



ABIM Annual Biocontrol Industry Meeting
Basel October 2018
Plenary Session 1
EU Plant Protection Regulatory Issues

Developments concerning Biocontrol during 2018

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What's up in Europe?

- *Low-risk action plan*
- *Guidance documents from Biopesticides WG*
- *News from the Standing Committee*
- *Evaluation/REFIT process*
- *Research Projects*
- *Better Training for Safer Food activities*
- *A new team !*



1. Implementation plan - Low Risk Products (LRP) and IPM

- *Initiated under NL presidency (2016)*
- *Implementation plan:*
 - *40 actions agreed : COM, MSs, stakeholders, EFSA, EPPO; deadline or continuous*
- *Creation of a working group on Sustainable Plant Protection*
- *Progress report (finalised) to be endorsed at AGRIFISH Council*



1. Implementation plan - Low Risk Products (LRP) and IPM

Key actions for COM

- **COM notice** on the list of potentially low risk of active substances approved for use in plant protection (C/2018/4828 - OJ C 265, 27.7.2018, p. 8–11)

This Notice is intended to assist Member States in achieving the objectives of Directive 2009/128/EC and specifically the implementation of the provisions of Article 12 and 14 of that Directive as well as the application of the general principles of integrated pest management. For this purpose it provides a list of active substances approved under Directive 91/414/EEC that are expected to meet the low-risk criteria of Article 22 of the Regulation.

The list is established for informative purposes on the basis of information available

2.1 Micro-organisms

Substance Name	Pesticide Category
Adoxophyes orana GV strain BV-0001	Insecticide
Ampelomyces quisqualis strain AQ10	Fungicide
Bacillus amyloliquefaciens subsp. plantarum D747	Fungicide

2.2 Other substances

Substance Name	Pesticide Category
Aluminium ammonium sulphate	Repellent
Ammonium acetate	Attractant
Ascorbic acid	Fungicide



1. Implementation plan - Low Risk Products (LRP) and IPM

Key actions for COM (2)

- *Draft Technical Guidance for the assessment of compliance of active substances with the criteria for the approval of low-risk active substances and for their low risk plant protection products :*
 - Almost there ! → Anti Microbial Resistance criteria to be finalised



1. Implementation plan - Low Risk Products (LRP) and IPM

Other actions

- *Expedite approval/renewal of low risk substances (continue)*
 - Screening of renewal date for low risk substances and RMS
- *Optimise zonal system approval (+ Post Approval Issue WG)*
- *Optimise procedure on MRL for LRP*
- *EPPO guideline on efficacy evaluation of LRP (finalised)*
- *Demonstrations farms*
- *Develop a webportal with relevant information on Integrated Pest Management in EU and MSs level (to be launched)*



2. Draft Guidance documents from Biopesticides WG

- *3 meetings (May-September-November)*
- *Draft Guidance Document on Metabolites (now "potential metabolite of concern"):*
 - Several clarifications, restructuring ...agreed by experts but still to be clarified is 'present in significantly higher concentration than the background'
- *Draft Guidance Document on Anti-microbial Resistance :*
 - Reference to EFSA guidance on microbials used as feed additives....a bit less advanced (priority for LRP guidance)
- *Updated Straight-Chain Lepidopteran Pheromones Guidance: almost finalised*



2. Biopesticides WG

- Revision of data requirements, uniform principles, testing guidances:
 - Discussion initiated
 - Approach: identify topics for discussion, consult MS/stakeholders, discuss solutions
 - Timing: it's a priority but time-consuming – no false expectations ! (external support, interaction with OECD activities).



3. News from the Standing Committee (since ABIM 2017)

Bio-control agents:

- Several dossiers (microorganisms) recognised as admissible
- Two plant extracts rejected/withdrawn
- Basic substances: 4 approvals, one rejected
- (Low-risk) microorganisms: one approval – 4 dossiers at final stage + one Yeast extract



3. Evaluation/REFIT process (reminder)

- *Regulatory Fitness and Performance : under the Better Regulation scheme COM committed to **ensure EU legislation is effective and efficient** in achieving its public policy objectives at minimum cost*
- *Objectives of REFIT : collate evidence and rely on sensible monitoring arrangements – compare performance against what was expected to happen – 5 main criteria **effectiveness - efficiency - relevance – coherence - EU added value***
- *Steered by an ISG and supported by a consultation strategy (public consultation) and study*

3. REFIT process

- Effectiveness**
- Protecting human health
 - Protecting the environment, including wild and water
 - Minimisation of animal testing
 - Improving the functioning of the internal market
 - Improving agricultural production and competitiveness of EU agriculture
 - Facilitating international trade
 - Enforcement and monitoring

- Effectiveness**
- Improving agricultural production and competitiveness of EU agriculture
 - Availability of PPPs in the EU
 - Low-risk active substances
 - Basic substances
 - Minor uses
 - Outermost regions
 - Access to a reliable and affordable crop protection.
 - Socio-economic considerations

- Relevance**
- Sustainable Development Goals
 - Sustainable agriculture in the EU
 - Risk communication
 - Transparency and confidentiality
 - Innovation

- Coherence**
- Policy area of pesticides
 - EU legislation
 - International agreements

- EU added value**
- Data generation and scientific knowledge
 - Capacity building
 - Equal EU-wide protection of human health
 - Simplified system for trading partners
 - Economies of scale
 - Global added value
- Compare the EU regime against other regulatory systems:
- The US system
 - An EU wide single authorisation system
 - An EU evaluation of active substances but no vote for approval/non-approval
 - The (pesticides approval) authorisation system

Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)

Final report
10 October 2018

→ Commission Staff Working Document and Report:
→ first half of 2019

4. Recent Research Projects (H2020)



OPTIMA - Optimised Pest Integrated Management to precisely detect and control plant diseases in perennial crops and open-field vegetables



SuperPests - Innovative tools for rational control of the most difficult-to-manage pests ("super pests") and the diseases they transmit

4. Recent Research Projects (H2020)



Viroplant project: viruses to protect plants



5. Better Training for Safer Food

- **IPM:** since 2018, series of training courses from 2018 onwards for Member State experts on the implementation of IPM



6. A new team for biocontrol products

New Head of sector + new desk officers

A big "thank you" to those who have left recently !

Any question please contact us:
sante-consult-e4@ec.europa.eu



THANK YOU FOR YOUR ATTENTION!

For up-to-date information DG SANTE website:
https://ec.europa.eu/food/plant/pesticides_en

Commission website on the evaluation:
http://ec.europa.eu/food/plant/pesticides/refit_en