



Data Requirements and Uniform Principles Relevant to Biocontrol

Ulf Heilig - IBMA - Regulatory Affairs Director

ABIM 2019 – Basle – 22nd October 2019





Contents

01

Background

02

EU COM revision of data requirements

03

IBMA work on decision trees

04

IBMA expectation for DR revision and REFIT

05

Conclusions



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 283 and 284/2013 unlike DRs for chemicals

3

DRs and Ups for microorganisms are not fully harmonised

Example: Living microorganisms in PPP DRs, living and dead in UPs



Background



REBECA (2006/2007) and EP readings for future reg. 1107/2009 (2007/2008)



IBMA Position Papers on low-risk biocontrol AS and PPPs in 2013 and 2015



EP Resolution on low-risk pesticides of biological origin in February 2017



REFIT programme of EU COM since 2017



Arche Report and White Paper in 2018



IBMA
demands for
specific
approach to
biocontrol

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 ...



IBMA launched Work on decision trees

Briefing Document from IBMA Secretariat to three Professional Groups and invitation to National Groups to nominate experts (10th July)

The Concept

- Identify areas of risk
- Do not develop data requirements
- Propose a decision tree

**Change paradigm:
innocent until proven guilty**



Thinking out of the box

Work on Decision Trees

Timelines



Microbials and Natural Substances

Delayed for Semiochemicals:



July/August

Set up ad hoc groups



September

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



October – **NOW!**

Consider comments – finalise decision tree – present it to PG at ABIM



November

Stress test Workshop



December

Target submission to EU COM

Launch at ABIM 2019 → delivery in June 2020





Priority subject of high importance

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



Decision trees Current Status

Presented to the members:

→ Microbials PG and

→ Natural Substances PG

Challenges



Thinking out of the box



Separating risk areas from data requirements



Hierarchy of decision points
Biology for microbials,
source for natural substances)



Terminology and wording
Development of definitions



Importance of production process
e.g. fermentation for microbials or
extraction process for natural substances

Good experience



Fast action at short notice




Good collaboration and work-sharing



Large support by Professional Groups, National Groups and member experts



First objective met: Draft decision trees available for ABIM



Encouraging for
the way forward



Stress or Robustness Test

Intended schedule: November 2019 (for MOs)

Lead: Roma Gwynn assisted by
IBMA secretariat and
PG chairs

Participants: IBMA experts and
external experts

Expertise is about science, not about politics!



Testing of different cases





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



REFIT and IBMA expectation

COM DG SANTE's **REFIT report on hold** until new COM operational

Expected in November or December ... ?

No COM Interservice Consultation yet

New COM (= political level): high priority to sustainable use of pesticides, increased use of non-chemical solutions

COM REFIT report

shall identify shortcomings and give **leads for improvement**

will be discussed with co-legislators

Decision on way forward should be taken **in 2020**



We expect changes: priority and fast-track
for biocontrol and low-risk

Conclusions

1

COM is working with Member States on revision of data requirements for microbials

2

IBMA has opportunity to contribute decision trees on risk areas

- ✓ Large support from member experts, PGs and NGs
- ✓ Drafts presented in IBMA MPG and NSPG at ABIM
- ✓ Stress test intended for November
- ✓ Submission to COM in Dec 2019 (microbials, ...)

Way forward?

COM will give IBMA / stakeholders the opportunity to comment on proposed data requirements at a later stage



Let's be optimistic!

Thank You



Current situation of the applicant?

