Industrial Perspective on Exposure Assessment, Legislation and Standardization

Conference on Workplace and Indoor Aerosols, Lund 2012

Dr. Stefan Engel
BASF SE, Hazardous Chemicals Management

Hazardous Chemicals - Safe and Professional Use in the Workplace
Industrial Perspective on Exposure Assessment, Legislation and Standardization

Contents

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   - New Threshold Limit Value Concepts – New TLVs
   - …

4. Conclusions
Industrial Perspective …

Hazardous Chemicals Management in BASF -
A Little Bit About Us

source: BASF SE


April 2012

Hazardous Chemicals -
Safe and Professional Use in the Workplace
Center of Expertise
Hazardous Chemicals Management
Our Mission

The Hazardous Chemicals Management is BASF´s Center of Expertise …

- … to support our licencees in implementing European and national occupational safety and hazardous substance legislation.

- … to ensure safety and health handling hazardous substances based on the results of a reliable and valid exposure assessment.

- … to improve the safety level by introducing new scientific findings.

- … to develop new industrial hygiene standards for BASF.

- … to safeguard BASF´s stakes in national and international regulatory bodies.
Center of Expertise
Hazardous Chemicals Management
Our Competencies

- Exposure Measurement and Assessment
- Risk Management
- Advocacy
- Applied R&D for Occupational Safety

Hazardous Chemicals -
Safe and Professional Use in the Workplace

http://www.eat.lth.se/aerosols2012
Center of Expertise
Hazardous Chemicals Management
Exposure Assessment

- exposure assessment of hazardous chemicals
  - certified according to ISO 17025 and accredited for …
    - aerosols (dust including nanoscale aerosols)
    - inorganic and organic gases and vapours
    - special samplings (e.g. superabsorber polymer)
  - validated measurement methods for about 500 substances and elements available
- analyses of hazardous chemicals of contaminated construction materials and in soil
- assessment of indoor contaminants
- exposure assessment of biological substances
Principles of Industrial Risk Assessment in the Workplace
Industrial Perspective on Exposure Assessment, Legislation and Standardization

Focus of this Presentation

- Industrial Perspective
  - Chemical Industry, especially BASF perspective
  - Perspective of a manufacturer and early down-stream user
- Standard exposure assessment towards hazardous substances in industrial setting
- Routine operations
- Focus: Particulate aerosols, but also vapours and gases

Workplace and Indoor Aerosols 2012
http://www.eat.lth.se/aerosols2012
Risk Paradigm
The Role of Exposure Assessment in Industrial Hygiene

Only the high quality assessment of …

Hazard and Exposure

… will adequately characterize potential health risks in the workplace.
Risk Assessment and Management in the Workplace

Purpose

Information Gathering
- Hazard Assessment
- Exposure Assessment

Risk Assessment

Effectiveness Test

Safe Workplace

Risk Management

source: BASF SE

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Workplace and Indoor Aerosols 2012

http://www.eat.lth.se/aerosols2012
Exposure Assessment in the Workplace
More than Characterization of the Concentration of a Contaminant in Workplace Air

- Release
- Exposure
- Uptake, Deposition, Distribution
- Response

Exposure Assessment

Workplace Aerosol

Emission Source

Dose

(Adverse) Health Effect

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Principles for Exposure Assessment
Legal Basis and Quality Standards

- legal basis: risk assessment in the workplace
  - in EU: Chemical Agents Directive 98/24 EG
  - in D: Hazardous Chemicals Ordinance, substantiated by TGD 402
    ⇒ level, type and duration of exposure

- quality management
  - ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories
  - DIN EN 689 Workplace Atmospheres: Guidance for the Assessment of Exposure by Inhalation to Chemical Agents
    ⇒ scientifically valid and justiciable results
Exposure Assessment …
From Industrial Perspective

- specific
  Do we assess the most important contaminant?

- representative
  Will the data well characterize the exposure in the workplace?

