose-Response-Relation**
- Dose-Response-Relation
- Endpoint-specific Toxicity
- Risik-specific Dose

**Documents for Risk Characterization**
- Comprising Risk Information
- Uncertainty of the Data

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Federal Institute for Risk Assessment (BfR)

Former Federal Health Office (BGA 1994)

- Staff ca. 650 Co-workers
- Ca. 150 Scientists
- Headquarter Berlin
- Working Fields / Departments
  - Foods
  - Chemicals
  - Cosmetics
  - Commodities
  - Zoonoses
  - Pesticides

BfR DocCentre for Documentation and Assessment of Poisonings

Declaration des Produits Chemiques: German Experience, 27th September 2012, Paris,
47 Years „Poison’s Committee and Poison DocCentre“

Meeting Place „Farmhouse“ Berlin- Alt Marienfelde

45 years of successful preventive work by the BfR Committee for the Assessment of Poisonings


The national Committee for the Assessment of Poisonings located at the Federal Institute for Risk Assessment (BfR) marked its 45th anniversary with a celebration. It was established in 1964 within the former German health authority (Bundesgesundheitsamt), modelled on the American Food and Drug Administration (FDA) committee “National Clearing House for Poison Control Centers”, together with a centre for documentation on the identification and treatment of poisonings. Likewise, poison information centres were established in the Länder (German federal states) according to the American model. Renowned experts were appointed to the Committee who supported the German poison information centres’ consultation and treatment of accidents. The tailor-made and individual treatment of such accidents in collaboration with poison information centres as well as improved prevention and consumer protection – especially through new product compositions, warning labels and prohibitions of sale – drastically reduced fatal cases of poisoning accidents in children.
1. Reports of Poisonings with Chemical Products / Compounds by attending Physicians (Ambulances, Hospitals, Accidents Insurances, Environmental Ambulances, Public Health Services etc.) even in suspected Cases

Records of ca. 5,000 Medical and Clinical Treatments/Year

BfR DocCenter

- Indications from 9 German PCs
- ca. 200,000 Inquiries/Year
- 4 Centres with Clinical Treatment

2. Information about Poisonings with Chemical Products/Compounds from German PCs
German Toxicological Network “Toxicovigilance”

Co-Operation between BfR/9 Poison Centres/Industry for Public Health Issues

Industry

Industrial Associations
Frankfurt/River Main

PC Göttingen
PC Bonn
PC Homburg
PC Mainz
PC Erfurt
PC Freiburg
PC Nuremberg
PC Munich
PC Berlin

BfR Berlin DocCenter

Declaration des Produits Chemiques: German Experience, 27th September 2012, Paris,
National Monitoring of Poisonings (BfR-DocCenter)

„Poisons“ Committee

Input

Reports
§ 16e ChemG Para. 2
Physicians

Indications
§ 16e ChemG Para 3
Poison Centres

/Year
Case Database
ca. 86,000

Assessment
Analysis

Output

Human Case Collection

Publications

Risk Identification

9 PCs

Start 1967, Mandatory since 1990

Notifications
INDUSTRY
§ 16e ChemG Para 1
Dangerous Products
Biocides
Detergent Regulation
(Cosmetics 1996-2007)
Voluntary Reports
Art. 45 CLP

INDUSTRY

Case Data Base

Annual Reports

„Adverse“ Effects
of Commercial Products

Rapid Communications

Voluntary Reports

Art. 45 CLP

Input

Reports
§ 16e ChemG Para. 2
Physicians

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/Year
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INDUSTRY

Case Data Base

Annual Reports

„Adverse“ Effects
of Commercial Products

Rapid Communications
Documentation and Assessment of Poisonings
### Actual Risk Listing of Chemical Products

