IBMA presentation to the South Zone Steering Committee Meeting, Oeiras 7th July 2016

“Issues for co-operation between regulators and the biocontrol industry”

David Cary, Executive Director of IBMA
Low-risk active substance and PPP Procedures & Criteria
low-risk changes sought

- Fast track or provisional approval system for low-risk a.s.
- Time unlimited approval status given for low-risk a.s.
- Retain 120day evaluation timeline for low-risk PPPs
- Time unlimited approval status given for low-risk PPPs
- Reduced efficacy data requirements for low-risk PPPs
- Label claims for low-risk PPPs
<table>
<thead>
<tr>
<th>Category</th>
<th>Procedure</th>
<th>Candidate for substitution</th>
<th>Standard Case</th>
<th>Low-risk active substance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active substance renewal</td>
<td>7 year approval</td>
<td>15 year approval</td>
<td>15 year approval</td>
</tr>
</tbody>
</table>

Priority given for renewal evaluations for active substances anticipated to be low-risk as was priority given for active substances designated as candidates for substitution

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<tbody>
<tr>
<td></td>
<td>Active substance expiry</td>
<td>2029</td>
<td>30/11/2036</td>
<td>31/8/2035</td>
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<tr>
<td></td>
<td>dates assuming an evaluation of 3 years</td>
<td></td>
<td>21/5/2039</td>
<td></td>
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</tbody>
</table>
Inconsistencies between Criteria main text and annex or implementation

- Microbials
- AMR
- Guidance to be prepared by EU Biopesticides EG

- Semiochemicals
- Issue of inconsistency
Other issues
Niche uses of highly specific biocontrol solutions

- Types of species specific biocontrol solutions
  - Pheromone attractants
  - Baculoviruses

- Low-risk criteria
  - Both a.s. groups separately identified & characterised

- Markets
  - Some large markets eg. *Cydia pomonella*
  - Many very small markets eg. *Spodoptera littoralis* & *Adoxophyes orana*
Possible regulatory solutions

- OECD Seminar discussions:
- Grouped a.s. approvals
- Single EU regulatory zone for low-risk PPPs
- Linkage with minor uses
- Indefinite approval & authorisations
- REACH style tonnage limits for notification
Where do biological inputs fit within regulation?

**PPP Regulation**
- Biopesticide
- Botanical
- Microbial
- Mating disruption
- Plant
- Strengtheners
- Soil Conditioners
- Probiotics
- Natural remedies
- Food & feed
- Additives
- Food

**Organic Regulation**
- Fermentation product
- Biosimilar
- Predator parasite
- Nematode

**Fertilisers Regulation**
- Biofertilisers
- Biostimulants

**Biostimulant for biotic stress**
- Endophyte
- Mass trapping
- Monitoring

**Natural remedies**
- Food & feed additives
- Probiotics
- Soil Conditioners
- Plant Strengtheners
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Engagement with EU Sustainable Agriculture EG and MUCF

- Support of Implementation plan
- Support of specified issues low-risk and IPM
- Support of MS prioritised issues in DK, NL, SE and IT
- Participate in MUCF meetings and issues
- Promote minor uses with IBMA members
- Global minor uses meeting and outcomes
- Single zone
Issues under REFIT

- Zonal authorisations
- Mutual recognition
- Timelines
- Biological active substance and product specific issues
- Invasive pests and diseases
- Efficacy
- Terminology
- Emergency authorisations
Possible additional regulatory solutions sought under REFIT

- Single EU Agency eg EMA
- Minor uses & niche solutions
- REACH style notification system
- Data call in system
- Expert group of biopesticide evaluators
- Biopesticide stream for evaluations
- Biological inputs into agriculture
- Data relevance / waiver system
- Specialised evaluation of any true risks posed!
Many thanks!

David Cary