Outcome of the OECD-EGBP seminar

Jeroen Meeussen

EU Minor Uses Coordination Facility

Annual Biocontrol Industry Meeting

22-24 October 2018, Basel

MinorUses
EU Minor Uses Coordination Facility

Coordination Facility - Mission

The mission of the Facility is 'to enable farmers in the EU to produce high quality crops by filling minor uses gaps through efficient collaboration to improve availability of chemical and non-chemical tools within an integrated pest management (IPM) framework'.

Definition of "non-chemical methods"

Sustainable Use Directive (2009/128/EC):

‘Non-chemical methods’ means alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques, or physical, mechanical or biological pest control methods.

The Organisation for Economic Co-operation and Development

- Today the OECD has 35 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.

EU Regulatory Steps

Reg. 1107/2009	• Approval Criteria
Reg. 546/2011	• Uniform Principles • Protection Goals
Reg. 283 & 284/2013	• Data requirements • US-EPA 1996 Test methods

Seminar on ”Test Methods for Micro-organisms”

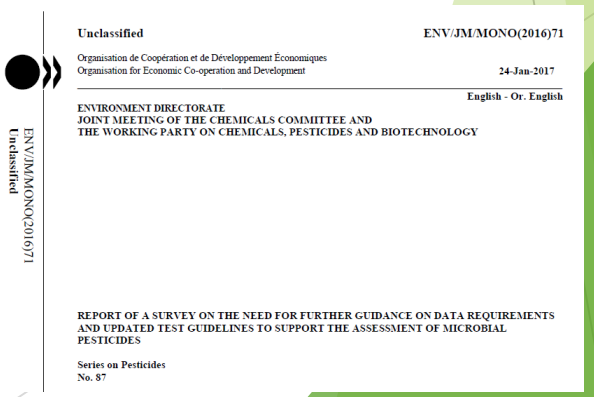
The topic “Test methods for micro-organisms” was selected based on the results of an OECD survey conducted in 2012 to identify where existing test methods or guidance are not sufficient to generate data needed to assess microbial pesticides.

Micro-organisms used as pesticides are regulated in ways that are similar to chemical pesticides. However, the biological properties of living micro-organisms differ from the properties of chemical pesticides, and, hence, the test methods used may not be the same as used for a chemical pesticide.

(18 June 2018, OECD HQ, Paris)

Survey

- Distributed to members of the OECD Expert Group on Bio-Pesticides (EGBP) in December 2012
- Questionnaire: table listing all of the data elements in the *OECD Dossier Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents* (2004)
- For each element: indicate if existing test methods for generating relevant data is not sufficient to meet their needs (e.g. lack of test guidelines, different interpretations of guidelines or of data points)
- Identify where additional guidelines or guidance is either *necessary* or could be *supportive*


Unclassified ENV/JM/MONO(2016)71

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development 24-Jan-2017

English - Or. English

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

ENV/JM/MONO(2016)71
Unclassified

REPORT OF A SURVEY ON THE NEED FOR FURTHER GUIDANCE ON DATA REQUIREMENTS AND UPDATED TEST GUIDELINES TO SUPPORT THE ASSESSMENT OF MICROBIAL PESTICIDES

Series on Pesticides
No. 87

Part A (OECD data requirements for Microbial Pest Control Agents);
Part B (OECD data requirements for Microbial Pest Control Products);
Report Appendix 1 (responses to the survey).

OECD Annex IIM point	**Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)**	**Problems with TGs (Y / N)? If Y, please specify the TG number and describe the problem**	**Overall Conclusion:** Suitable method available without modification / Suitable method available with modifications / No suitable method available
		IBMA: N Acute intratracheal toxicity testing of MCPA according to OPPTS 885.3150	
5.3.4	Acute intravenous/intraperitoneal infectivity	EU: N EU: **Y:** **OECD:** Guideline missing **OPPTS 885.3550 (tier II):** too less detailed **N:** **OPPTS 885.3200** (tier I, might need to be updated) EU: Y: In our opinion there is no need to perform the intraperitoneal test since this represent the "worst case", which is not realistic according to the use of the MPCP JP: Y There is no OECD TG applicable for this study. EU: Y Can the tox data requirements for infectivity studies be waived if the microorganism does not grow at temperatures above 30ºC? How to include immunocompromised individuals? EU: N. OPPTS guideline available. IBMA: N	OECD: no suitable test guideline OPPTS: Open questions when to perform and how to address immunocompromised status

Seminar - Scope

- The applicability of existing test methods for micro-organisms.
- How to interpret results performed in tests for micro-organisms?
- Ensure that information on the biology of the active organism strain / species is considered when designing tests.
- Novel mechanisms of biopesticide action may require consideration of new or amended guidelines and test methods.
- Remove sewage treatment from data requirements for PPP?
- Is the current regulatory framework appropriate to register micro-organisms?