#### Cases of Poisoning Reported by Physicians

<table>
<thead>
<tr>
<th>Range of toxicants</th>
<th>Reports, total numbers</th>
<th>Moderate/Severe Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First level</strong></td>
<td><strong>Moderate/Severe</strong></td>
<td><strong>Total</strong></td>
</tr>
<tr>
<td>Second level</td>
<td><strong>Total</strong></td>
<td><strong>Children</strong></td>
</tr>
<tr>
<td><em>Third level</em></td>
<td><strong>Adults</strong></td>
<td><strong>Home</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Work</strong></td>
<td></td>
</tr>
<tr>
<td>Hair care products</td>
<td>273</td>
<td>30</td>
</tr>
<tr>
<td>• Permanent wave products</td>
<td>55</td>
<td>4</td>
</tr>
<tr>
<td>• Depilatory products</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>• Hair conditioners</td>
<td>30</td>
<td>2</td>
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<tr>
<td>• Hair dyes/colorants</td>
<td>129</td>
<td>6</td>
</tr>
<tr>
<td>• Hair tonics</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>• Shampoos</td>
<td>32</td>
<td>15</td>
</tr>
<tr>
<td>Skin care products</td>
<td>466</td>
<td>73</td>
</tr>
<tr>
<td>• Bath oils/salts</td>
<td>41</td>
<td>13</td>
</tr>
<tr>
<td>• Tanning products</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>• Creams/ointments</td>
<td>107</td>
<td>15</td>
</tr>
<tr>
<td>• Deodorants</td>
<td>31</td>
<td>6</td>
</tr>
<tr>
<td>• Face tonics</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>• Make-up products</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>• Perfumes/aftershaves</td>
<td>49</td>
<td>19</td>
</tr>
<tr>
<td>• Powders</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>• Soaps</td>
<td>193</td>
<td>5</td>
</tr>
<tr>
<td>• Sun blockers</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>• Oils</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Oral care/dental products</td>
<td>75</td>
<td>4</td>
</tr>
<tr>
<td>Nail care products</td>
<td>72</td>
<td>18</td>
</tr>
<tr>
<td>Cosmetics/personal hygiene products</td>
<td>932</td>
<td>125</td>
</tr>
</tbody>
</table>

**Declaration des Produits Chemiques: German Experience, 27th September 2012, Paris, 10**
## BfR „Rapid Tox Communications“ of Severe Health Impairments

<table>
<thead>
<tr>
<th>Year</th>
<th>Product</th>
<th>Toxicologically relevant substance</th>
<th>Person exposed</th>
<th>Outcome</th>
<th>Proposal by BfR (P) and results (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>Detergent</td>
<td>Surfactants</td>
<td>Elderly female</td>
<td>Death</td>
<td>None</td>
</tr>
<tr>
<td>2007</td>
<td>Impregnation spray for tents</td>
<td>Cannot be identified</td>
<td>Adult female</td>
<td>Pulmonary oedema</td>
<td>P: Investigation</td>
</tr>
<tr>
<td>2008</td>
<td>Manual dishwashing detergent</td>
<td>Surfactants</td>
<td>Elderly female</td>
<td>Foam aspiration, death</td>
<td>P: Information</td>
</tr>
<tr>
<td>2008</td>
<td>Shoe impregnation spray</td>
<td>Cannot be identified</td>
<td>Adult male</td>
<td>Pulmonary oedema</td>
<td>P: Investigation</td>
</tr>
<tr>
<td>2009</td>
<td>Baby powder</td>
<td>Talc</td>
<td>Infant</td>
<td>Aspiration pneumonia, respiratory insufficiency</td>
<td>P: Information, R: Distributed</td>
</tr>
<tr>
<td>2010</td>
<td>Descaler and rust remover</td>
<td>Nitric acid</td>
<td>Young child</td>
<td>Severe chemical burns, haematemesis, aspiration, gastric perforation</td>
<td>P: Measures to reduce the share of nitric acid in the product, control</td>
</tr>
<tr>
<td>2010</td>
<td>Drain cleaner</td>
<td>Sodium hydroxide</td>
<td>Young child</td>
<td>Severe chemical burns, respiratory insufficiency</td>
<td>None</td>
</tr>
</tbody>
</table>

In Addition we send about 300- 400 Summary Reports („Blue Letters“) annually!
Human Case Report Database
BfR Case Report Database of Poisonings

Here you can find Case Reports of Poisonings reported to the BfR, and Case Reports from literature.

