IBMA’s view on registration of biopesticides

Willem Ravensberg, President of IBMA

‘4th Annual Eastern Europe Regulatory Conference: Registration of Plant Protection Products’

taking place in Budapest, Hungary, on the 12-13 April 2016.
What is IBMA?

- International Biocontrol Manufacturers Association
- Established in 1995
- Over 230 members
- Global (European focused) Association
- Strong growth from 10 original founding members
- Diverse membership
  - SME’s to multinationals
  - Organic and biocontrol only to IPM and conventional
  - Principally involved in agriculture and horticulture
- Member of BioProtection Global
- Accreditation by COM, EP, EChA, EFSA
What is the focus of IBMA?

- Ensuring proportionate regulation of members’ products
- Promoting the interests and activities of the sector and its’ members
- Promote members main interest – biologically-based crop protection
- Accelerate strong growth in the use of biocontrol products
- Maintain a strong European focus
- Assist in establishing a global network to deal with global issues
- Promote diversification into other areas (e.g. non-crop uses)
What “tools” are available from the Biocontrol Industry?

- **Macrobials**: Predators, parasitoids & beneficial nematodes. Living organisms found to naturally protect crops.
- **Microbials**: Viruses, Bacteria and 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
Where do biological inputs fit within regulation?

- **Biopesticides**
- **Biostimulants**
- **for biotic stress**
- **Fermentation products**
- **Biosimilars**
- **Endophytes**
- **Mass trapping**
- **Monitoring**
- **Predators Parasites Nematodes**
- **PPP Regulation**
- **Biopesticides**
- **Biostimulants for biotic stress**
- **Fermentation products Biosimilars**
- **Pollinators**
- **Biofertilisers**
- **Biostimulants**
- **Plant Strengtheners**
- **Soil Conditioners**
- **Probiotics**
- **Natural remedies**
- **Food and feed additives**
- **Food**

*IBMA* (International Biocontrol Manufacturers Association)
Low-risk active substances
Biopesticides and low risk a.s. and products

• “Biopesticides’ are not mentioned in Reg. 1107/2009 and Dir. 128/2009
• Instead: low risk active substances (Art. 22) and Products (Art. 47) and basic substances (Art. 23)
• Incentives for low risk a.s. and products:
  • Data protection 13 years
  • Approval period for 15 years
  • Product authorization in 120 days
  • Advertising allowed, but not on the label (Art. 66)

• Low risk criteria: being revised
• Low risk a.s. status only given after the full evaluation procedure
• SUD: priority for non-chemical methods
Approved 'biopesticides' in the EU (≈150 of 484 a.s.)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbials</td>
<td>50</td>
<td>19 fungi, 22 bacteria, 6 viruses, 3 yeasts</td>
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<tr>
<td>Naturals and biochemicals</td>
<td>68</td>
<td>18 plant extracts, 46 biochemicals, 5 minerals</td>
</tr>
<tr>
<td>Semiochemicals</td>
<td>32</td>
<td>32 Pheromones</td>
</tr>
<tr>
<td>Macrobials</td>
<td>86</td>
<td>12 predatory mites, 78 insects, 6 nematodes</td>
</tr>
</tbody>
</table>

- **IBMA**

International Biocontrol Manufacturers Association
'Biopesticides' under evaluation (19 of 34 a.s.)

Microbials: 15
- 7 fungi
- 4 bacteria
- 2 virus
- 2 yeasts

Naturals and biochemicals: 4
- 3 botanicals
- 1 animal derivative

Semiochemicals: 1
low-risk today

- Five a.s. approved as low risk active substance
  - *Isaria fumosorosea strain Apopka 97* (renewal)
  - COS-OGA (new a.s.)
  - Cerevisane (new a.s.)
  - Ferric Phosphate (renewal)
  - Pepino mosaic virus strain CH2 (new a.s.)

- New actives: procedure took ≈ 36 months
- Product authorization: procedure took ??
- Existing candidate low risk a.s. ≈ 120
- Status only acquired after renewal procedure
- Why not as soon as revised criteria are adopted? → impact check already done
Low-risk Procedures
IBMA proposal for Low-risk active substances and products under 1107/2009

• Incentives in 1107/2009
  • Approval for 15 years (10/15 years usually)
  • Data protection for 13 years (10 years usually)
  • Product approval in 120 days
  \(\rightarrow\) not relevant incentives for industry (except 120 days procedure)

IBMA proposal
• Approval for an unlimited period, unless documented reports of harmful effects
• “Fast track” procedure for low risk active substance
• Confirm low risk status of presumed low risk a.s. and products as soon as possible
• Consistent and reasonable fees
<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>
<tr>
<td>Duration of initial a.s. approval</td>
<td>7 years</td>
<td>10 years</td>
<td>15 years</td>
</tr>
<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>
<td>7 years</td>
<td>15 years</td>
<td>15 years</td>
</tr>
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</table>

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 120 day procedure which Member States often do not meet. Realistically little benefit is currently seen from having low-risk status.

