Low-risk Criteria and Procedures Development in Europe

David Cary, Executive Director, IBMA
What “Non-chemical solutions” are currently available from the Biocontrol industry?

**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

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

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

Regulated as PPPs
Not usually regulated as PPPs
What range of non or minimally regulated products are currently available to the farmer?

**Not usually regulated as PPPs**

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

- **Microbials**
  - Viruses, Bacteria & Fungal Pathogens
  - Used as biostimulants, biofertilisers, plant strengtheners, soil amendments etc.

- **Semiochemicals**
  - Pheromones, Plant volatiles
  - Monitoring traps

- **Natural & Biochemical Products**
  - Botanicals & Other Natural substances
  - Used as biostimulants, biofertilisers, plant strengtheners, soil amendments, etc.
What non or minimally regulated products are currently available to the consumer?

**Microbials**
- Viruses, Bacteria & Fungal Pathogens
- Used as food and food additives.

**Macrobials**
- Predators, parasites & nematodes
- Consumed as food.

**Semiochemicals**
- Pheromones, Plant volatiles
- Used in perfumes, air fresheners, etc.

**Natural & Biochemical Products**
- Botanicals & Other Natural substances
- Consumed as food.
Current list of low-risk active substances

- Cerevisane
- COS OGA
- Feric phosphate
- Isaria fumosorosea Apopka strain 97
- Pepino mosaic virus strain CH2 isolate 1906
- Saccharomyces cerevisiae strain LAS02
- Trichoderma atroviride strain SC1
Low-risk criteria development
Low-risk Plant Protection Products Criteria Development

- EU Expert Group established
- Criteria proposed & discussed
- IBMA & other stakeholder input
- Incentives & procedures removed
- New criteria added
- SCoPAFF
- Enter as an Annex
- Review criteria

**• IBMA input**
- From Professional Groups
- Criteria and incentives
- Different criteria to conventional chemistry solutions

**• IBMA Chair of sub-group on incentives**
- Proposal of revised Incentives and Procedures
Low-risk Plant Protection Products Incentives and Procedures Development

EU Expert Group established

Criteria proposed & discussed

IBMA & other stakeholder input

Incentives & procedures removed

New criteria added

SCoPAFF

Enter as an Annex

Review criteria

IBMA need to separately handle incentives & procedures

Stakeholders identified & approached

Consultant PA Europe engaged

Activities of PA Europe, IBMA & Copa and Cogeca
Low-risk procedures and incentives activities
Approach to amend Incentives and Procedures

- Poll of key stakeholders and influencers
- Engagement of partners and supporters
- EU Commission approaches
- European Parliament approaches
Full Agreement Among All Stakeholders

• Formal letter European Commissioner for SANTE Dr Vytenis Andriukaitis 01/08/16: “The Commission shares the same interest to promote low risk solutions for plant protection”

• Since 12/10/16 Draft LRP Resolution Supported by ALL PARTIES in the European Parliament – No Opposition Left!!!

• Elite Poll of 5/5/15: 93% of all experts want the European Commission to facilitate and accelerate the approval procedures of low-risk bio-pesticides

• EU Council of Ministers: Unanimously support implementation plan of EU Sustainable Plant Protection EG on 28/06/16
OQ/MfR Co-Sponsors

• Mr Herbert Dorfmann (EPP)
• Mr Pavel Poc (S&D)
• Ms Julie Girling (ECR)
• Ms Frédérique Ries (ALDE)
• Ms Lynn Boylan (GUE/NGL)
• Mr Bart Staes (Greens/EFA)
• Ms Mireille D’Ornano (ENF)
Biological low-risk pesticides Resolution Time Table

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Oral Question in ENVI 28/11/16: Call on EC to immediately provide access for LRP to market through specific protocol</td>
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<tr>
<td>Motion for Resolution in ENVI 23/01/17: Demand Specific Access Procedure for LRP to be available via these modified procedures in two-three years</td>
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<tr>
<td>Vote in European Parliament Plenum: 13/02/17</td>
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Additional contributions to low-risk procedures

• 40 point Implementation Plan developed by EU Biopesticides Expert Group
• Harmonisation in interpretation eg. Human toxicology
• Development of EPPO Efficacy Guidelines
• Adherence to Mutual Recognition & Zonal Reviews
• Biopesticide stream similar to US EPA Biopesticides Unit
  • Evaluation by dedicated individuals with expertise and mindset
• Netherlands CtgB in bilateral discussions and implementation
Low-risk procedures and incentives possible outcomes
Possible outcomes

• REFIT ONLY
  • No benefits for 8-10 years
  • One of several issues wrong with legislation
  • Lack of focus on our issue
  • Little chance of total support for the full package of changes
  • Low-risk is firmly on the agenda at EUP, Sante, stakeholders, EU Sustainable PPP Expert Group and Council of Ministers

• REFIT + EU Sustainable EG PPP recommendations
  • 40 recommendations
  • Specific action to accelerate l-r PPP authorisations
  • Provisional listing (non legally binding) of existing approved low-risk ais
  • Advice to utilise the list to authorise l-r PPPs in 120 days
Preferred outcome

• Simple Fitness check of EC Reg 1107/2009
  • Low-risk substances reviewed via modified fast track procedure through simple modification to articles 22 and 66
  • Guidance developed to ensure low-risk PPPs reviewed within 120 day period
  • Work with EU Sustainable Plant Protection EG to implement additional means of acceleration
Many thanks – any questions?

David Cary