



# Update on EU developments on biological control

**ABIM 2023 –  
Regulatory environment**

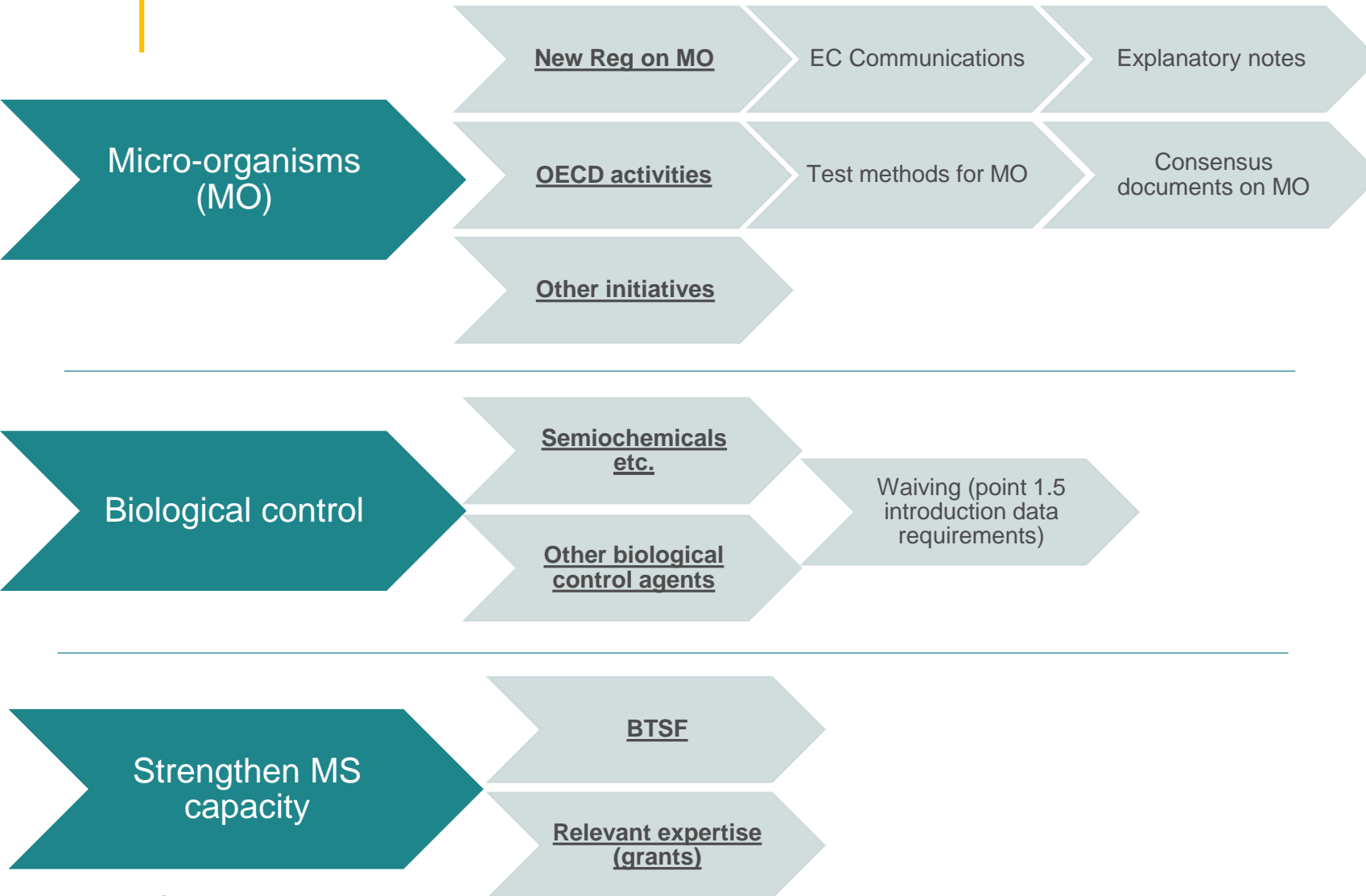
*Eric Liégeois*

*EU Commission, Unit SANTE E.4*

# Overview of ongoing activities regarding bio-control

- Micro-organisms:
  - Regulatory supporting documents recently endorsed:  
Explanatory notes and dRR
  - "Instruments": IUCLID, Test protocols following OECD Conference, consensus documents (group reviews), BTSF
  - Starting: study on background levels, review of biology/ecology
  - To come soon: EFSA conclusions, labelling requirements (bees, sensitisation)
- Other bio-control groups: guidance document on semio-chemicals, ASONOS, first application for peptides and RNAi,
- "Horizontal work": problem formulation, compendium conditions of use/RMM, co-formulants discussion, availability of LR products, SUR <sup>2</sup>

