Evaluation of Tier 1 tools for estimating occupational exposure

Martie van Tongeren
background

- REACH advocates at tiered approach for the safety of use of chemicals.
- REACH heavily relies on efficient, simple tools for exposure assessment (tier 1 tools)
- However, despite being used heavily within REACH, little independent evidence exist on the performance of these tools.
- BAuA initiated and funded the eteam project
eteam Project

- Funded by BAuA
- Collaboration between IOM and Fraunhofer-ITEM
- Advisory Board, consisting of
  - Tool developers (ECETOC, TNO/ArboUnie, BAuA, EBRC)
  - Major data providers (IFA, NIOSH, HSE, SECO)
- Links with other projects (Switzerland, US, Sweden)
Tools

- ECETOC TRA Versions 2 & 3
- EMKG-EXPO-Tool
- MEASE Version 1.02.01
- Stoffenmanager Version 4.5
- RISKOFDERM Version 2.1
Aims of eteam Project

- Evaluate the scientific basis of the tools
- Determine their user-friendliness
- Assess the between-user reliability
- External validation of tool estimates via comparison with measurement data
- Provide practical recommendations to developers, users and regulators on how to use the tools most effectively
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BURE study

- To determine the reliability of the tool or tool users
- Recruited 150-200 tool users in Europe and elsewhere
- Each participant was asked to assess inhalation and dermal exposure for 20 scenarios
  - Standard 1 page A4 format
  - Textual description of typical workplace exposure settings
  - Professional & industrial settings
Results: BURE participant population

- 146 participants, performing in total 4066 assessments
  - 57% were consultants or industry
  - 84% from EU

- Experience of tools
  - Most experience of ECETOC TRAv2/v3, then Stoffenmanager
Assessor-related variation/ total variation-applicable situations only

<table>
<thead>
<tr>
<th>Tool</th>
<th>N</th>
<th>Var$_{Total}$</th>
<th>Ratio (97.5%ile: 2.5%ile)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalation exposure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECETOC TRAv3 (mg/m³)</td>
<td>326</td>
<td>2.59</td>
<td>549</td>
</tr>
<tr>
<td>ECETOC TRAv2 (mg/m³)</td>
<td>365</td>
<td>2.28</td>
<td>372</td>
</tr>
<tr>
<td>MEASE (mg/m³)</td>
<td>151</td>
<td>4.44</td>
<td>3866</td>
</tr>
<tr>
<td>EMKG-EXPO-TOOL (mg/m³)</td>
<td>313</td>
<td>3.23</td>
<td>1147</td>
</tr>
<tr>
<td>STOFFENMANAGER (mg/m³)</td>
<td>280</td>
<td>1.77</td>
<td>184</td>
</tr>
<tr>
<td><strong>Dermal exposure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECETOC TRAv3 (mg/kg/day)</td>
<td>326</td>
<td>1.93</td>
<td>231</td>
</tr>
<tr>
<td>ECETOC TRAv2 (mg/kg/day)</td>
<td>365</td>
<td>1.31</td>
<td>88</td>
</tr>
<tr>
<td>MEASE (mg)</td>
<td>151</td>
<td>4.66</td>
<td>4732</td>
</tr>
<tr>
<td>RISKOFDERM (hands) (mg)</td>
<td>674</td>
<td>6.40</td>
<td>20270</td>
</tr>
</tbody>
</table>
Situation 7: Changing of filters in paint spray booth
Exposure to Nickel during packing

$\text{DNEL} = 0.05 \text{ mg/m}^3$
External validation

- Exposure measurement data and descriptive contextual information were collected from a wide variety of data providers
  - Advisory Board members (BAuA, EBRC, HSE, IFA, NIOSH, SECO)
  - Lund University, BEAT dermal database
  - Project team: ITEM and IOM

- Personal samples
  - Powders/ liquids/ metal processing fumes/ metal abrasion
  - Mix of task-based and time weighted average representative samples
  - REACh-relevant where possible

- Inhalation and dermal data sought, however dermal data limited in scope and quality
Coding of situations into the tools

- Team of experienced exposure scientists
- Quality control manual
  - “Best” option chosen in first instance
  - Agreed defaults where the description was unclear - “middle” option chosen
  - Recorded level of uncertainty in choice
- Coding meetings
- Data checking
  - Data checking
    - Outliers
    - Consistency checks across tools and scenarios
    - Blind recoding of 10% of situations
Summary tool performance for volatile liquids

