

WAYS FORWARD TO ACCELERATE ACCESS TO MARKET OF BIOCONTROL PLANT PROTECTION PRODUCTS – OVERVIEW

DIRECTION 1 › TARGETED MODIFICATIONS PPPR

1 Targeted modifications PPPR

Actions needed:

Input by MS in ongoing process, e.g. regarding:

- › Definition of biocontrol
- › Unlimited approval for low-risk substances and 15-year approval for other biocontrol substances
- › Provisional authorisations for biocontrol
- › Amended criteria for low-risk substances

Results:

- › **Key solution:** Definition of biocontrol active substances and PPP
- › Fewer renewal assessments for biocontrol substances
- › Faster first product authorisation for new active substances
- › Harmonised interpretation of low-risk criteria

DIRECTION 2 › IMPROVEMENTS WITHIN REGULATORY FRAMEWORK

2 Improvements within regulatory framework (other than targeted modifications)

Assessment:

- › **Key solution:** Appropriate risk assessment approach for biocontrol substances
- › Test guidelines for biocontrol substances
- › Amended data requirements and uniform principles

Procedural:

- › Prioritisation of biocontrol applications
- › EU sounding board for harmonised pre-submission advice
- › Grouping of highly similar substances for approval (e.g., for certain microbial species)
- › Guidance on low-risk substances + PPP
- › Guidance on mutual recognitions/national specific elements for low-risk PPP

Actions needed:

Assessment:

- › Contribute to ongoing projects to develop test guidelines (e.g., by OECD, Horizon Europe RATION project¹)
- › Contribute to ready-to-use guidance on the risk assessment approach for biocontrol substances ‘Problem formulation using likelihood pathways’² (ongoing EFSA-funded project and OECD project³)
- › Implement grouping of substances (e.g., consensus documents)
- › Next step based on the above: amend data requirements and uniform principles

Procedural:

- › Set up system for prioritisation
- › Set up sounding board of EU experts
- › Draft guidance documents

Results:

Assessment:

- › Better dossiers
- › More efficient and fit-for-purpose assessments
- › Improved risk communication to risk managers – faster decisions

Procedural:

- › Biocontrol applications are prioritised
- › More certainty for applicants and RMS on acceptance of pre-submission advice
- › Faster timelines
- › More efficient approval procedures for active substances within a group
- › Level playing field EU for low-risk PPP
- › More efficient PPP authorisation procedures for low-risk PPP

DIRECTION 3 › CAPACITY BUILDING

3 Capacity building (MS, COM, EFSA)

Actions needed:

- › Provide training for biocontrol assessments (BTSF)
- › Share information on how to install dedicated teams for biocontrol
- › Install Co-RMS program

Results:

- › Faster approval and authorisation

¹ Home – Ration ² general information on approach Steenbergh et al., 2025 Environmental Sciences Europe ³ EFSA-funded project: [grant & 2025 workshop](#); OECD proposal to develop guidance for the risk assessment of microbial pesticides using problem formulation and likelihood pathways was approved at 2025 WPP

Biocontrol plant protection products for sustainable agriculture

To accelerate the access to the EU market of ‘biocontrol plant protection products’ (see COM(2025) 75 final), the current risk assessment of biopesticides must be made more efficient and fit for purpose.

An appropriate risk assessment approach and a clear definition of the group of substances which are eligible for this approach are needed. Below we present a solution for both this definition and risk assessment approach.

KEY SOLUTIONS

Definition of biocontrol active substances

CHALLENGE

Natural substances are not inherently safe – they can exhibit a broad-spectrum toxicity to humans and the environment.



SOLUTION

Define biocontrol substances based on their mode of action as well as on their natural occurrence.

To ensure that biocontrol substances contribute to resilient agricultural systems (integrated crop management) and to human and environmental health, natural substances with a broad-spectrum, toxic mode of action should be excluded from the definition of biocontrol substances.

Biocontrol substances should include:

- › All active substances which are living microorganisms; and
- › Natural or nature-identical substances which either
 - have a non-toxic mode of action (e.g., pheromones, certain oily or inorganic substances, substances which induce resistance in plants); or
 - a highly specific mode of action (e.g., RNAi)

Appropriate risk assessment approach for biocontrol substances

CHALLENGE

A more efficient, fit for purpose and harmonized approach is needed for the risk assessment of biocontrol substances.



SOLUTION

Ready to use guidance on risk assessment approach ‘Problem formulation using generic likelihood pathways’¹

‘Problem formulation using generic likelihood pathways’ is an approach which is adapted from other regulatory frameworks and tailored to biocontrol substances. This approach is further developed in two ongoing projects (EFSA-funded and OECD).

Advantages of Problem formulation using generic likelihood pathways:

- › Suitable for hazards other than toxicity (e.g., effects such as suffocation and desiccation, RNAi, pathogenicity of microorganisms)
- › Suitable for qualitative and quantitative information
- › Structured, transparent approach for better communication with all stakeholders (including risk assessors and risk managers)
- › Harmonised approach based on generic likelihood pathways & analysis plans

WAY FORWARD

Define biocontrol

A definition of biocontrol should be included in Regulation (EU) 1107/2009, along with a procedure to earmark approved substances as biocontrol substances at EU-level.

Provide ready to use guidance on ‘Problem formulation using generic likelihood pathways’

- › Finalise EFSA-funded project (Q3 2025); output is a draft guidance for biocontrol substances excluding microorganisms;
- › Copy and adapt approach to microbial biocontrol substances in OECD project resulting in draft guidance for microbial active substances (2025 – 2027; MS can express interest to participate to Ctgb).

Implement approach ‘Problem formulation using generic likelihood pathways’

The outcome of the EFSA-funded project and the OECD-project on this approach should be endorsed and implemented.

Provide training to increase EU capacity

Training on applying this approach should be provided (e.g., as part of Better Training for Safer Food).

¹ More information on problem formulation using likelihood pathways and ongoing projects: 1) EFSA-funded project to develop a stepwise approach for substances of low concern (grant & 2025 workshop); 2) OECD proposal to develop guidance for the assessment of microbial pesticides using likelihood pathways was approved at 2025 WPP meeting; 3) general information on the approach: [Steenbergh et al. Environmental Sciences Europe \(2025\) 37:24](#).