

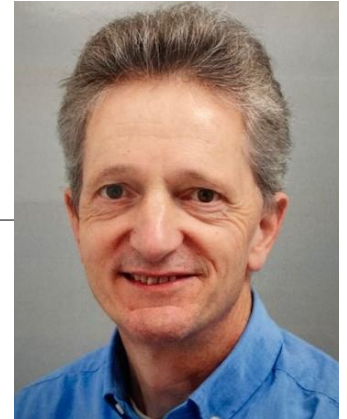


UPDATE ON THE WORK OF THE OECD EXPERT GROUP ON BIOPESTICIDES

Jeroen Meeussen – ERM
ABIM Regulatory Seminar
19-21 October 2020



My Background



▶ Until October 2010: Ctgb

ctgb

▶ October 2010 – July 2015: DG Sante



▶ September 2015 – April 2020: EUMUCF



▶ Since 14 September 2020: ERM



▶ Since 2005: Chair of the EGBP





Biological Pesticides: EU and OECD

► Macro-organisms

- Predators, parasites & nematodes
- **Not usually regulated as PPPs**

► Microbial pesticides

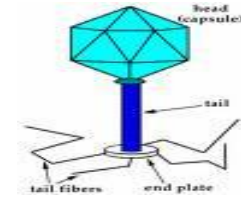
- Viruses, Bacteria & Fungal Pathogens

► Semiochemicals

- Pheromones, Plant volatiles

► Plant extracts/Botanicals

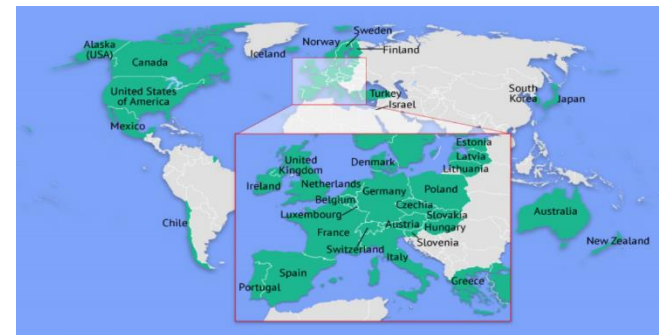
- Botanicals & Other Natural substances





The Organisation for Economic Co-operation and Development

- ▶ Today the OECD has **37 member countries**
- ▶ **More than 70** developing and transition economies are engaged in working relationships with the OECD (Brazil, Russia, India, China and South Africa)





Expert Group on Biopesticides



The **Expert Group on Biopesticides** (EGBP) was established by the Working Group on Pesticides in 1999 to help member countries to **harmonise** the methods and approaches used to **assess biological pesticides**.



Focus on the development of **harmonised guidance** for data submissions and reviews.

Promote **communication** and **exchange of information** by organising **seminars** and **workshops** on topics of common interest.

Publications on biopesticides

Report of the 9th Biopesticides Expert Group Seminar on Test Methods for Micro-organisms

Series on Pesticides No. 100

[ENV/JM/MONO\(2019\)8](#), [ANN](#)

Working Document on the Risk Assessment of Secondary Metabolites of Microbial Biocontrol Agents

Series on Pesticides No. 98

[ENV/JM/MONO\(2018\)33](#), [ANN](#)

Guidance Document for the Assessment of the Equivalence of Technical Grade Active Ingredients for Identical Microbial Strains

Series on Pesticides No. 96

[ENV/JM/MONO\(2018\)8](#)

Report of the 8th Biopesticides Steering Group Seminar on Niche Uses of Highly Specific Biocontrol Products

Series on Pesticides No. 95

[ENV/JM/MONO\(2018\)5](#), [ANN](#)

Guidance Document on Semiochemical Active Substances and Plant Protection Products

Series on Pesticides No. 93

[Note: this document replaces the GD No. 12 (ENV/JM/MONO(2001)12) on Semiochemicals]

[ENV/JM/MONO\(2017\)33](#)

Report of the 7th Biopesticides Steering Group Seminar on Sensitisation Potential of Micro-Organisms

Series on Pesticides No. 91

[ENV/JM/MONO\(2017\)8](#), [ANN](#)

Guidance Document on Botanical Active Substances Used in Plant Protection Products

Series on Pesticides No. 90

[ENV/JM/MONO\(2017\)6](#)

Report of the 6th Biopesticides Steering Group Seminar on Hazard and Risk Assessment of Secondary Metabolites Produced by Microbial Pesticides

Series on Pesticides No. 89

[ENV/JM/MONO\(2017\)5](#), [ANN](#)

OECD Series on Pesticides:

- 29 out of 100 are related to Bio-Pesticides
- 12 out of the last 20 publications



OECD-EGBP

CURRENT
ACTIVITIES



A lot of information is available, but ...