- valid
  Are the data reliable?

- standardized ⇔ e.g. DIN EN 689
  Are the data comparable with other in-house data and also results obtained from others in different occupational settings?
Guidance on Exposure Assessment …
DIN EN 689 …

… gives guidance on …

- the appropriate process
  - identification of likely exposure (hazardous substances inventory)
  - identification of basic information (e.g. process, operation, workplace, protective measures, ventilation, etc.)
  - exposure assessment
- personal monitoring (preferred) compared to stationary measurements
- minimum number of samples (assessment of an 8h TWA)
  - e.g. 5 min sampling time: 20 samples/8h shift
  - 15 min sampling time: 4 samples/8h shift

…
Industrial Perspective on Exposure Assessment, Legislation and Standardization
The Situation of Industrial Hygiene

Regulator, Health Insurances

Scientific Findings

Employer

Industrial Hygiene

Academia

Occupational Safety Management System

CEN / ISO / Accreditation Bodies

Quality Standards

Regulation, Technical Guidance

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http://www.eat.lth.se/aerosols2012

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Industrial Perspective …

Developments and Challenges
Respirable Dust

Nanoscale Aerosols

New Threshold Limit Value Concepts
  - DNELs
  - Exposure Risk Relationships for Carcinogenic Substances

...
New …

- Tightening Regulation ⇔ Technical Limitations
- Technologies ⇔ Knowledge Gaps
- TLVs ⇔ Technical Limitations and Knowledge Gaps
Developments and Challenges
Respirable Dust in the Workplace

- established gravimetric methods, e.g. IFA method no. 6068 or EN 481

- new MAK value for respirable dust (alveolar dust fraction) 0,3 mg/m³ (density 1 g/cm³), not applicable for ultrafine dust

  - in evaluation, if the MAK value will be adopted as OEL in TGD 900

- consequence: reduction of LOD required

  - applicability of established measurement methods

  - suitability of standard sampling systems, e.g. PM 4 F, MPG II, FSP-10
## Developments and Challenges

Respirable Dust: LODs of Established Sampling Systems

<table>
<thead>
<tr>
<th>Sampling System</th>
<th>Flow Rate [mg/m³]</th>
<th>LOD Absolute [mg]</th>
<th>LOD Relative [mg/m³] in Sampling Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>15 min</td>
<td>2 h</td>
</tr>
<tr>
<td>PM 4 F</td>
<td>4,00</td>
<td>0,6</td>
<td>0,60</td>
</tr>
<tr>
<td>MPG II</td>
<td>2,80</td>
<td>0,6</td>
<td>0,86</td>
</tr>
<tr>
<td>FSP-BIA</td>
<td>0,12</td>
<td>0,3</td>
<td>10,00</td>
</tr>
<tr>
<td>FSP-10</td>
<td>0,60</td>
<td>0,3</td>
<td>2,00</td>
</tr>
<tr>
<td>Respicon</td>
<td>0,19</td>
<td>0,3</td>
<td>7,52</td>
</tr>
</tbody>
</table>

Source: DGUV-IFA

Workplace and Indoor Aerosols 2012

http://www.eat.lth.se/aerosols2012
Developments and Challenges
Nanoscale Aerosols in the Workplace

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NOAA

nano-objects
aggregates and agglomerates comprising nano-objects
inhalable/respirable dust

nm scale or µm scale ?