Sensitisation potential

Micro-organisms have the potential to provoke sensitisation reactions by inhalation as well as through dermal exposure.

However, the available skin sensitisation study protocols routinely used for testing chemical active substances might not be useful as:

- none of the currently available methods for testing dermal sensitisation are validated for micro-organisms,
- if conducted, results may be difficult to interpret,
- micro-organisms do not penetrate skin barriers.

BUT…

Sensitisation potential

- In general, a warning phrase on labels regarding the potential for sensitisation from exposure to microbials is used (e.g., "*Contains Xx strain Y. Micro-organisms may have the potential to provoke sensitising reactions*") in EU.
- This does not mean that they are sensitisers, but they may have the potential. However, this is being interpreted differently by regulators, industry and users.
- Is it necessary to classify each micro-organism as a potential sensitiser (with a warning phrase), or can classification be specific for each (type of) micro-organism?

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Daphnia study (OECD 202)

- *Daphnia magna* are a useful indicator of the presence of toxic metabolites or manufacturing impurities when exposed to sterile filtrates, but they are also extremely sensitive to environmental stressors such as suspended particulate matter.
- Daphnia are largely non-selective filter feeders, which do not discriminate between food particles with regard to their nutritional quality.
- Daphnids, due to their small size and short generation times, respond rapidly to changes in algal food densities.
- Filter feeding invertebrates are generally less tolerant of turbid conditions than other aquatic species

Daphnia study

Possibilities for redesigning the microbial Daphnia study:

- Limit to a 10-day study, which will show both mortality and reproductive effects.
- Filtration to remove larger particles which would settle more quickly anyway.
- Increase algae feeding levels.
- Start with older Daphnia, who already have some food reserves.

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Earthworm study (OECD 222)

- Earthworms are adapted to life in the most microbially challenging environment on Earth, and the robustness of their immune systems has been studied extensively by immunologists since the early 1960s.

- There are no known microbial pathogens of earthworms.

- OECD Biopesticide Workshop (2013) concluded that an earthworm study was not necessary if the microorganism was naturally present in soil.

- Still an EU data requirement, and non-submission has to be justified in detail every time.

From: Dr Mark Whittaker, APIS (Applied Insect Science)

Honey bees US-EPA Test Guideline

- Is 30 days really necessary? If the organism is pathogenic it will show adverse effects much faster than that!
- Standard 2-4 day study is known to induce stress in confined bees. How do we manage this in 30 day studies?
- Environmental conditions (humidity, temperature): optimised for bees or for the test item/MPCA?

