

Agenti di biocontrollo per la difesa fitosanitaria

Le nuove sfide della sicurezza alimentare

23 Giugno 2026



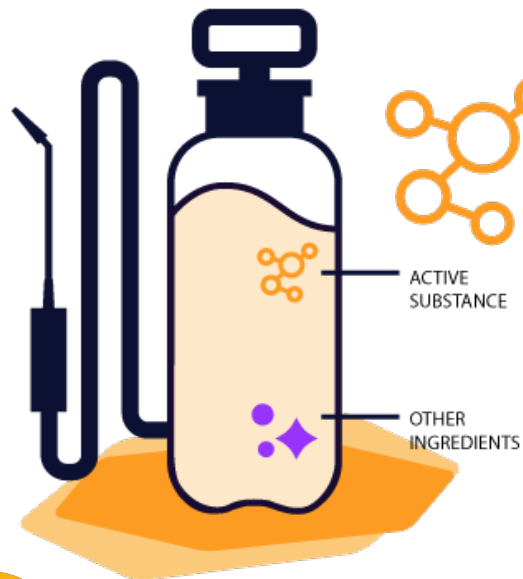
IL RUOLO DI EFSA NEL PROCEDIMENTO AUTORIZZATIVO DEGLI AGENTI DI BIOCONTROLLO

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DUAL SYSTEM: ACTIVE SUBSTANCE AND PLANT PROTECTION PRODUCT (PPP)

EFSA role: to serve as an impartial source of scientific advice to risk managers based on scientific risk assessment

- **Active substances:** components of PPP that actually prevent, destroys or control harmful organisms (the so-called pests, such as insects, fungi and weeds) or plant diseases.



→ Approved at **EU level**

New active substances
Reg. (EC) No 1107/2009

Renewal of approval
Reg. 844/2012 and No 2020/1740

- **Plant protection products:** mixtures containing one or several active substance(s) and other ingredients (so-called co-formulants).

→ Authorised at **Member State (or zonal) level**

CONCLUSION ON PESTICIDES PEER REVIEW



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Peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AT10

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, France, for the pesticide active substance *Trichoderma atroviride* strain AT10 and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative use of *Trichoderma atroviride* strain AT10 as a fungicide on lettuce (field use). The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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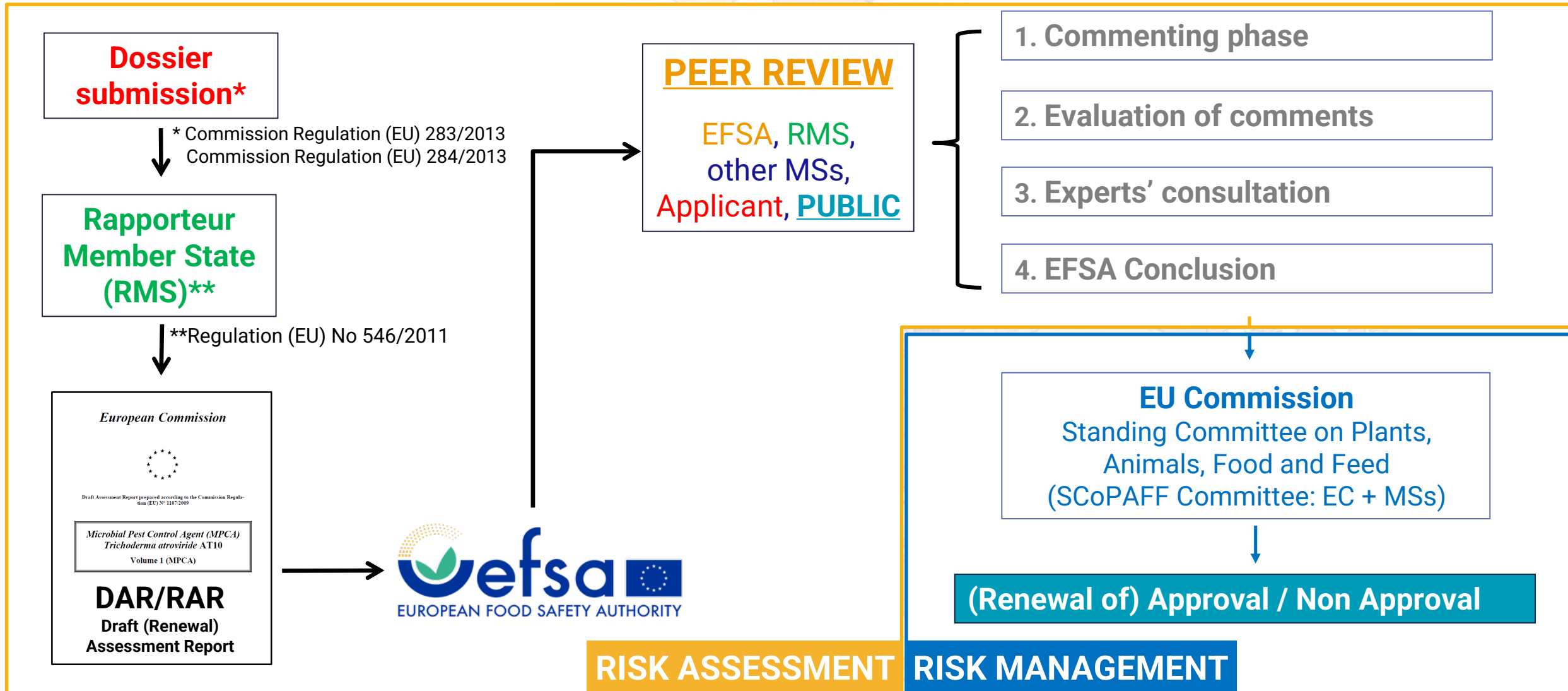
Keywords: *Trichoderma atroviride* strain AT10, peer review, risk assessment, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2019-00113