Workplace and Indoor Aerosols 2012
http://www.eat.lth.se/aerosols2012

April 2012
"standard" gravimetric measurements

"classical" respirable fraction

"classical" inhalable fraction

may or may not comprise nano-objects

1 nm 100 nm ~ 4 µm ~ 10 µm

- sampling devices
- counting devices

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Development and Challenges
Harmonization of Exposure Assessment of Nanoscale Aerosols in the Workplace

- TNO, IFA, PEROSHS Initiative
  - Harmonized Exposure Assessment Approach
- BAuA, DGUV, IFA, IUTA, TUD, VCI Working Group
  - Tiered Exposure Assessment Approach
- NanoGEM Project
  - Standard Operating Procedures

courtesy: Dr. Schmitt, DIN Deutsches Institut für Normung
Development and Challenges
Tiered Approach to Exposure Assessment of Nanoscale Aerosols (1/2)

- combines
  - principles of exposure assessment of nanoscale aerosols with
  - established industrial hygiene practices

- step-by-step approach:
  - Tier 1: Information Gathering
  - Tier 2: Basic Exposure Assessment
    - focus: particle number concentration
    - limited set of easy-to-use equipment (counting devices)
  - Tier 3: Extended Exposure Assessment
    - latest state-of-the-art technologies (counting and sampling devices including off-line analyses)
Developments and Challenges
Tiered Approach to Exposure Assessment of Nanoscale Aerosols (2/2)

Tier 1 – Information Gathering
Case A and B

Emission of nanoscale aerosols released from ENMs into workplace air during production, handling or processing can be reasonably excluded?

Yes

No

Tier 2 – Basic Exposure Assessment
(e.g. CPC)
Case C, D and E

Significant increase over background concentration detected?

Yes

No

Health based OEL established?

Yes

No

Interference value exceeded?

Yes

No

Evidence on chemical identity of the ENM available?

Yes

No

ENMs from operations are not present, the chemical identity of the ENM is known, their origin is elsewhere

Take additional risk management measures to mitigate exposure accordingly

Risk management measures efficient?

Yes

No

Document and archive

Check after 2 years or in case of changes

Tier 3 – Expert Exposure Assessment
(e.g. SMPS, CPC, Filter samples and off-line analytics)
Case F and G

Take additional risk management measures to mitigate exposure accordingly

Risk management measures efficient?

Yes

No

Document and archive

Check after 2 years or in case of changes
Developments and Challenges
New Threshold Limit Value Concepts

- REACH Directive (EG) 1907/2006
  - Exposure Scenarios
  - DNELs

- Announcement 910: Acceptable and Tolerable Risks
  - Exposure-Risk Relationships for Carcinogenic Hazardous Substances
Developments and Challenges
Exposure-Risk Relationships for Carcinogenic Hazardous Substances (1/2)

- Tolerable Risk
  - above the tolerable risk: protective measures mandatory

- Acceptable Risk
  - between acceptable and tolerable risk: protective measures optional
  - below the acceptable: no specific actions

  **Interim limit**
  - 4 : 10,000 ALz
  - 1 : 2,500 ALz
  - no later than as of 2018

  **ALZ** = working lifetime (continuous exposure over 40a, 220d/a, 8h/d)

ALZ = working lifetime (continuous exposure over 40a, 220d/a, 8h/d)
Developments and Challenges
Exposure-Risk Relationships for Carcinogenic Hazardous Substances (2/2)

Cancer Risk

High-Risk Area
measures immediately to be implemented

Medium-Risk Area
measures required

Low-Risk Area
basic measures

Tolerable Risk

Acceptable Risk

4 : 1.000
4 : 10.000 / 4 : 100.000
(no later than of as 2018)

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http://www.eat.lth.se/aerosols2012
### Developments and Challenges