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Safety of the Food Chain
Chemicals, contaminants, pesticides

SANCO/12823/2012 –rev. 4
12 December 2014

GUIDANCE DOCUMENT FOR THE ASSESSMENT OF THE EQUIVALENCE OF TECHNICAL GRADE ACTIVE INGREDIENTS FOR IDENTICAL MICROBIAL STRAINS OR ISOLATES APPROVED UNDER REGULATION (EC) No 1107/2009



Unclassified ENV/JM/MONO(2018)8

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development 22-May-2018
English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

ENV/JM/MONO(2018)8
Unclassified

Cancelled & replaces the same document of 16 May 2018

GUIDANCE DOCUMENT FOR THE ASSESSMENT OF THE EQUIVALENCE OF TECHNICAL GRADE ACTIVE INGREDIENTS FOR IDENTICAL MICROBIAL STRAINS AND ISOLATES

Series on Pesticides
No. 96

Unclassified ENV/JM/MONO(2016)54

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development 07-Sep-2016
English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

ENV/JM/MONO(2016)54
Unclassified

GUIDANCE DOCUMENT ON STORAGE STABILITY OF MICROBIAL PEST CONTROL PRODUCTS

Series on Pesticides
No. 85

Review

Ecological arguments to reconsider data requirements regarding the environmental fate of microbial biocontrol agents in the registration procedure in the European Union

Kees Booij¹, Jürgen Köhl^{1*}, Rogier Kolnaar² and Willem J. Ravensberg³

¹ Wageningen University & Research (WUR), Wageningen, The Netherlands, ² Linge Agroconsultancy b.v., Oosterhout, The Netherlands, ³ Koppert Biological Systems, Berkel en Rodenrijs, The Netherlands.



OECD-EGBP Current activities (I)

Overview Document/Manual on Microbials

Aim: Make the information available and more accessible to regulators (*webpage based*)

- Listing of the different data requirements
- Introduction with regulatory requirements of different regions/jurisdictions
- Reference to existing OECD and the member countries' Guidance Documents, test guidelines and relevant scientific publications
- Develop criteria for 'scientific publications'



OECD-EGBP: Current activities (II)

Issue papers are prepared on **Test Methods for Micro-organisms** aiming to identify their limitations and how they can be addressed

Issue papers are intended as discussion papers and do **not** provide **mandatory guidance**

Revised:

- Tiered approach for mammalian toxicity testing of microbials
- Justifications for not providing mammalian toxicity studies with microbial PPPs
- Comparing study guidelines for avian toxicity testing of microbials
- Impact of microbial pesticides on earthworms

Newly issued:

- effects of Microbial Biocontrol Agents on sewage sludge
- Comparing study guidelines for fish toxicity testing of microbials

Commenting period EGBP: autumn 2020



OECD-EGBP Current activities (III)

Update on the review of the **EU data requirements for microbials**

- EU: revising data requirements active substance, PPPs and Uniform Principles for evaluation and authorization of PPPs
- Agreed principles: (i) no need to start from scratch, (ii) “Need to know” approach, (iii) New scientific approaches, (iv) Tiered based approach (mandatory and conditional requirements)
- Drafting UP, SCoPAFF, Consultations (EFSA, Stakeholders), Formal adoption process (*ongoing in 2020*)

Biological properties: cornerstone chapter

The EU Working Group on Biopesticides works complementary to the OECD-EGBP





OECD-EGBP Current activities (IV)

Update on **Anti Microbial Resistance**

- Antimicrobial resistance develops when microorganisms (such as bacteria, fungi and viruses) adapt in response to exposure to antimicrobial drugs
- The WHO regards development of antimicrobial resistance in pathogenic microorganisms as one of the **biggest threats to human health**
- Develop OECD **overview** document on how member countries handle AMR of microbials
- Input from member countries requested by end **October 2020**



OECD-EGBP Current activities (V)

Update on a **Codex project** on compounds of **low public health concern** that could be **exempted** from the establishment of **Maximum Residue Levels**

- EGBP members are invited to follow up the work through their respective Codex contact points

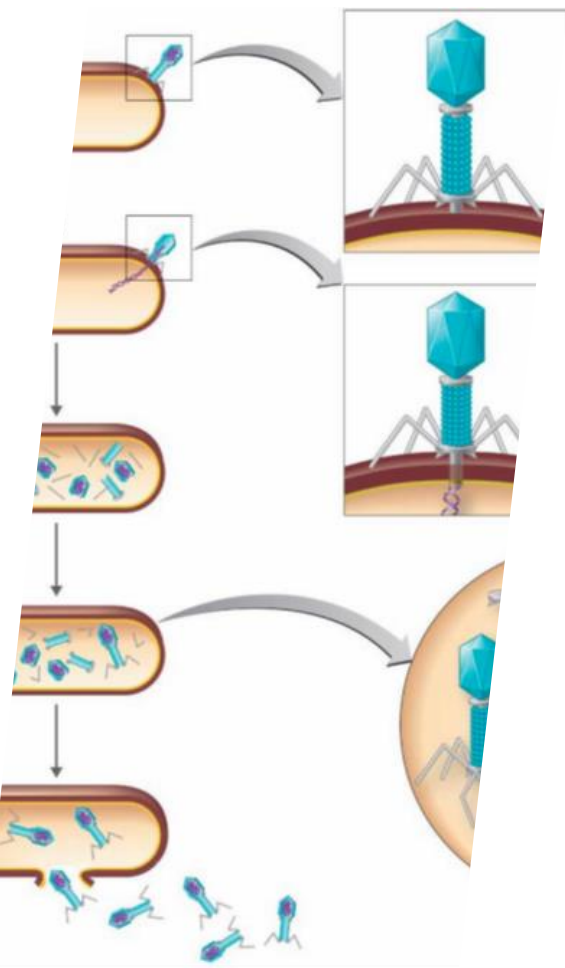
Update on **joint EGMU (Expert Group on Minor Uses) and EGBP activities**