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ACTIVE SUBSTANCE EVALUATION PROCESS



RISK ASSESSMENT: HAZARD VS RISK

Hazard

A Hazard is something that has the potential to harm you

vs.

Risk

Risk is the **likelihood** of a hazard causing harm

SHARK

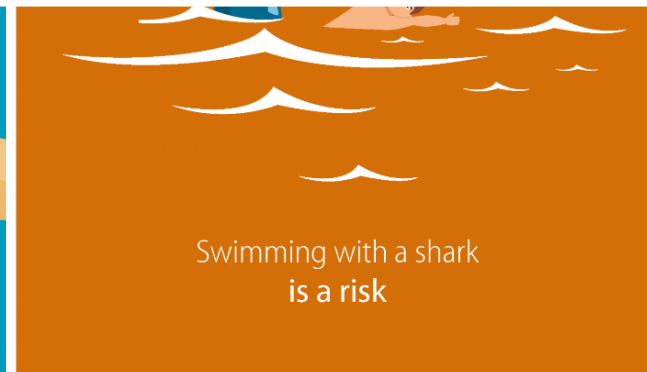


A shark in the sea is a hazard

LIGHTNING



Risk = hazard + exposure



Swimming with a shark is a risk



Lightning is a hazard



Standing under a tree during a thunderstorm is a risk

REGULATORY FRAMEWORK

Regulation (EC) 1107/2009:

'any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material'.

Purpose:

- i) to ensure a **high level of protection** for both **human** and **animal health** and the **environment**
- ii) to **safeguard** the **competitiveness** of Community agriculture.

- ✓ Applicable to **all types** of pesticides, including **microbials**
- ✓ **!** Microorganisms which are **infective** or **pathogenic** to humans or other vertebrate animals will **not** be **eligible** for approval
- ✓ Currently **> 70 microbials are approved in the EU** after a scientific RA confirmed that their use in PPP is safe

Commission Regulation (EU) 283/2013:

Data Requirements for active substances

Commission Regulation (EU) 284/2013:

Data Requirements for the PPP

Commission Regulation (EU) 546/2011:

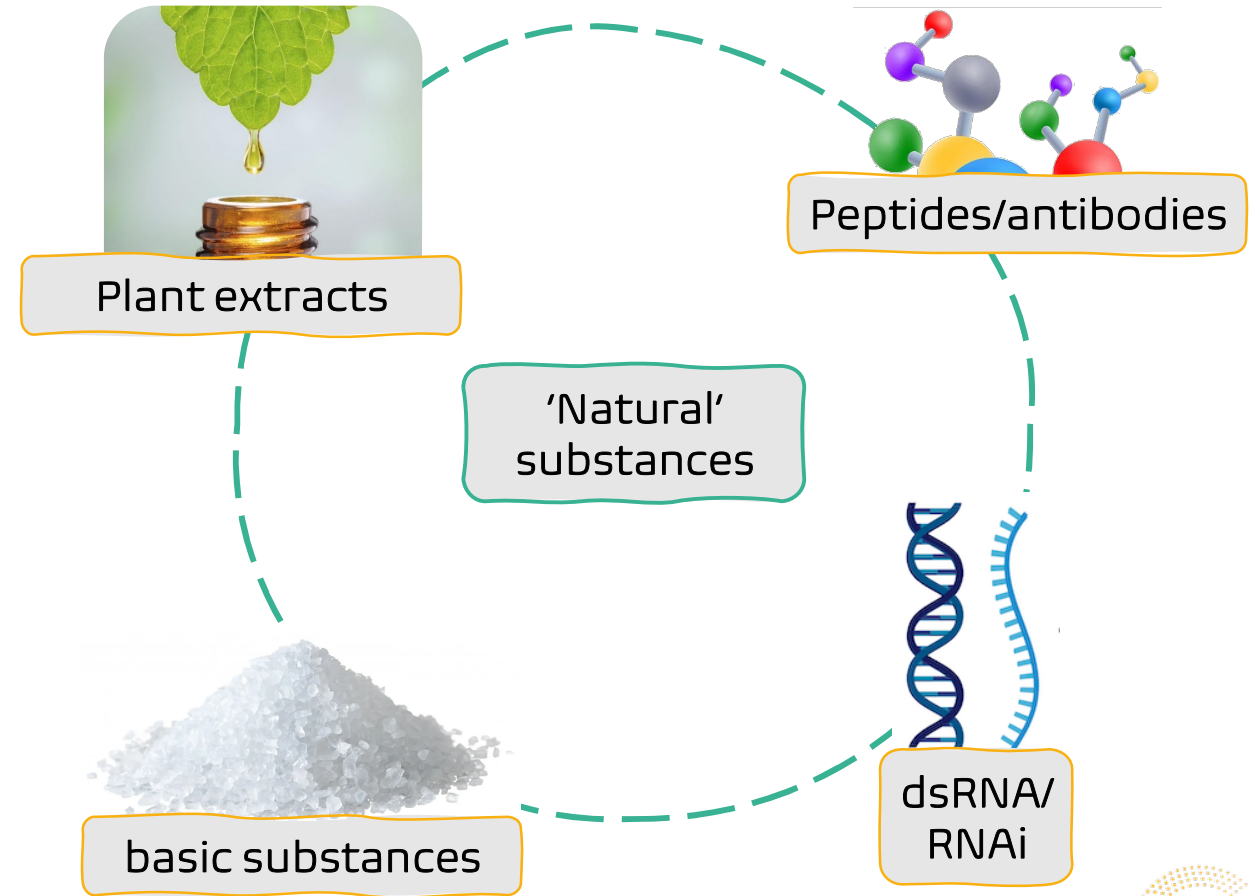
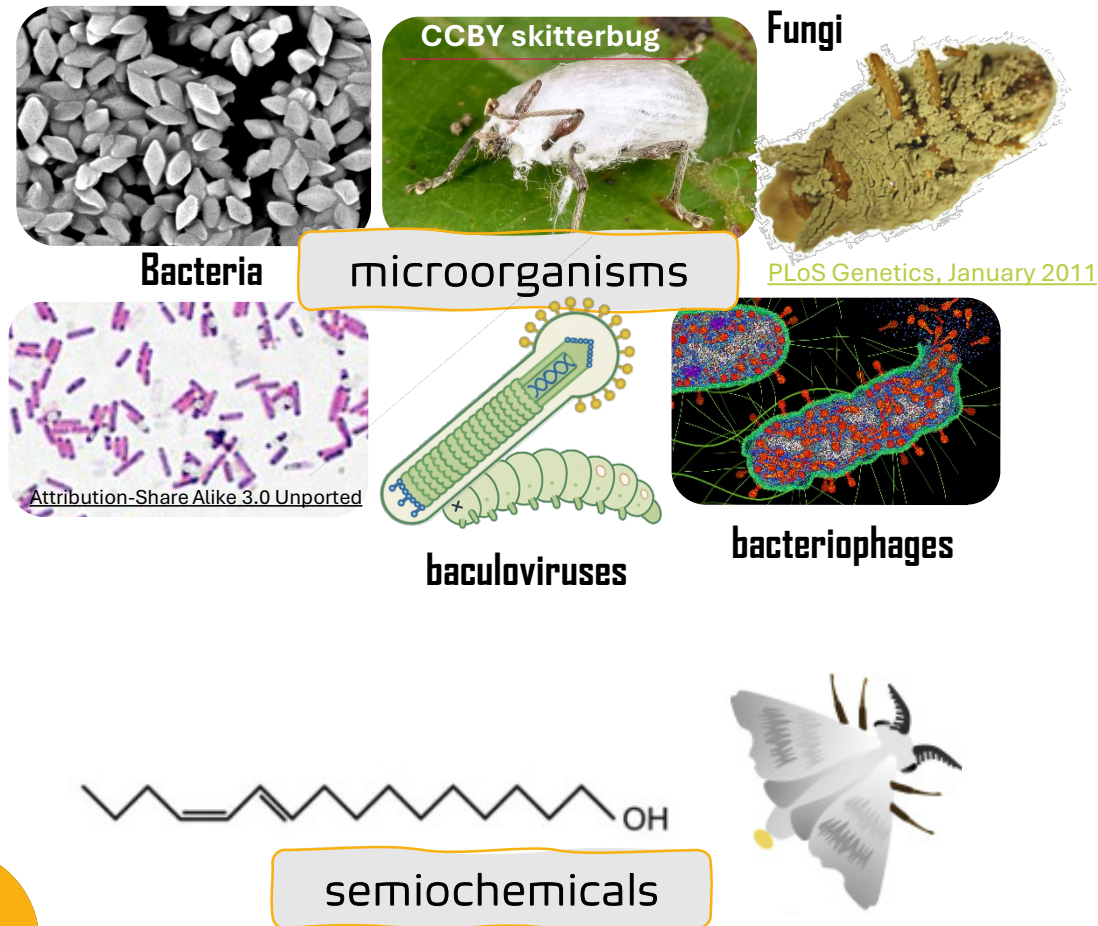
Uniform Principles for the evaluation and authorization of PPPs