Established Acceptable and Tolerable Risks

<table>
<thead>
<tr>
<th>Substance</th>
<th>Acceptable Risk</th>
<th>Tolerable Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$4 \times 10^{-4}$</td>
<td>$4 \times 10^{-3}$</td>
</tr>
<tr>
<td>acrylamide</td>
<td>$0.07 \text{ mg/m}^3$</td>
<td>$4 \times 10^{-3}$</td>
</tr>
<tr>
<td>acrylnitrile</td>
<td>$0.26 \text{ mg/m}^3$</td>
<td>$2.6 \text{ mg/m}^3$</td>
</tr>
<tr>
<td>aluminum silica fibres</td>
<td>$10,000 \text{ fibres/m}^3$</td>
<td>$100,000 \text{ fibres/m}^3$</td>
</tr>
<tr>
<td>asbestos</td>
<td>$10,000 \text{ fibres/m}^3$</td>
<td>$100,000 \text{ fibres/m}^3$</td>
</tr>
<tr>
<td>benzo[a]pyrene</td>
<td>$70 \text{ ng/m}^3$</td>
<td>$700 \text{ ng/m}^3$</td>
</tr>
<tr>
<td>1,3-butyadiene</td>
<td>$0.50 \text{ mg/m}^3$</td>
<td>$5.0 \text{ mg/m}^3$</td>
</tr>
<tr>
<td>ethylene oxide</td>
<td>$0.20 \text{ mg/m}^3$</td>
<td>$2.0 \text{ mg/m}^3$</td>
</tr>
<tr>
<td>4,4’-dimethyl aniline</td>
<td>$0.07 \text{ mg/m}^3$</td>
<td>$0.7 \text{ mg/m}^3$</td>
</tr>
<tr>
<td>trichloroethene</td>
<td>$33.00 \text{ mg/m}^3$</td>
<td>$60.0 \text{ mg/m}^3$</td>
</tr>
</tbody>
</table>
## Developments and Challenges

### Example: Metals and Metal Compounds

TLVs - In Discussion

<table>
<thead>
<tr>
<th>Substance</th>
<th>DNEL/DMEL</th>
<th>Acceptable Risk</th>
<th>Tolerable Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>inhalation</td>
<td>$4 \times 10^{-4}$</td>
<td>$4 \times 10^{-3}$</td>
</tr>
<tr>
<td>arsenic</td>
<td></td>
<td>0.80 µg/m³</td>
<td>8.3 µg/m³</td>
</tr>
<tr>
<td>cadmium</td>
<td></td>
<td>0.16 µg/m³</td>
<td>1.6 µg/m³</td>
</tr>
<tr>
<td>chromate (VI)</td>
<td></td>
<td>0.20 µg/m³</td>
<td>2.0 µg/m³</td>
</tr>
<tr>
<td>nickel</td>
<td>DMEL</td>
<td>50.0 µg/m³</td>
<td></td>
</tr>
<tr>
<td>chloro platinates</td>
<td>DNEL</td>
<td>0.16 µg/m³</td>
<td>1.6 µg/m³</td>
</tr>
</tbody>
</table>

http://www.eat.lth.se/aerosols2012
### Developments and Challenges
Metals and Metal Compounds
Environmental Concentrations and LODs

<table>
<thead>
<tr>
<th>Substance</th>
<th>Air Concentration 1) (Fine Dust)</th>
<th>Method</th>
<th>LOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>arsenic</td>
<td>0.0010 µg/m³</td>
<td>ICP/MS</td>
<td>0.34 µg/m³</td>
</tr>
<tr>
<td>cadmium</td>
<td>0.0005 µg/m³</td>
<td>AAS</td>
<td>0.02 µg/m³</td>
</tr>
<tr>
<td>chromate (VI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>nickel</td>
<td>0.0075 µg/m³</td>
<td>AAS</td>
<td>0.04 µg/m³</td>
</tr>
<tr>
<td>chloro platinates</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1) annual average value 2008 in Wetzlar, Germany  
Source: DGUV-IFA
Exposure Assessment in the Workplace

Conclusions
Conclusions

- Industrial Hygiene has to comply with
  - changing regulation and new technical guidance
  - quality standards and quality management systems
  - company internal occupational safety management systems

- Industrial Hygiene challenged by
  - reduced OELs/TLVs = decreasing LODs (based on new scientific findings)
  - new, sophisticated measurement methods and complex measurement strategies

- partnering with academia as a success criterion
Thank you very much for your attention!

Questions?

Dr. Stefan Engel
BASF SE, Hazardous Chemicals Management
📞 +49-621-6041614
E-Mail stefan.engel@basf.com