- EGBP is supportive to follow-up on identified activities: acceptance of international data, collect incentives and policies related to reducing risks, capacity building, worksharing and cooperation



OECD-EGBP Activities (VI)

Issue paper on **Bacteriophages**



- A virus that infects and replicates within a bacterium.
- The key aspects for using bacteriophages as a biocontrol product are:
 - (1) high virulence,
 - (2) high specificity to host,
 - (3) rapid mode of action, and
 - (4) short persistence without host.
- Commenting and follow-up: autumn 2020



OECD-EGBP Activities (VII)

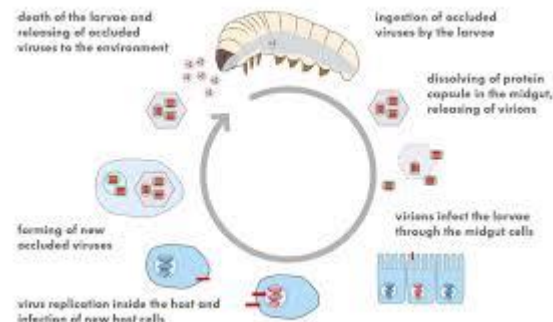
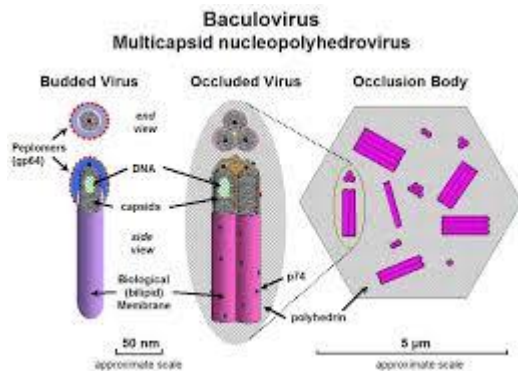
Issue paper on **Baculoviruses**

Baculoviruses are a family of arthropod-specific, enveloped viruses with a circular double-stranded DNA genome

Building upon 'Consensus Document on Information used in the Assessment of Environmental Applications involving Baculoviruses, OECD Series on Harmonization of Regulatory Oversight in Biotechnology, No.20'

A review panel will be established for commenting on first draft (Oct/Nov 2020)


Commenting period for EGBP: mid-November until first week of January 2021





OECD-Publications

- Report of Seminar on: **Bioinformatics and Regulation of Microbial Pesticides (2019)**
(OECD Series on Pesticides *in publication*)

First gain experience with bioinformatics, genome sequencing, etc. at regional level  discuss the identification of possible case-studies on how bioinformatics can be used to facilitate the registration of microbial biopesticides.





OECD-EGBP Seminar



- Seminar on "**Different aspects of efficacy evaluation of biopesticides**" has been postponed to 2021.
- In the framework of the Seminar 'efficacy' comprises the efficacy against pests, diseases and weeds as well as adverse effects on pest antagonists and on the cultivated plant itself, i.e. phytotoxicity.
- The Seminar will cover the efficacy evaluation of:
 - *the different categories of biopesticides,*
 - *new application techniques,*
 - *efficacy evaluation of biopesticides based on plant defence inducers (PDI) when applied to plants to induce defence responses against pests,*
 - *comparison of efficacy requirements for biostimulants versus biopesticides,*
 - *how to evaluate different Integrated Pest Management (IPM) modules,*
 - *registration pathways with limited or no evaluation of efficacy (e.g. low risk, minor-use registrations).*



Biopesticides Conference 2022

OECD's **Co-operative Research Programme (CPR)** funds conferences/workshops to support policy decisions related to the sustainable use of natural resources, in the areas of food, agriculture, forests and fisheries

The **EGBP is supportive** to the idea to organise a biopesticides conference

Possible topic: data requirements for microbials covering regulatory requirements, test methods, guidance documents, issue papers, etc.

The preferable timing is **2022**





THANK YOU FOR YOUR ATTENTION

ANY QUESTIONS



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