Purpose:

- ✓ To **define the information needed** for **risk assessment** and **regulatory decision-making** for pesticides in the EU → What data are needed
- ✓ To **ensure harmonised risk assessment** and **decision-making** by MSs, including protection of human/animal health and the environment → how the data are evaluated for authorisation

ACTIVE SUBSTANCES FOR BIOCONTROL*

***Biocontrol:** Currently, no official definition of biocontrol substance is endorsed



NEW SUBSTANCES IN THE PIPELINE – IN PEER REVIEW

Active substance	Product	Function	technology	Formulation type	RMS	EFSA Q-number	Link
Agrobody anti-fungal VHH (variable domain of camelid heavy-chain antibody)	ASFBIOF01-02	Fungicide	Peptide	SG Water Soluble Granules	NL	EFSA-Q-2021-00491	Sanitised Dossier Initial DAR
Baculoviruses against <i>Adoxophyes orana</i>	ABC V67	Insecticide	baculoviruses	SC Suspension concentrate)	LV	EFSA-Q-2023-00566	Public IUCLID Dossier Initial DAR
Bacteriophage of Potato Soft Rot Enterobacteriaceae (BPSRE)	Biolyse	Bactericide	bacteriophages	SC Suspension concentrate	NL	EFSA-Q-2021-00670	Sanitised Dossier Initial DAR
> 10 new strains of microorganisms	various	various	microorganisms	various	various	various	various



NEW SUBSTANCES IN THE PIPELINE - UPCOMING

Active substance	Product	Function	technology	Formulation type	RMS	EFSA Q-number	Link
Ledprona	SFORM14	Insecticide	dsRNA	SL Soluble concentrate	BE	EFSA-Q-2023-00794	Public IUCLID Dossier
Unecyna (ES43)	PF-ES43-F-022	Fungicide	dsRNA	SL Soluble concentrate	DE	EFSA-Q-2026-00076	Public IUCLID Dossier
GS-omega/kappa-HxTx-Hv1a (spider venom derived)	VST-006340 (Spear Lep)	Insecticide	Peptide	SL Soluble concentrate	NL	EFSA-Q-2023-00506	Public IUCLID Dossier
Bacteriophages against <i>Erwinia amylovora</i> (BAEA)	PEA-02® (PM014)	Bactericide	bacteriophages	SC Suspension concentrate (= flowable concentrate)	BE	EFSA-Q-2023-00786	Public IUCLID Dossier
Bacteriophages against <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> (BACMM)	PCM-03 ® (PM013)	Bactericide	bacteriophages	SC Suspension concentrate	BE	EFSA-Q-2024-00675	Public IUCLID Dossier
Bacteriophage against <i>Walnut Xanthomonas arboricola</i> pv. <i>juglandis</i>	BW-XAJ	Bactericide	bacteriophages	SC Suspension concentrate	FR	EFSA-Q-2025-00168	Public IUCLID Dossier
PLEURAN Complex Cell Wall Extract	COV 17-01	Plant defence inducer (against fungi)	Mushroom extract	SL Soluble concentrate	FR	EFSA-Q-2023-00390	Public IUCLID Dossier

