David Cary, Executive Director of IBMA
Low-risk active substance and PPP Procedures
<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><strong>Procedure</strong></td>
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<tr>
<td>Evaluation Timeline for initial a.s. approval</td>
<td>3 years+</td>
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<td>7 years</td>
<td>10 years</td>
<td>15 years</td>
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<tr>
<td>Evaluation Timeline for initial product authorisation (registration)</td>
<td>1 year+</td>
<td>1 year+</td>
<td>120 days</td>
</tr>
<tr>
<td>Duration of a.s. approval at renewal</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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<td>3 years+</td>
<td>0.5 years to Completeness + LR Check Provisional Approval 2.5 years after Completeness Check</td>
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<td></td>
<td>Duration of initial a.s. approval</td>
<td>7 years</td>
<td>Unlimited apart from data call-ins</td>
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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.

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The benefit of being granted the status of low-risk would be provisionally inferred when the DAR is published at then confirmed at the end of the procedure. PPP applications can be submitted after provisional approval.

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 120day 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.

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IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION
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
Species specific biocontrol active substances and products: a special case!
• Point 4. Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.
Pinpointed control = advantages & disadvantages

- 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*
Species specific control
Possible regulatory solutions

• Grouped a.s. approvals
• Single EU regulatory zone for low-risk PPPs
• Exemption for species specific control measures
• Indefinite approval & authorisations
• REACH style tonnage limits for notification
Biological inputs into agriculture and regulation
Future Sustainable Agriculture

• Holistic approach
• Founded on prevention and monitoring
• New tools all nature-based solutions
• Biopesticides, biostimulants, biofertilisers
• Intervention only when needed via a licensed PCA written recommendation
• Resilient soils and resilient plants (microorganisms, seed treatments, etc.)
• Automation, ICT tools and intelligent equipment minimised use of products and exposure
Where do biological inputs fit within regulation?
Factors affecting adoption: Macro factors

• Political and societal needs favour the use of bioprotection (environment, biodiversity, food safety)
• Increased legislation of chemicals will stimulate development of diverse biological solutions
• We need to check or monitor that these are the low-risk ones
• Many driving forces: influence of retailers and consumers for residue-free food, environmental responsibility & farmers wanting a diversity of tools
• The biocontrol, biostimulant and related industry has reached a sufficient level of maturity enabling realistic participation and continued solid growth in future agriculture
Possible regulatory solutions

• Single EU Agency
• REACH style notification system
• Biological inputs into agriculture
• Biological inputs into the environment
• Specialised evaluation of any true risks posed!
Many thanks!

David Cary