# Road to 2030!



**2030**



# Activities on micro-organisms used in PPP

## New Regulations on MO

- Four implementing Regulations
- Applicable as from Nov 2022

## Two Communications from the European Commission

- List recommended test methods/guidance documents
- Support dossier-preparation
- Not legally binding
- Endorsed in March 2023
- Additional database of useful guidance documents

## Explanatory notes + dRR

- Support understanding of the new EU Reg
- Support dossier-preparation
- Harmonise risk assessment and risk management
- Not legally binding
- Endorsed at PAFF October
- dRR also endorsed
- Check our SANTE website

## Tools

- IUCLID
- New test methods (OECD)
- Consensus documents
- ....

Completed/available

On-going

# Explanatory notes for Micro-organisms used as PPP

- Stakeholders consulted: some refinement
  - E.g. conclusions on Whole Genome Sequencing: part of the MO characterisation, so no need for GLP certification
- Still not fully concluded:
  - Pathogenicity to NTO ? Consistency with Problem Formulation Document
  - Sensitisation labelling – proposed sentences (« May have »; « May cause ») + consequences for Low-risk status – to be finalised with Labelling Requirement Implementing Act (ongoing)
  - Consortium
- Endorsed on 13 October 2023 – publication on SANTE website ([https://food.ec.europa.eu/plants/pesticides/micro-organisms\\_en](https://food.ec.europa.eu/plants/pesticides/micro-organisms_en))

## dRR for Micro-organisms used as PPP

- Technical guidelines on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report (SANCO 6895/2009)
- New dRR (draft Registration Report) templates
- Both endorsed at PAFF on 13 October 2023
- Transitional periods between old and new templates:
  - If application for PPP submitted according to the new data requirements, the new templates apply.
  - If the application submitted according to old data requirements, old templates may still be used, but only until 21 November 2024. After this date the new templates will be used in any case.

# “Instruments” for MO: IUCLID, Test protocols following OECD Conference, OECD consensus documents (group reviews), grants, BTSF

- **IUCLID** (EFSA lead): pilot case under assessment, regular meetings by EFSA:

Report generator to prepare the new DAR/RAR + Trainings, potentially for applicants and evaluators

- **OECD:**
  - Bees: ongoing (JKI lead)
  - Sensitisation : stand-by (ECHA,WHO,...) – NAM expertise !
  - Insects for testing: ongoing
  - Consensus document: *Beauveria bassiana* (ready)
- **EU Grants** (recruiting new staff in MS): allocated to 6 MS for focusing on priority review of biocontrol products
- **BTSF** on MO (training staff in MS): 2 years reconduction

# Starting: studies on background levels, review of biology/ecology

1. Literature study on the **occurrence and population levels** in soil of micro-organisms species used in plant protection
  - Started 1 September 2023 (12 months)
  - Aim: literature review on background levels for 36 species approved in EU
  
2. Review of **Biology and Ecology** of micro-organisms species used in plant protection
  - Started before end 2023 (18 months)
  - Aim: benchmark reviews of biological and ecological properties for 36 species approved in EU (similar to OECD *Beauveria bassiana*)