GETTING READY

EFSA Working Group on microbial pesticides

- ✓ **Established** in January 2024
- ✓ To give **advice** to peer review experts (EFSA and MSs) supporting the discussions and agreements/conclusions in the course of peer review of microbial a.s.
- ✓ To **cover expertise** in different fields of the peer review, e.g. **WGS, identity, taxonomy, secondary metabolites**

EFSA Documents

- ✓ Guidance on the **characterisation of microorganisms** in support of the risk assessment of products used in the food chain (covering e.g. WGS, AMR): [Link](#)
- ✓ External scientific report on **fit for purpose risk assessment for low concern active substances and uses**: [Link](#)

Participation to OECD activities

- ✓ **OECD Expert Group Biopesticides (EGBP)**
- ✓ OECD project for a GD on **Problem Formulation** for microbial pesticides
- ✓ Other ongoing OECD activities/development of Guidance documents

Involvement in Pre-Submission activities

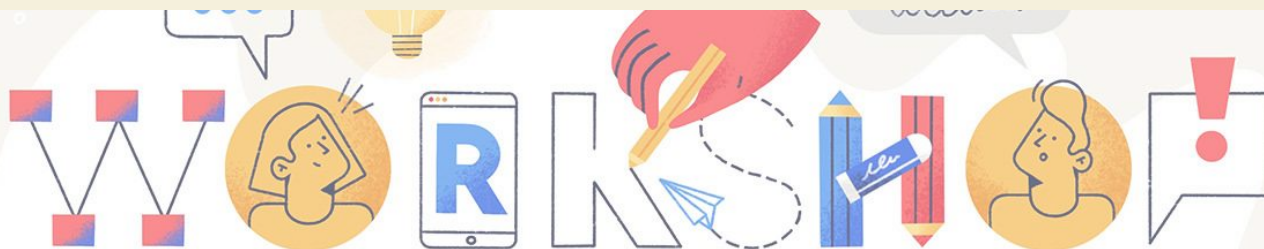
- ✓ **Meetings** with RMS and applicant(s) before submission of a dossier



GETTING READY

Workshops on innovative biopesticides (bioNAS)

- ✓  The EFSA Pesticides Peer Review Unit is organizing a series of **workshops** focused on **innovative biopesticides** (BioNAS).
 - ✓  **Objective:** to establish a **forum** where EFSA and Member State experts can engage with industry representatives regarding innovative biopesticide technologies (**not related to specific active substances** for which a dossier has been submitted in the EU).
 - ✓  **Approach:** promoting interaction between participants through **discussions** and **Q&A sessions** to address any questions or uncertainties, which may be **beneficial** for the assessment of future dossiers or substances based on these technologies.
-
- ✓ 1st workshop: **June 13, 2025 – online** | Topic : **dsRNA/RNAi-based PPP** | Presenter: The US company GreenLight Biosciences
 - ✓ 2nd workshop: **April 17, 2026 – online** | Topic: **bacteriophage-based active substances** | Presenters: Biopesticides Ltd, APS Biocontrol Ltd, and De Ceuster Meststoffen NV (DCM)
 - ✓ 3rd workshop: **June 11, 2026 – online** | Topic: **semiochemical active substances** as PPP | Presenters from IBMA



CONCLUSIONS

1 Biocontrol

A major **opportunity** for more **sustainable** plant protection - but **safety** must be demonstrated **case by case**, based on **adequate data** and **robust scientific assessment**.

2 EFSA's role

EFSA provides the **independent scientific assessment**; regulatory decisions are made by the **European Commission** and **Member States**.

3 New technologies

Require **scientific rigour** and **early preparation**: workshops, working groups, guidance, OECD activities and pre-submission.

Thank you
for your attention



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