You can start working with the database by using the Link “Search Case Reports”.

Searching without search criteria results in a list of all Case Reports.

Actual Data Content: 808 Case Reports

You are logged on as:
Name: Hahn, Axel
Email: a.hahn2403@gmx.de
Access Group: read access
<table>
<thead>
<tr>
<th>Type</th>
<th>Case Report No.</th>
<th>Abstract</th>
<th>Date</th>
<th>Poisonings</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>0381</td>
<td>female adult was private, in usual application, inhalative exposed to chlorpyrifos through a silverfish bait; mild manifestation, polynuropathy, joint swelling, skin rash; ambulant; parvovirus infection confirmed</td>
<td>06-01-2005</td>
<td>1</td>
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<tr>
<td></td>
<td>0382</td>
<td>woman ingested private, suicidal, oral 150ml of a dishwashing containing ethylene glycol; severe manifestation, intracranial failure, pneumonia, coma, respiration; inpatient treatment; haemodialysis, antidote: sodium hydrogen carbonate, ethanol</td>
<td>06-01-2005</td>
<td>1</td>
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<tr>
<td></td>
<td>0383</td>
<td>female infant, head injury, oral cooked boiling poppy seed; severe manifestation, respiratory insufficiency; inpatient treatment; oxygen mask, antidote: naloxone</td>
<td>06-01-2005</td>
<td>1</td>
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<tr>
<td></td>
<td>0384</td>
<td>man was occupational, accidental, dermal exposed to sodium hydroxide solution; severe manifestation, complete loss of the exterior diaphragm muscles; inpatient treatment after four months; delirium, conditioning of the wound ground, soft tissue grafting; persistent defect after healing</td>
<td>06-01-2005</td>
<td>1</td>
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<td>0385</td>
<td>man ingested private, accidental, oral 10-20ml liquid ammonia, 10 % sodium bicarbonate, 10 % ammonia; mild manifestation, caustic burns of the oesophagus and stomach; inpatient treatment; administration of proton pump inhibitors, antibiotics</td>
<td>06-01-2005</td>
<td>1</td>
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<tr>
<td></td>
<td>0386</td>
<td>female infant; achieved private, accidental, rectal 100mg tramadol syrup; moderate manifestation, respiratory depression, convulsive seizure; inpatient treatment; administration of diazepam, administration of neostigmine</td>
<td>06-01-2005</td>
<td>1</td>
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<tr>
<td></td>
<td>0387</td>
<td>several pupils ingested at school accident, oral dose of a peashrub tree (Carpinus betulus); mild manifestation, gastrointestinal complaints; tendency to collapse, headache; inpatient treatment</td>
<td>06-01-2005</td>
<td>11</td>
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<tr>
<td></td>
<td>0388</td>
<td>several adults and teenagers consumed private, accidental, oral milkshakes (Aesculus hippocastanum): mild and moderate manifestation, numbness, arrhythmia; nasopharyngeal; gastric lavage, charcoal administration, i.v. administration of magnesium</td>
<td>06-01-2005</td>
<td>5</td>
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<tr>
<td></td>
<td>0389</td>
<td>two men were occupational, accidental, inhalative exposed to carbon monoxide; moderate manifestation, headache, nausea; inpatient treatment; hyperbaric oxygenation</td>
<td>06-01-2005</td>
<td>1</td>
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<tr>
<td></td>
<td>0390</td>
<td>man was occupational, in usual application, inhalative exposed to lacquers and adhesives (ingredient: solvents); moderate manifestation, polynuropathy; inpatient treatment</td>
<td>06-01-2005</td>
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<tr>
<td></td>
<td>0391</td>
<td>woman was private, in usual application, inhalative exposed to varnish (dichloroethane, solvent); moderate manifestation, edema, hepatoencephalopathy; right ventricular failure, pleural effusion, pancytopenia, obstructive ventilatory disorder; inpatient treatment</td>
<td>06-01-2005</td>
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<td>0392</td>
<td>Reports in 1990-1998 on pyrethroid-containing carpets. Exposure data in 29 cases, patterns of manifestations from chronic exposure</td>
<td>06-01-1992</td>
<td>36</td>
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<td>0393</td>
<td>child (trisomy 21) and infant ingested private, accidental, oral antifreeze agent (ethylene glycol); mild manifestation, mild acidosis; inpatient treatment; antidote: fructose</td>
<td>06-01-2005</td>
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<td>0394</td>
<td>case series / major accident rail transport occupational and private, accidental, inhalative, dermal and on the eye conditional exposition with vinyl chloride; mild and moderate manifestation, respiratory system irritation; raw voice, difficulties swallowing, respiratory difficulties, distress, eye irritation, dermatitis, skin irritation, gastrointestinal complaints, headache, anxiety, breathlessness, dizziness, lack of concentration, isolated singleresults; ambulant and inpatient treatment; oxygen therapy with steroids inhalative</td>
<td>06-01-1996</td>
<td>228</td>
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<td>0395</td>
<td>case series / major accident, severe adults and teenagers were occupational and ecological, accidental, inhalative, dermal and on the eye exposition to a violent explosion in the plant protection department with release of oxalic and fum gases; mild and moderate manifestation, headache, eye irritations, breathing difficulties; ambulant and inpatient treatment; steroids and therapy</td>
<td>06-01-1990</td>
<td>95</td>
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<td></td>
<td>0396</td>
<td>elderly woman was private, accidental, inhalative exposed to nitric acid; severe manifestation, cyanosis, delayed lung edema, respiration, pneumonia, total atelectasis left lung; inpatient treatment; CT, bronchoscopy: thoracodrains; steroid administration</td>
<td>06-01-2005</td>
<td>1</td>
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</table>
Documentation of Product Formulations
BfR Standard Data File for German Poison Centres since 1990