+ includes stop the clock time
Standard timelines 1107/2009
(typical case example with request for additional information)

Active Substance

- AS dossier submission
- DAR
- Approval AS

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q1</th>
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<th>Q3</th>
<th>Q4</th>
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<th>Q2</th>
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<th>Q4</th>
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<td>Year 3</td>
<td>Year 4</td>
<td>Year 5</td>
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</table>

PPP dossier submission ZRMS
Zonal Authorization PPP
Mutual recognition Application
Mutual Recognition
### IBMA Proposal 1:

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 confirmed. 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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<tr>
<td><strong>Procedure</strong></td>
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<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</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Provisional Approval</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2.5 years after Completeness Check</td>
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<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>
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<td>1 year+</td>
<td>120 days</td>
</tr>
<tr>
<td>Duration of a.s. approval at renewal</td>
<td>7 years</td>
<td>15 years</td>
<td>Not applicable</td>
</tr>
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+ includes stop the clock time
Timelines 1107/2009 (proposed low-risk case)

Low-risk Active Substance

C Check
Incl. low-risk status

DAR

Provisional low-risk a.s. approval

Full Approval AS

Mutual recognition

Provisional Zonal Authorization PPP

PPP dossier submission ZRMS

Low-risk a.s. based PPP

Full Zonal Authorization

Low-risk a.s. based PPP
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+ includes stop the clock time

IBMA Proposal 2:
The benefit of being granted the status of low-risk would be provisionally inferred when the DAR is published and 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 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.
Low risk based PPP

AS dossier submission

DAR and Provisional low-risk a.s. approval

Full Approval AS

Low-risk Active Substance

C Check

Full Zonal Authorization I-r PPP

Mutual recognition

Provisional Zonal Authorization PPP

PPP dossier submission ZRMS

Low-risk a.s. based PPP

Low risk based PPP

Timelines 1107/2009 (proposed low-risk case)
IBMA proposal for a “fast track” for Low-risk active substances

- Active substances proposed as low-risk are submitted with a full dossier according to the data requirements will be given priority by Member States and EFSA
- A revised completeness check, including an assessment of low-risk status according the low risk criteria (and working document)
- Dossiers satisfying the requirements of this revised completeness check will lead to a provisional approval of the active substance
- This would be followed by the full assessment, with possibly additional dossier/ information requirements, and possibly due to a withdrawal of low-risk status during the approval process
- The low-risk active substance approval (currently 15 years) shall not be time-limited and subject to automatic re-evaluation
IBMA proposal for a “fast track” for Low-risk products

- Product applications only containing low-risk substances shall be given an automatic accelerated (fast-track) authorization process for low-risk products. Art. 47: authorization within 120 days- already in place
- No authorization expiration date and hence no time-related re-evaluation should be seen as the standard practice for products meeting low-risk criteria
- Advertising that a product is low-risk should be permitted and encouraged on the product label (adapt Art. 66.2)
Green Deal “Green PPPs in Netherlands”

- 2.5 years project on “Green PPPs”
- Aim: facilitate and accelerate product authorizations
- Participants: Ministry, Ctgb, NVWA, industry, farmers, NGO
- Install “Green Team” and develop practical processes
- Evaluate options and lessons learned
- Develop a better process and share within Europe
- Adapt EU legislation if deemed needed
Green Deal “Green PPPs in Netherlands”

• Lessons learned so far
• Hurdles for evaluation:
  • Human toxicology
  • Efficacy assessment
• Follow up:
  • Workshop on human tox (12 November 2015)
  • Workshop on efficacy (6-7 April 2016)
Green Deal “Green PPPs in Netherlands”

Programme outline Working Groups

Workshop Efficacy Requirements and Evaluation of Plant Protection Products based on Low-Risk Active Substances, The Netherlands, April 6 & 7 2016

C. Jilesen (NVWA), J. Roman (NVWA), W. Ravensberg (IBMA), H. Brouwer (Ctgb), J. van Etten (Ctgb)
Summary of low-risk changes sought

• Revert to a Provisional approval system for low-risk a.s.
• Unlimited approval given for low-risk a.s.
• Retain 120day evaluation timeline for low-risk PPPs
• Unlimited authorization 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 team of expert biopesticide evaluators
Thank you for your attention

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