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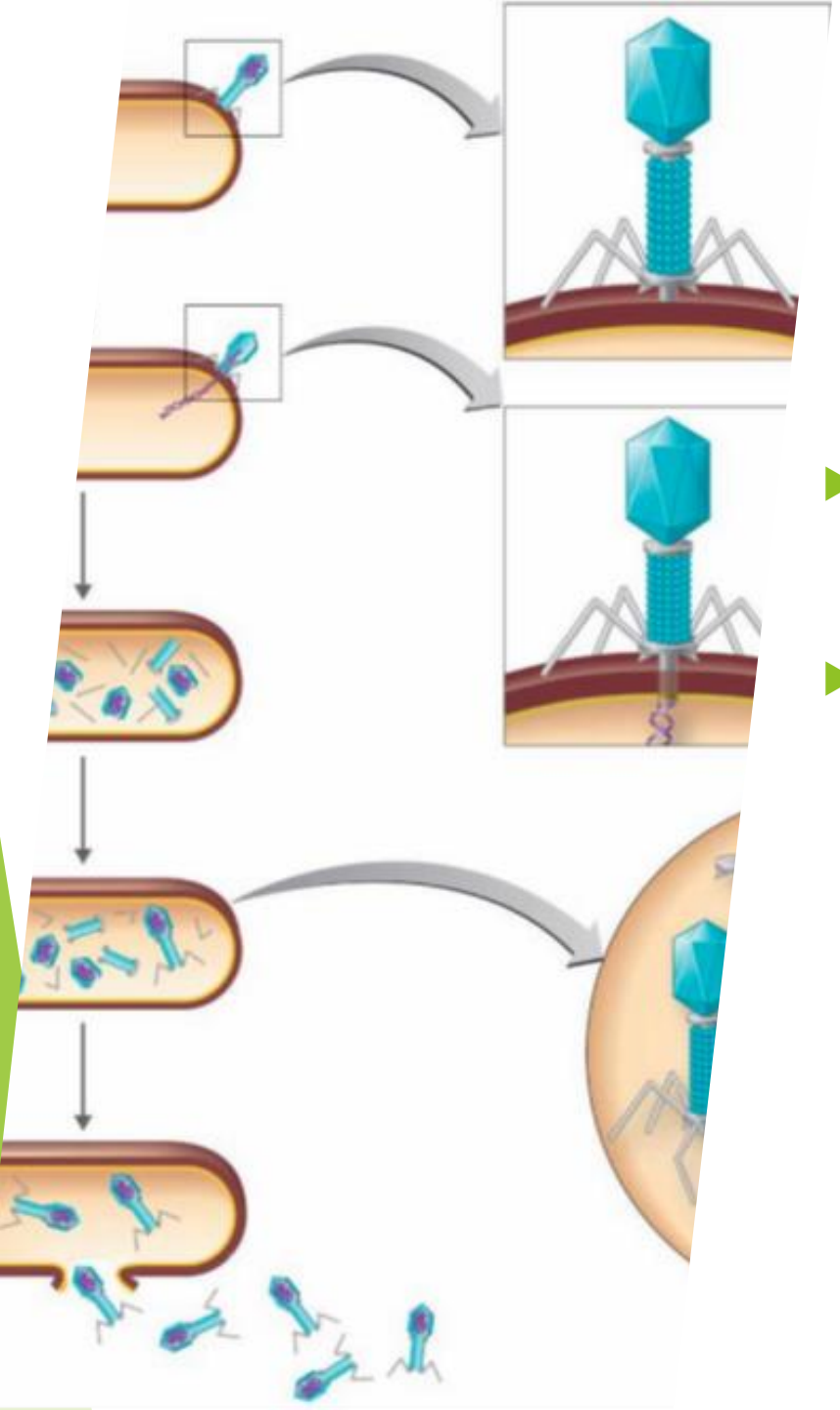

Bacteriophage

- 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.

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Are activated sludge studies necessary for microbial products?

- Sewage is a mixture of waste water, including rain water and domestic water from toilets, baths, etc.
- After filtering out solids, the remaining material is left to ‘settle’ to the bottom of a tank.
- The liquid portion, or effluent, is rich in suspended organic matter and microbes.

Regulatory Studies

Microbes used in agricultural applications:

- will not reach sewage sludge in large numbers (microbes are not seen to be mobile in soils);
- would not interfere with degradation of nutrients by other microbes;
- Would only increase the use of organic matter if their nutritional requirements are met;
- Still an EU data requirement, and non-submission has to be justified in detail every time.

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What is needed to overcome some problems

- Clarify protection goals
- Acknowledge that some biopesticdes are living organisms
- Guidance on interpretation of data requirements
- Adequate study/test guidelines
- Agreement how to interpret the results

Seminar - Outcome

A scoping document will be prepared to identify in more detail than in the survey report the key areas for further work on test methods and guidelines, and to take this work forward in small groups of experts.

> Testing of chemicals
> Assessment of chemicals
> Risk management of chemicals
> Chemical accident prevention, preparedness and response
> Pollutant release and transfer register
> Safety of manufactured nanomaterials
> Agricultural pesticides and biocides
> Biosafety - BioTrack

Publications on biopesticides

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**
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

Report of a Survey on the Need for Further Guidance on Data Requirements and Updated Test Guidelines to Support the Assessment of Microbial Pesticides
Series on Pesticides **No. 87**
ENV/JM/MONO(2016)71

Guidance Document on Storage Stability of Microbial Pest Control Products
Series on Pesticides **No. 85**
ENV/JM/MONO(2016)54

Report of a Survey on Regulatory and Testing Issues for the Sensitisation Potential of Micro-Organisms: Survey Results (2014)
Series on Pesticides **No. 84**
ENV/JM/MONO(2016)37

http://www.oecd.org/chemicalsafety/pesticides-biocides/publications-on-biopesticides.htm

THANK YOU FOR YOUR ATTENTION

ANY QUESTIONS

Jeroen Meeussen
Coordinator
European Union Minor Uses
Coordination Facility
21 boulevard Richard Lenoir
75011 Paris
FRANCE

T +33(0)1 84 79 07 55
M +33(0)7 60 82 22 36
E jeroen.meeussen@minoruses.eu

website: www.minoruses.eu