Implementation of comparative assessment

-Portuguese approach-

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Topics to be covered:

- Comparative assessment;
- Portuguese approach;
- Results;
- Concluding remarks.
Comparative assessment

Comparative assessment (CA) shall be performed by Member States (MS) when evaluating an application for authorisation for a PPP containing an active substance approved as a candidate for substitution.

Article 24

✓ approved active substances meeting one or more of the conditions listed in point 4 of Annex II, of Regulation 1107/2009:

<table>
<thead>
<tr>
<th>CFS - criteria</th>
<th>N. of active substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low ADI/ArfD/AOEL</td>
<td>18</td>
</tr>
<tr>
<td>Two PBT criteria</td>
<td>53</td>
</tr>
<tr>
<td>Non-active isomers</td>
<td>1</td>
</tr>
<tr>
<td>Toxic for reproduction 1B/1B</td>
<td>4</td>
</tr>
<tr>
<td>Endocrine disruption properties</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>81</strong></td>
</tr>
</tbody>
</table>

EU pesticide DB, 23-10-2018
Comparative assessment

• Comparative assessment (CA) shall be performed by Member States (MS) when evaluating an application for authorisation for a PPP containing an active substance approved as a candidate for substitution.

✓ have been evaluated and are approved for use in the EU in authorised PPP;

✓ Uses of PPP considered under the CA process:

- have all been evaluated
- all have an acceptable risk assessment in accordance with Regulation 1107/2009.
Comparative assessment

- **Guidances:**
  - EPPO standard PP 1/271: EPPO Guidance on CA;
  - Guidance for UK applicants for plant protection authorisations.
Portuguese approach

Tasked to ‘sort out how to deal with it’

Developed ideas and procedures

PT guidance (2015)
Comparative assessment

- Portuguese guidance -

- When should be provide information for CA?
- How should be provide information for CA?
- What does the information needs to cover?
  - How to address CA for zonal applications?
  - Regulatory action in the end of CA
- What if the availability of alternatives changes after a decision?
- Final conclusion and Report

- Keep it as simple as possible;
- Involves applicants;
- Reach a conclusion at the earliest possible step.
Comparative assessment
- Portuguese guidance -

When should be provide information for CA?

• EU guidance on comparative assessment came into force on 1 April 2015;

• The list of Candidates for Substitution came into force on 1 August 2015;

• Applicants need to provide information for comparative assessment from 1 August 2015 (submission date at ZRMS);

• Applicants need to provide the information in this guidance for:

new authorization, extension of authorization, renewal and mutual recognition
Comparative assessment

- Portuguese guidance -

- When should be provide information for CA?
- How should be provide information for CA?
- What does the information needs to cover?
- How to address CA for zonal applications?
- Regulatory action in the end of CA
- What if the availability of alternatives changes after a decision?
- Final conclusion and Report
- CA portuguese guidance -

How should be provide information for CA?

Step 1
Do you want to make the use of the derogation in art. 50 (3)

Step 2
Is your proposed new/additional use a minor use?

Step 3
What is/are the major uses of your PPP to be considered in a CA?

Step 4
What other options are available for the uses to be assessed?

Step 5
Is the chemical diversity of the as in alternative PPP adequate to minimize the occurrence of resistance?

Step 6
What are the potential consequences on minor uses?

Step 7
Alternatives can be used with similar effect on the target pest?

Step 8
Comparability of risks for health and environment

Step 9
Additional information
Comparative assessment

- Portuguese guidance -

- When should be provide information for CA?
- How should be provide information for CA?
- What does the information needs to cover?
- How to address CA for zonal applications?
- Regulatory action in the end of CA
- What if the availability of alternatives changes after a decision?
- Final conclusion and Report
Comparative assessment  
- Portuguese guidance -

**What does the information needs to cover?**

- Consider steps 1-9 of Annex 2 and decide which steps need to complete for the PPP;

- It is recommended to start the assessment in areas, where there might be a problem, e.g., development of resistance;

- CA shall be performed to additional use or uses, the previous authorized uses do not require comparative assessment;

- Any relevant conclusions will not be applied to other existing authorizations for products containing the same candidate for substitution.
- Portuguese guidance -

- When should be provide information for CA?
- How should be provide information for CA?
- What does the information needs to cover?
- How to address CA for zonal applications?
- Regulatory action in the end of CA
- What if the availability of alternatives changes after a decision?
- Final conclusion and Report
What if the availability of alternatives changes after a decision?

- If the applicant believes that suitable significantly safer alternatives to the PPP are no longer available and a comparative assessment would not reach the conclusion that a substitution is appropriate:
  - may make an application for re-instatement of the product using the appropriate regular application route.
  - this application should include a new consideration for comparative assessment together with any other data or information that may be required for re-instatement at that time.
## Comparative assessment

- Portuguese guidance -

### Results

<table>
<thead>
<tr>
<th>Number of PPP with Cs</th>
<th>PPP that have been substituted</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

### Step 2

Is your proposed new/additional use a minor use?

### Step 6

What are the potential consequences on minor uses?
Importance of Minor uses in Portugal

- Total of applications: 4478
- Extensions granted: 2326
- Minor use in major crop: 4% total
New pests every year

<table>
<thead>
<tr>
<th>Pest</th>
<th>Crop</th>
<th>Detected at</th>
<th>Losses (Estimation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scaphoideus titanus</td>
<td>vine</td>
<td>1999 (North of Portugal)</td>
<td></td>
</tr>
<tr>
<td>Tuta absoluta</td>
<td>tomato</td>
<td>May 2009 (Algarve)</td>
<td>60-80% of the yield</td>
</tr>
<tr>
<td>Drosophila suzukii</td>
<td>cherry blackberries</td>
<td>July 2012 (Odemira)</td>
<td>10-80% of the yield</td>
</tr>
</tbody>
</table>
Emergency authorisations (art.º 53)

262 EA

2010-2017

- pedidos
- autorizados
- não autorizados
Concluding remarks

Comparative assessment

Requires:

- A clear justification should be given for the conclusion of each step;
- Clarifications (Cfs – mixture);
- More robust information about alternative methods;

Offers the opportunity to:

- Share the experiences between applicants and CA;

Guidance will be updated in the light of experience (art. 53).
Thank you for your attention!

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