# *Progress towards Proportionate regulation for Biocontrol Technologies*

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IBMA
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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

# IBMA White Paper 2018

1

## Proportionate Regulation: Dual Track

Reg. 1107/2009 – Amend data requirements
New Biologicals regulation

2

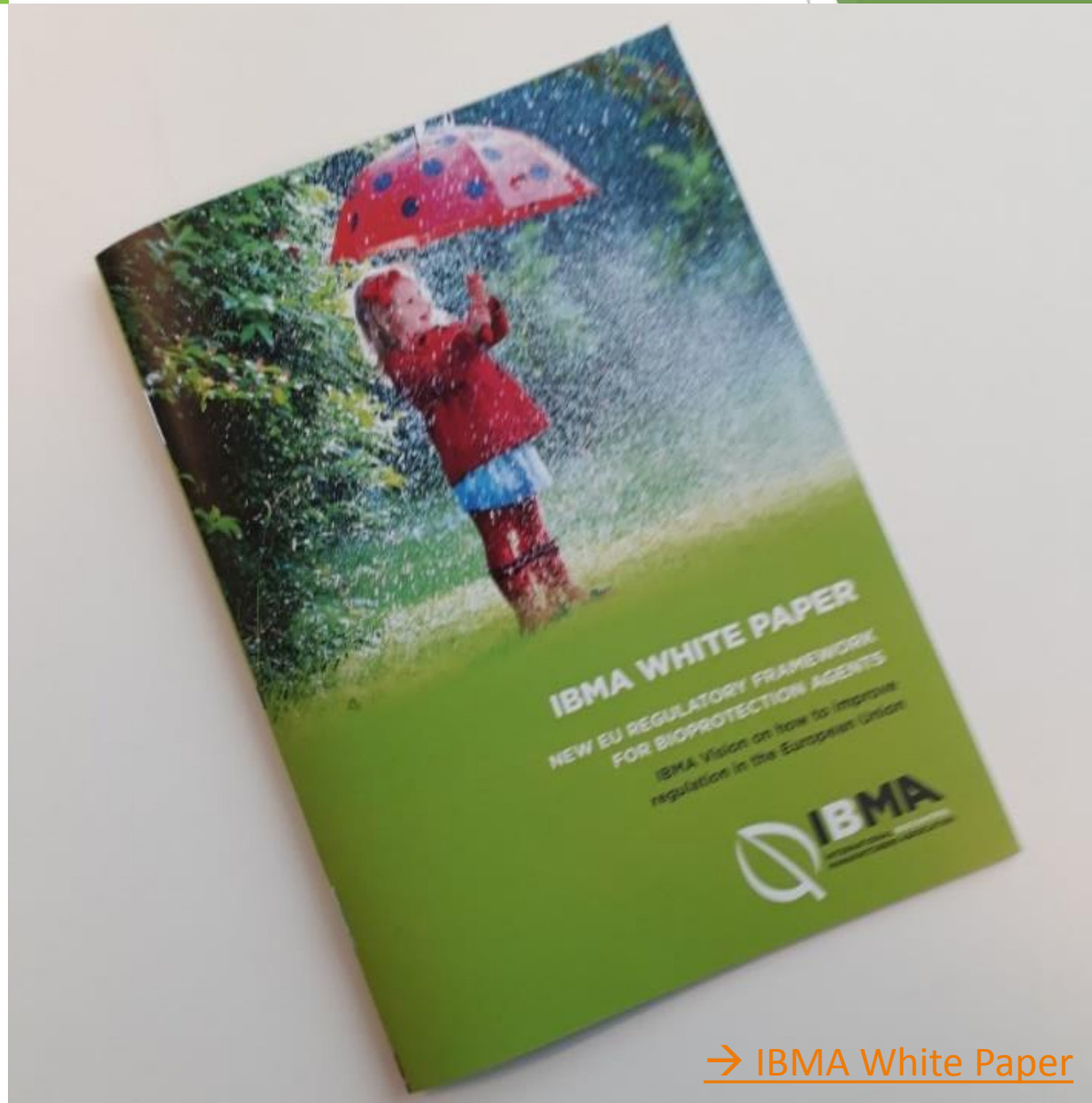
## Reg. 1107/2009 Data Requirements

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

# IBMA White Paper reviews the following

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

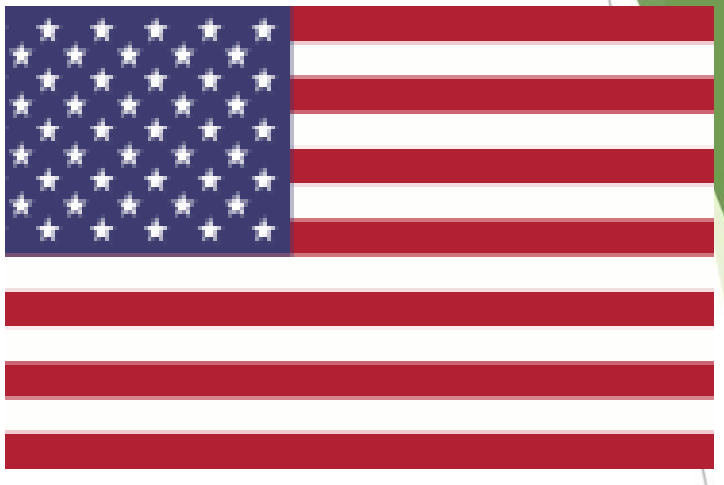
2. **Other Regulated Products in Europe**
   Assessment of e.g. medicines to see what other solutions may be available