<table>
<thead>
<tr>
<th>Tool Name</th>
<th>$R_{\text{ind}}$</th>
<th>$G\text{M}_{\text{ratio}}$</th>
<th>$nM$</th>
<th>$nM&gt;T$</th>
<th>$%M&gt;T$</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECETOC TRA v2</td>
<td>0.35</td>
<td>0.1</td>
<td>1842</td>
<td>485</td>
<td>26</td>
</tr>
<tr>
<td>ECETOC TRA v3</td>
<td>0.34</td>
<td>0.2</td>
<td>1842</td>
<td>586</td>
<td>32</td>
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<tr>
<td>EMKG-EXPO-TOOL</td>
<td>0.28</td>
<td>0.03</td>
<td>1372</td>
<td>70</td>
<td>5</td>
</tr>
<tr>
<td>STM 75th percentile</td>
<td>0.54</td>
<td>0.1</td>
<td>1854</td>
<td>359</td>
<td>19</td>
</tr>
<tr>
<td>STM 90th percentile</td>
<td>0.54</td>
<td>0.04</td>
<td>1854</td>
<td>209</td>
<td>11</td>
</tr>
</tbody>
</table>
Tool comparison for volatile liquids
(individual data only)
Summary tool performance for powders

<table>
<thead>
<tr>
<th>Tool</th>
<th>R_{ind}</th>
<th>GM_{ratio}</th>
<th>nM</th>
<th>nM&gt;T</th>
<th>%M&gt;T</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECETOC TRA v2</td>
<td>0.59</td>
<td>0.05</td>
<td>1101</td>
<td>180</td>
<td>16</td>
</tr>
<tr>
<td>ECETOC TRA v3</td>
<td>0.69</td>
<td>0.1</td>
<td>1101</td>
<td>231</td>
<td>21</td>
</tr>
<tr>
<td>MEASE</td>
<td>&lt;0</td>
<td>0.02</td>
<td>1081</td>
<td>115</td>
<td>11</td>
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<tr>
<td>EMKG-EXPO-TOOL</td>
<td>0.7</td>
<td>0.6</td>
<td>1063</td>
<td>184</td>
<td>17</td>
</tr>
<tr>
<td>STM 75th percentile</td>
<td>0.83</td>
<td>0.04</td>
<td>1101</td>
<td>90</td>
<td>8</td>
</tr>
<tr>
<td>STM 90th percentile</td>
<td>0.83</td>
<td>0.01</td>
<td>1101</td>
<td>33</td>
<td>3</td>
</tr>
</tbody>
</table>
Tool comparison for powders
(individual data only)
Conclusions – volatile liquids

- Reasonable amount of data
- Tools appear to be reasonably conservative, in particular when estimating high exposure levels
  - EMKG, ECETOC TRA v2 and v3 less than MEASE and STOFFENMANAGER
- Model estimates appear to follow exposure measurements pretty well (better than for volatile liquids)
Conclusions – Powders

• Reasonable amount of data
• Tools appear to be conservative, again in particular for high exposures
• Although EMKG-EXPO-Tool less so than others
• Good correlation with measurement results for ECETOC TRAv2, ECETOC TRAv3 and STM (~0.8)
• Less correlation for EMKG-EXPO-Tool and no for MEASE
Discussion/Conclusions

- Limitations of the study
  - Data representativeness
  - Coding of exposure scenarios perhaps not done as Industry would do under REACH
- However, large between-user reliability remains a concern
  - Requires efforts to improve use of models
  - Training, certification, team coding, etc
- Tools appear conservative for volatile liquids and powders, in particular for high exposures levels
- However, in particular for TRAvs2 and vs3 care should be taken when using these tools for estimating exposure levels < 100 mg/m³
Acknowledgements

- IOM: Judith Lamb, John Cherrie, Karen Galea, Laura MacCalman, Brian Miller, Shaz Rashid
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  - BAuA (funding)
  - Tool developers (TNO/Arbo-Unie, ECETOC, BAuA, EBRC)
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- Other data providers (Lund University)
- BURE and workshop participants