Progress towards Proportionate regulation for Biocontrol Technologies

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Background

1. **Current data requirements (DRs) and Uniform principles (UPs)**
   Drafted for chemicals, not for biologicals: many DRs are deemed inadequate or unworkable

2. **DRs for microorganisms date back to 2001**
   Not been updated by Regs (EU) Nos 283 and 284/2013, unlike DRs for chemicals

3. **DRs and UPs for microorganisms are not fully harmonised**
   Example: Living microorganisms in PPP DRs, but viable and non viable in UPs
1. **Proportionate Regulation: Dual Track**
   - Reg. 1107/2009 – Amend data requirements
   - New Biologicals regulation

2. **Reg. 1107/2009 Data Requirements**
   - New data requirements under preparation by EU COM with MS – IBMA encouraged to make decision tree

3. **Push for New Regulation**
   - Revise White Paper after REFIT
   - IBMA-member endorsement
   - Seek alignment with MSs (e.g. NL)
IBMA White Paper reviews the following

1. Competent Authorities in other regions
   Review of regulation of biologicals by other authorities *around the world*

2. Other Regulated Products in Europe
   Assessment of e.g. medicines to see what other solutions may be available

3. Regulation of Products from SMEs
   Review how SMEs are treated and what assistance is provided to SMEs

4. Speedy Approvals and Provisional Authorisations
   What routes to speedy authorizations exist in other legislations?
✓ Register within 2 years
✓ Separate evaluation route for MOs and biochemicals
✓ Proportionate DRs

What can we learn from other regulatory authorities?

✓ Specific legislation
✓ Case-by-case evaluation
✓ Flexibility in DRs
The Key Messages of the White Paper

- Other regulations in Europe support SMEs
- Other regulations in Europe offer provisional authorisation
- Regulated biological PPPs in other regions operate fast-track and have delivered more products
- Other regulations in Europe work on a notification basis

⇒ Regulatory Framework Review
What can we learn from regulation of other Products?

Medicinal Products Regulation
Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet

What can we learn about support for SMEs and quicker PPP approvals?

Netherlands: Proactive approach to improving dossier preparation and speed through the registration process

Germany: Article 53 derogation for wireworm protection in potatoes based on Metarhizium or baculovirus vs Tuta

Belgium and SC PAFF: Fast-track evaluation for weak strain pepino virus to reinforce immunity to Pepino mosaic virus (PepMV) in tomato
Dedicated Data Requirements
Dedicated Uniform Principles
Specialist evaluators
Specialist peer review

Success in 4 areas

Mo

More difficult
Labelling to acknowledge low-risk or similar
A separate regulation specific for Biological PPPs

Very difficult
Provisional Authorisation
Current situation

EU COM response to continued demand by IBMA and EP and need for green solutions

Revision of data requirements

IBMA Board meeting with DG SANTE senior level on 30th April 2019

DG SANTE in EU WG on BioPesticides in May 2019

DG SANTE Pesticides Team at IBMA Annual Assembly in May 2019

IBMA Secretariat meeting with DG SANTE Biopesticides Team in September 2019

EU COM started work on DRs for microbials Meetings with MSs in July, August, September …

EU COM Expert Meeting on Biopesticides – IBMA presentation on Microbials Decision Tree in November 2019
Way forward

EU COM response to continued demand by IBMA and EP and need for green solutions

Microbials data requirements

EU WG on Biopesticides – IBMA MS EU COM
Further review data requirements in January 2020

EU COM Expert Meeting on Biopesticides – IBMA MS EU COM review of data requirements in May 2020

Consultation on New Data requirements in June 2019

SCoPAFF sign-off in October 2020
IBMA Work on Decision Trees
Initial Timelines

Microbials and Natural Substances

July/August
Set up ad hoc groups

September
Convene group - prepare proposal for decision tree - circulate for commenting

October
Consider comments – finalise decision tree – present it to IBMA PGs at ABIM

November
Stress test Workshop

December
Target submission to EU COM

Delayed schedule for Semiochemicals:

Launch at ABIM 2019 → delivery in June 2020
IBMA Work on Decision Trees

NEW Timelines

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January
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Microbials and Natural Substances

Delayed schedule for Semiochemicals:

Launch at ABIM 2019 → delivery in June 2020
Priority subject of high importance

IBMA Work on decision trees

Organisation
General decision tree and 5 section trees:
- Identity / Biology
- Human health (Toxicology)
- Residues
- E-fate
- Non-target Organisms

Contributors
Natural substances:
- Lead: Chair & Co-chair
- 24 participating + 6 corresponding experts

Microbials:
- Lead: Chair
- 30 participants
IBMA expectation for Data Requirements and Uniform Principles

**Decision trees** shall

- Allow simplified approach with increased reliability
- Focus on relevant DRs, avoid unworkable DRs
  - Focused assessments ⇔ reduced work and time

Moving from regulatory science to scientific science
Ecology and Biology of microorganisms

DRAFT 4
Biol. Properties and Related risk areas

START
Molecular identification and phylogenetic position

What is it?

Biology of the microorganism - Ecology and host range

1

1.1
Obligate parasite

1.1.1
Host range: species or genus specific

1.1.2
Host range: Not plant pest or disease specific (not genus)

1.2
Facultative/saprophyte parasite

1.2.1
specialist

1.2.2
generalist

1.3
Non-systemic endosymbiont or true endophyte

1.3.1
Known to produce mycotoxins (MCsH) in the plant

1.3.2
Not known to produce mycotoxins (MCsH) in the plant

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NTO 2 E-fate 2

HuSa 2
NTO 2 (only terr. plants)

HuSa 2
NTO 2 E-Fate 2

HuSa 1+2
NTO 1+2 E-fate 2 Residues (in the plant)

HuSa 2
NTO 2
Clear up to date phylogenetic information is the starting point for the literature assessment.

The relevance for the strain under evaluation needs to be clear.

All decisions need to be taken based on reliable data from published literature, internal studies, or “formal” studies.

**MCscH** - Microbial produced compounds that may be of safety concern for **humans** captured on a list, which is kept up-to-date.

**MCscE**: Microbial produced compounds that may be of safety concern for the **environment** including vertebrates captured on a list, which is kept up to date.
Decision tree biological properties

Microbial compounds known to be present in the MPCP?

From 1; to 2.1
If MPCA/MPCP contains
MCscE or MCscH

HuSa 1
NTO1
Residue 1
E-Fate 1
Hazards are identified based on understanding of the biology and ecology of the microorganism.

The tiered approach progresses dependant on the outcome of identified risk.

The IBMA proposal for Decision Tree is still under development.
Conclusions

1. EU COM is working with Member States on revision of data requirements for microbials.
2. IBMA has opportunity to contribute decision trees on relevant risk areas.
3. EU COM proposal for revised data requirements for microbials will be completed in 2020.

What Next?

IBMA will review White Paper in the light of REFIT and make the necessary proposals for changes to semiochemicals and natural substances.
Thank you

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