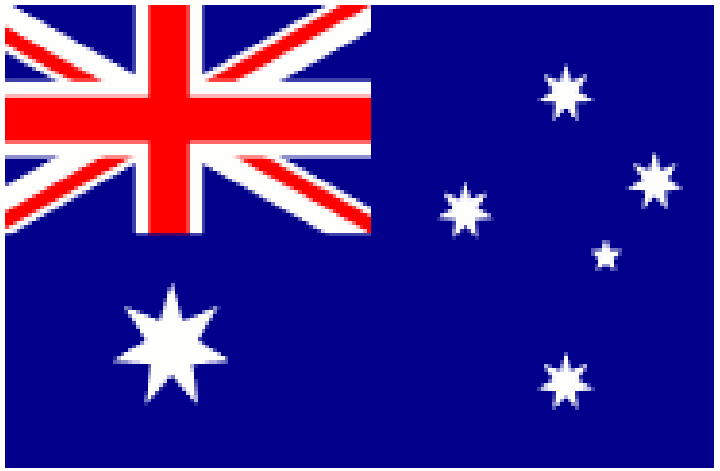
3. **Regulation of Products from SMEs**
   Review how SMEs are treated and what assistance is provided to SMEs

4. **Speedy Approvals and Provisional Authorisations**
   What routes to speedy authorizations exist in other legislations?

**What can we learn from other regulatory authorities?**

- ✓ Register within 2 years
- ✓ Separate evaluation route for MOs and biochemicals
- ✓ Proportionate DRs





- ✓ Specific legislation
- ✓ Case-by-case evaluation
- ✓ Flexibility in DRs

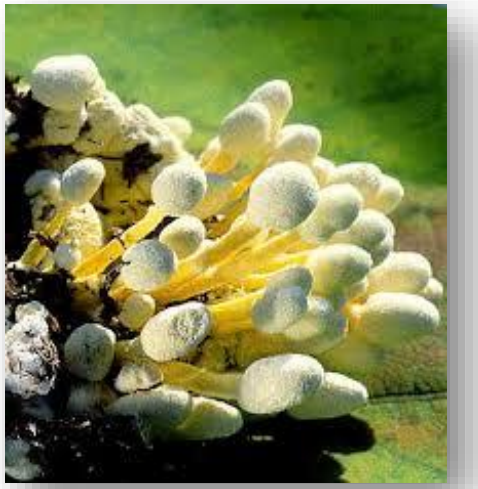
# The Key Messages of the White Paper

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

## Provisions for medicines give leads for bioprotectants

- ☞ Accelerated assessment
- ☞ Provisions for unmet medical needs (PRIME-Scheme)
- ☞ Conditional marketing approval
- ☞ Positive benefit-risk balance
- ☞ Specific approach to biosimilars

What can we learn from regulation of other Products?

Medicinal Products Regulation

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

ctgb

College voor toelating van gewasbeschermingsmiddelen en biociden

**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**


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

# IBMA White Paper 2018
# Ideal regulation would Deliver

## Success in 4 areas

- Dedicated Data Requirements
- Dedicated Uniform Principles
- Specialist evaluators
- Specialist peer review

## 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**

Delayed schedule for Semiochemicals:

## 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

Launch at ABIM 2019 → delivery in June 2020

# IBMA Work on Decision Trees

## NEW Timelines

**Microbials and Natural Substances**

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Presentation to EU COM

### January

Finalise Decision Tree

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

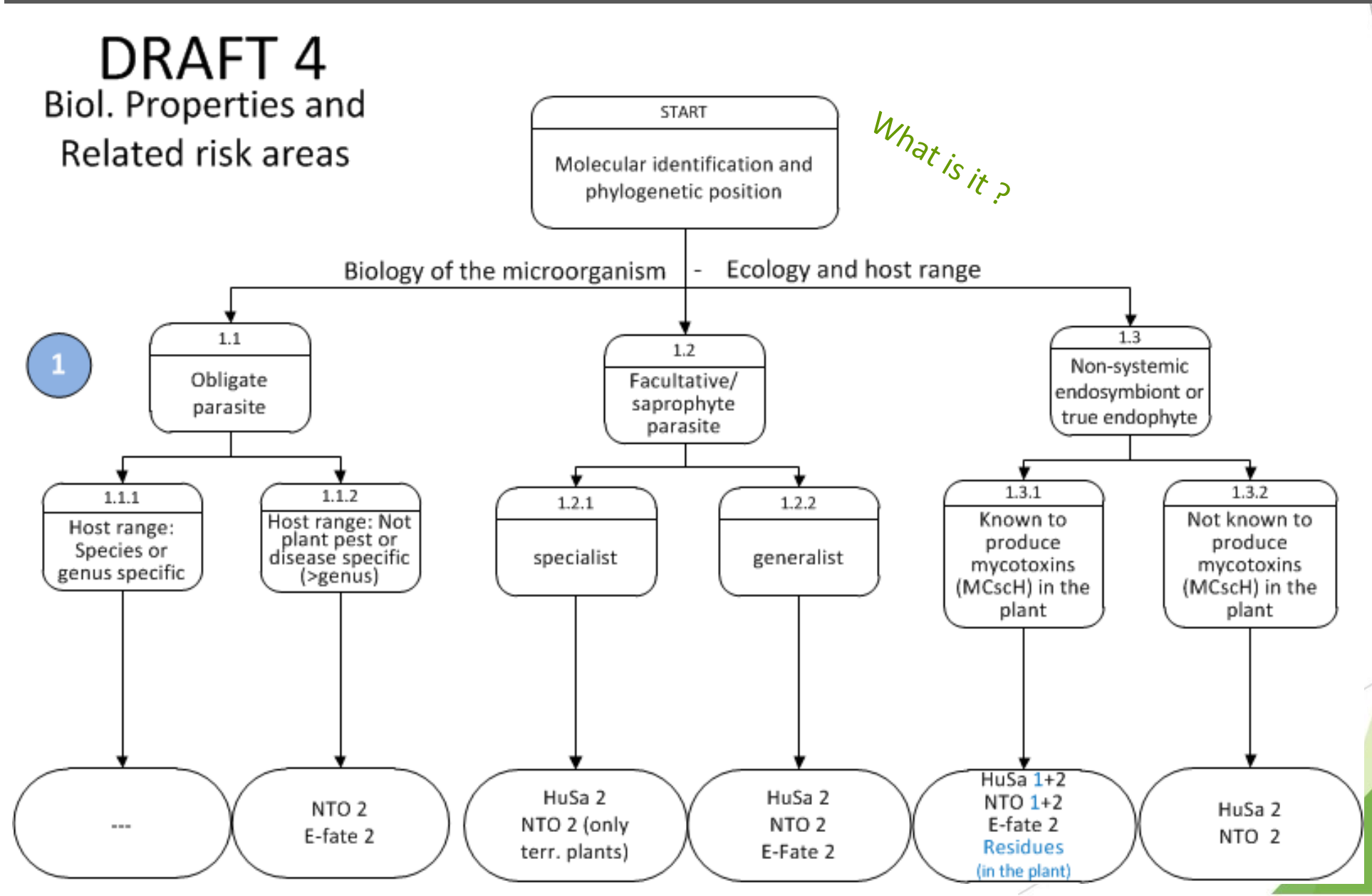
## for Data Requirements and Uniform Principles

**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



# Decision tree biological properties

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

Biology of the microorganism Defines ecology and host range

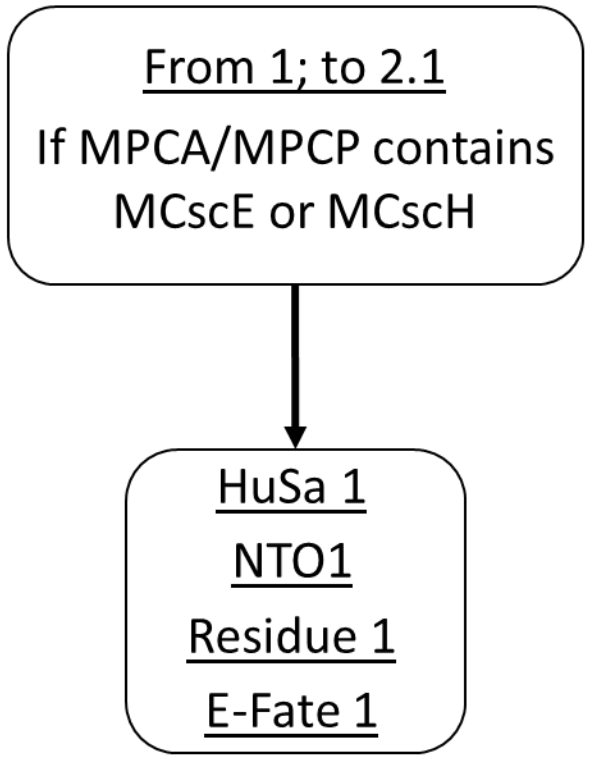
All decisions need to be taken based on reliable data from published literature, internal studies, or “formal” studies.

**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?



# Decision Tree Conclusions

1. **Hazards are identified** based on understanding of the biology and ecology of the microorganism

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

3. 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 **semio chemicals** and natural substances

# Thank you

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