## To come soon for MO (under discussion): EFSA conclusions, labelling requirements

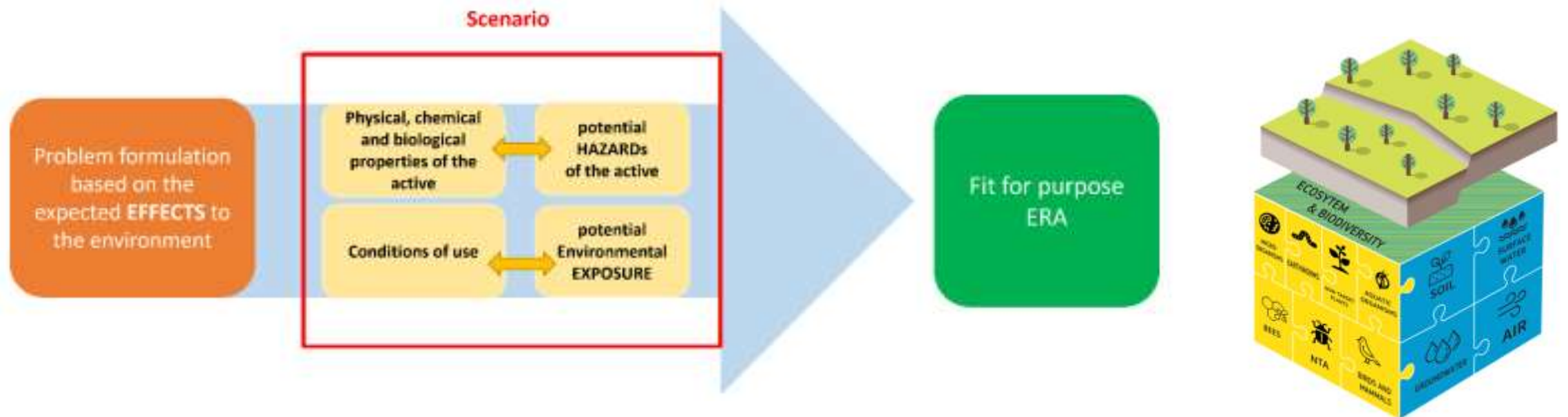
- **EFSA conclusions:** re-shuffling to match better data requirements (central role of biology/ecology), « need-to-know » approach
- Revision of **Labelling Requirement Regulation 547/2013** (draft under discussion with Member States, feedback mechanism consultation soon)
  - Standard phrases for hazard communication of plant protection products containing micro-organisms (sensitisation)
  - Standard phrase, pictogram and attribution criteria for HAZARDS to bee (tbc)

## Other biocontrol than MO (under discussion): semio-chemicals, ASONOS, peptides, RNAi, baculovirus

- **Semiochemicals** (under discussion with Member States):
  - Draft revised guidance document (SANTE/12815/2014): 3 additional groups structurally more or less related to existing SCLP identified as efficient against other pests taxa than lepidopterans
  - Aim: identify candidate new pheromones for application and group approval where justified.
- **ASONOS** (Active Substances of Natural Origin) (under discussion with Member States): refinement of ecotox risk assessment – “need-to-know” approach
- First application for **peptides** and **RNAi** dossier: “need-to-know” approach
- **Baculovirus/bacteriophages**: ongoing revision of guidance document

