Copa and Cogeca / IBMA Roadmap

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Willem Ravensberg, President of IBMA
What current “tools” are available from the Biocontrol industry for the roadmap?

- **Macrobials**
  - Predators, parasites & nematodes
  - Living organisms found to naturally protect crops

- **Microbials**
  - Viruses, Bacteria & Fungal Pathogens
  - Found naturally in soil, used in food, feed & and unregulated uses

- **Semiochemicals**
  - Pheromones, Plant volatiles
  - Communication tools found in nature with no killing effect

- **Natural Products**
  - Botanicals & Other Natural substances
  - Products derived from nature

Not usually regulated as PPPs
Regulated as PPPs
Platforms of Copa & Cogeca / IBMA roadmap

1. Information exchange and targeting solutions

2. Co-operation in EU Minor Uses

3. Low-risk active substances and products
Co-operation in EU Minor Uses
EU Minor Uses

• Combined approach from 2 organisations to:
  • Simplify and harmonise
  • Do not constantly repeat same activities
  • Utilise existing information
  • Ask for any information considering all needs

“Life is really simple, but we insist on making it complicated”
Confucius.
EU Minor Uses

- IBMA has a voice on EU Minor Uses HEG
- EU Minor Uses Co-ordinator understands the role and capabilities of biocontrol
- MRLs take time
- Biocontrols should be able to be brought in more quickly
- Biocontrols are often targeted at minor uses
- Some repairs to legislation need to be made
- September EU Minor Uses meeting will have a special topic on biocontrol
Low-risk Procedures
What is wrong and what do we want?

• The existing PPP regulatory system was designed for chemical and not biological systems
• EU Farmers are being deprived of solutions that are being made available in other parts of the world
• Biocontrol providers have their own “minor use products”
• Biocontrol Industry is diverse in structure including many SMEs

• More low-risk biological products available to farmers quickly – stop emptying and start filling the toolbox!
### Evaluation Timeline for initial a.s. approval

<table>
<thead>
<tr>
<th>Category</th>
<th>Candidate for substitution</th>
<th>Standard Case</th>
<th>Low-risk active substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation Timeline for initial a.s. approval</td>
<td>3 years+</td>
<td>3 years+</td>
<td>3 years+</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation Timeline for initial product authorisation (registration)</th>
<th>Candidate for substitution</th>
<th>Standard Case</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Duration of initial a.s. approval</td>
<td>7 years</td>
<td>10 years</td>
<td>15 years</td>
</tr>
<tr>
<td>Duration of a.s. approval at renewal</td>
<td>7 years</td>
<td>15 years</td>
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The benefit of being granted the status of low-risk is only inferred at the end of the procedure. The benefit achieved for being a low-risk active substance is a 5 year longer initial approval period. This is not given for subsequent renewals. The benefit achieved for a low-risk PPP (plant protection product) is the shortened 120day procedure which Member States often ignore and wish to lengthen. Realistically little benefit is currently seen from having low-risk status + includes stop the clock time
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<tr>
<td>Procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation Timeline for initial a.s. approval</td>
<td>3 years+</td>
<td>3 years+</td>
<td>0.5 years to Completeness + LR Check Provisional Approval 2.5 years after Completeness Check</td>
</tr>
<tr>
<td>Duration of initial a.s. approval</td>
<td>7 years</td>
<td>10 years</td>
<td>Unlimited apart from data call-ins</td>
</tr>
<tr>
<td>Evaluation Timeline for initial product authorisation (registration)</td>
<td>1 year+</td>
<td>1 year+</td>
<td>120 days</td>
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<tr>
<td>Duration of a.s. approval at renewal</td>
<td>7 years</td>
<td>15 years</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

The benefit of being granted the status of low-risk would be provisionally inferred when the revised Completeness Check is done and then confirmed at the end of the procedure. PPP submissions can be submitted after Completeness Check.

The benefit for being a low-risk active substance would then be for an unlimited initial approval period granted when full approval and status is noted. There is no requirement for subsequent renewals.

The benefit achieved for a low-risk PPP (plant protection product) is retained at a 120-day procedure. PPPs can then be brought to market.

 Provision for data call-in exists within the legislation and should be used if scientific evidence points to a risk that could affect the status of the active-substance and PPPs containing it.

+ includes stop the clock time
Summary of low-risk changes sought

• Revert to a Provisional approval system for low-risk a.s.
• Unlimited approval status given for low-risk a.s.
• Retain 120day evaluation timeline for low-risk PPPs
• Unlimited approval status given for low-risk PPPs
• Reduced efficacy data requirements for low-risk PPPs
• Label advertisement for low-risk PPPs
• Introduce a biopesticide stream for evaluations
• Establish a group of expert biopesticide evaluators
Low-risk procedures – where are we?

• Netherlands presidency
  • Low-risk on the agenda
  • Low-risk recommendations at conclusion of presidency

• EU Parliament
  • Cross party support
  • Envi Committee activity
  • Plenary activity

• EU Commission
• Stakeholder support
Information exchange and targeting solutions
Information exchange and targeting solutions

- The least progress to date and the biggest challenge
- Nature and structure of advisory services
- 2 levels of information
- General principles
- Regional / Local targeted information
Information exchange and targeting solutions

• The area of concentration for 2016 and beyond
• Close co-operation and working between Copa and Cogeca and IBMA and our joint members
• Principles in roadmap still valid
• Solutions have to satisfy farmer needs
• Systems have to be robust
• IBMA members need to focus on solutions where a need is perceived
• Label claims need to be realistic and achievable
Biocontrol

Important in sustainable Agriculture:

A key part of Integrated Pest Management

Working with and not against nature
Many thanks and let's keep working together!

David Cary