New EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products: Industry perspectives

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AGES interzonal workshop “Harmonisation of risk assessment in section toxicology”.

23rd & 24th June 2015.
Talk Outline

Industry’s position on the new guidance.
Development of the guidance.
Positive outcomes.
Areas of concern.
Conclusions.
Overall, the ECPA is supportive of the new guidance.

- The harmonisation of non-dietary risk assessment approaches in the EU is a positive step forward.
- Where industry and regulators have been able to work together the outcome has been a ‘win-win’ scenario – e.g. the AOEM.
Development of the guidance
Guidance document development process

2008

- November 2008 U.K. PSD (CRD) and University of Ghent published their report ‘Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure for workers, operators, bystanders and residents’. Report completed under EFSA agreement number EFSA/PPR/2007/01.
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2010

- This opinion raised a number of questions for risk managers which had to be addressed before EFSA could finalise the guidance document.
In May 2011 a working group of risk managers was set up and a meeting took place to discuss specific questions raised by EFSA. The outcomes of this meeting were presented to the SCoFCAH (June 2011) and communicated to EFSA. Based on the response to the opinion, EFSA was asked to proceed with the preparation of the Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents.
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1st April 2014 EFSA published the revised draft guidance document and its exposure calculator. A second (6 week) public consultation period (1st April – 20th May) was held as the guidance document had substantial changes in it compared to the original draft. The guidance document and calculator had already been reviewed by Member States in 2013.
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2014
Guidance document development process

In December 2014 ECPA wrote to key opinion leaders asking them to consider an extension to the envisaged implementation period to allow the generation of field data.

Industry has had criticism levelled against us due to this request.

– So why did we ask for a delayed implementation?
ECPA is currently starting two field projects with the aims of:

- Generating field data to address the data gap identified by EFSA concerning residential exposure associated with high crop applications.
- Generating an EU derived Transfer Coefficient for harvesting re-entry activities in grapes.

The extension was aimed to give industry a chance to get as much field data generated before the implementation of the GD.

The request for an extension was NOT a delay tactic or an indication that ECPA did not support the guidance document.
The EFSA guidance – positive outcomes

Operator exposure: EFSA’s approach is based on the AOEM which was developed and constructed by the BfR, CRD, ANSES and industry.

– A good example of a ‘win-win’ result when collaboration is used.

– This collaborative approach has continued with the development of a new greenhouse model.
The EFSA guidance – the not so positive

Re-entry worker and resident/bystander exposure: approaches are regarded by industry as being overly conservative and restrictive without scientific rationale.

– But, industry is looking to work with regulatory agencies and other stakeholders to address our concerns and provide field data.

– Could this situation have been avoided with stakeholder involvement in the development of these approaches?
Impact assessment

The ECPA has conducted a quick, initial impact assessment of the EFSA calculator.

Remit

- Member companies were asked to run the EFSA calculator for as many scenarios as possible.
- In total 228 scenarios were assessed which covered 96 active substances.
- No acute assessments were conducted as there is no clear guidance on the appropriate acute endpoint to use and also there is an error in the acute exposure calculations (which EFSA is aware of).
## Impact assessment continued

### Results

<table>
<thead>
<tr>
<th>Active target</th>
<th>Active substances</th>
<th>Scenarios passing</th>
<th>Scenarios failing</th>
<th>Operator</th>
<th>Re-entry worker</th>
<th>Resident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herbicides</td>
<td>35</td>
<td>87%</td>
<td>13%</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Insecticides</td>
<td>15</td>
<td>57%</td>
<td>43%</td>
<td>2</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Fungicides</td>
<td>46</td>
<td>51%</td>
<td>49%</td>
<td>14</td>
<td>63</td>
<td>34</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>96</strong></td>
<td><strong>62%</strong></td>
<td><strong>38%</strong></td>
<td><strong>19</strong></td>
<td><strong>77</strong></td>
<td><strong>51</strong></td>
</tr>
</tbody>
</table>

Overall summary: 38% of the tested scenarios fail.
Impact assessment continued

Largest number of failing scenarios is for re-entry workers.

- However, there is the possibility of refinement with the use of DFR data and foliar decline values.

51 (22%) of scenarios fail the resident assessment.

- There is currently very limited mitigation available for this scenario.

<table>
<thead>
<tr>
<th>Operator</th>
<th>Re-entry worker</th>
<th>Resident</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>14</td>
<td>63</td>
<td>34</td>
</tr>
<tr>
<td>19</td>
<td>77</td>
<td>51</td>
</tr>
</tbody>
</table>
### Impact assessment continued

<table>
<thead>
<tr>
<th>Scenario</th>
<th>N</th>
<th>Pass</th>
<th>Fail</th>
<th>Operator</th>
<th>Re-entry worker</th>
<th>Resident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brassica</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Bulb vegetables</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cereals</td>
<td>77</td>
<td>56</td>
<td>21</td>
<td>0</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Citrus</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fruiting veg</td>
<td>10</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Grapes</td>
<td>36</td>
<td>4</td>
<td>32</td>
<td>4</td>
<td>32</td>
<td>12</td>
</tr>
<tr>
<td>Grassland &amp; lawns</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Leaf veg &amp; herbs</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Legumes</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Low berries &amp; small fruit</td>
<td>8</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Oilseeds</td>
<td>13</td>
<td>13</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ornamentals</td>
<td>7</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Pome fruit</td>
<td>18</td>
<td>6</td>
<td>12</td>
<td>6</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Root &amp; tuber veg</td>
<td>31</td>
<td>26</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Stone fruit</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Vegetables</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>228</td>
<td>141</td>
<td>87</td>
<td>19</td>
<td>77</td>
<td>51</td>
</tr>
</tbody>
</table>
There are clear and significant impacts on re-entry worker and resident risk assessments.

- Re-entry workers and residents will often be the driver for the non-dietary risk assessment.
- To-date very, very few active substance fail the residential bystander assessment but more than 1 in 5 products fail based on the new guidance.
  - Is this increase in conservatism scientifically justified?
- Significant impacts are seen in some specific agricultural areas, e.g. grapes where 89% of the scenarios assessed failed due to re-entry worker exposure.
Solutions to apparent failures?

Re-entry workers:
- DFR and exposure data may be used to refine risk assessments.
- Refinement/modification of Transfer Coefficients (ECPA project).

Residents:
- Currently there is no accepted mitigation.
- Results from the ECPA project will start to become available in Q2 2016 but full results will not be available until 2017 – 2018.
- What should industry do until there is an agreed approach to refine the residential risk assessments?
Conclusions

One EU non-dietary exposure calculator is a positive step forward.

The results of the impact assessment indicate potentially large impacts on certain agricultural sectors.
Conclusions

- The calculator needs to have a realistic but protective level of precaution.

- Do Member States have approaches in place to deal with failing scenarios or will they simply refuse registrations?

- What are the consequences of new guidance that suddenly shows apparent unsafe use of currently registered products?
  
  - Does this actually help anyone and what are the potential agricultural, political and legal consequences of getting the level of conservatism wrong?
Looking forward

Cooperation and collaboration

– Can and will Member States work with industry to work through the concerns surrounding the new EFSA guidance?

We see genuine communication and collaboration with all stakeholders as key to ensure the guidance is properly implemented and revised as new data becomes available.
Thank you for listening