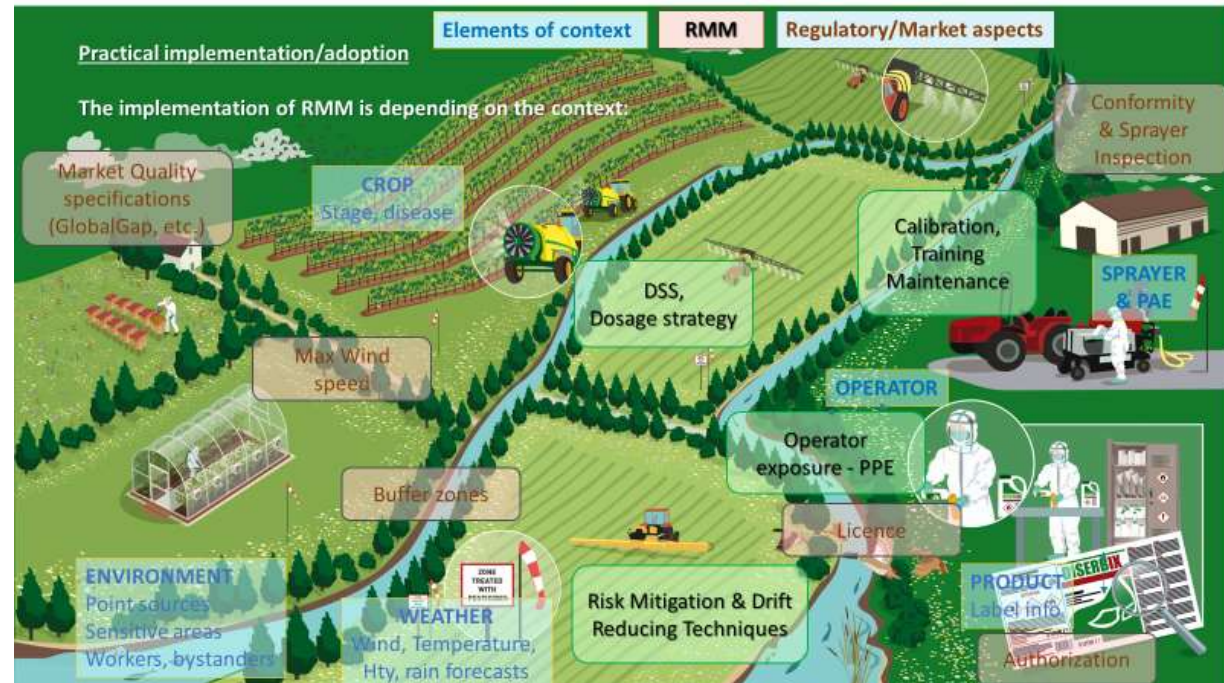
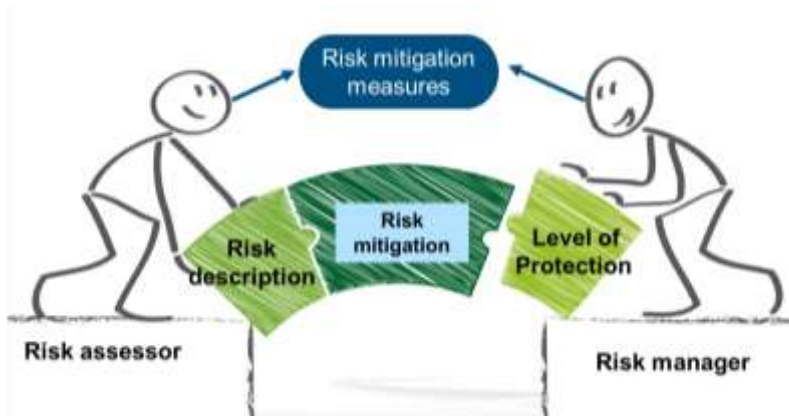
# “Horizontal work”: problem formulation

- Problem formulation for environmental risk assessment (to be endorsed by PAFF): template to build your scenario (properties, conditions of use, fate&behaviour, effects on NTO, ecosystem services)



# “Horizontal work”: compendium conditions of use/RMM

- Compendium on conditions of use/risk mitigation measures : could be relevant for your pesticide use scenario (GAP)



## “Horizontal work”: co-formulants

- Emerging topic
- First overview (EFSA) of co-formulants present in MO, pheromones representative products (from dossiers review programme)
- Please pay attention to presence of :
  - active substance (!)
  - ingredients of concern/classified
  - call for collecting wider information (BPWG).

## **“Horizontal works” - SUR amendments**

- No comments due to the ongoing negotiation.

## **“Horizontal works” - Availability of Low-risk products**

- Availability of products on local (smaller) markets (minor uses, mutual recognition, distribution,...): Who? How? What?
- Workshop (26 October): Member States case studies + reaction from industry stakeholders
- Workshop ZAPID (5 to 7 December): MS, COM, EFSA, applicant associations

## Some food for thoughts

- **The use pattern of plant protection products will be continuously modified:**
  - New political objectives: IPM, bio-control based
  - New elements in the risk assessment (ED, ... chemical hazardous active substances
  - New types of active substances: Micro-organisms, plant extracts, RNAi, Peptides,...
  - New types of application techniques: ... and precision techniques
- **Calling for more fit for purpose (need to know) in the risk assessment :**
  - Problem formulation
  - Need to know approach

**A unique momentum for biocontrol industry!**

# Keep in touch



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# Thank you



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