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<td>Preferred Chemical Name Link to BfR Monographs</td>
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<tr>
<td>Rank of Toxicity</td>
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<tr>
<td>1. Highest</td>
<td>2. Second</td>
<td>...</td>
<td>Lowest (e.g. Water)</td>
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</tbody>
</table>

BfR GIFAS Database

TDI-Rosetta XML-Format 2005

9 PCs
The Development of the BfR Product Data Base (GIFAS)

BfR GIFAS Database

New 1996
§ 15d Cosmetics

New 1996
§ 15d Cosmetics

New 2002
§ 16e + Biocides

New 2007
§ 10
Detergents

New §16e (art. 45 CLP-Reg.)
Juli 2012

Nearly Paperless

Total of all Product Reports

Start 1990
§ 16e ChemG

Declarations des Produits Chimiques: German Experience, 27th September 2012, Paris,
BfR Uniform Data XML Transfer for „All Products“

Option 1: Manufacturer Export Program
Option 2: BfR-Electronic Notification Assistance

Manufacturer Export Program

Industry Test 6 Months 2010

Harmonized Data Exchange Format „XProduktmeldung“

XML-File Transfer

Dataprotection -Portal

BfR-Database

German Poison Centres

Declaration des Produits Chimiques: German Experience, 27th September 2012, Paris,
Exact Identification of the Poison’s Agent

Especially in Chemical Products
BfR Efforts for a Product (Formulation) Identifier

EU Standard CEN (EN 15178) since Nov 2007

Start in 2002

BfR Recommendations based on the former UBA-Number

<table>
<thead>
<tr>
<th>BfR Company Code</th>
<th>Comp.-Code for Formulation</th>
<th>Hazard Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>12345</td>
<td>99999</td>
<td>C</td>
</tr>
</tbody>
</table>
• In Germany we have a Networking with Poison Centres
• The „Toxicovigilance“ is driven by the Chemicals Law
• We have different „Data-Elements“ for Poisonings,
• Product Documentation und Human Case Reports
• The most important Steps in „Toxicovigilance“ are
• exact ‚Product Identification‘ and „Authentic Clinical Data“!
• We should share our „Experience“ in Networking!

Conclusion