



OECD-EXPERT GROUP ON BIOPESTICIDES

**SEMINAR on “Bioinformatics and regulation
of microbial pesticides”**

**and
Current Activities and Future Plans**

Jeroen Meeussen

EU Minor Uses Coordination Facility

Annual Biocontrol Industry Meeting

21-23 October 2019, Basel



What is OECD?



A few words about OECD

OECD: The Organisation for Economic Co-operation and Development





The OECD . . .

- Established: **1961**
- Headquarters: **Paris**
- Membership: **36 countries and the European Commission**
- Structure:
 - Council (Ambassadors)**
 - Committees and Working Groups**
 - Secretariat**





OECD's work on Pesticides

Environment, Health and Safety Programme

- Industrial Chemicals
- **Pesticides (Working Group on Pesticides, WGP)**
- Biocides
- Manufactured Nanomaterials
- Genetically Modified Organisms (GMOs)
- Testing and hazard/risk assessment
- Risk management
- Prevention of accidents
- Information sharing



WGP has Expert Groups on:

- **Bio-Pesticides**
- Electronic Exchange of Pesticide Data
- Illegal Trade of Pesticides (ONIP)
- Minor Uses of Pesticides (EGMU)
- Pesticide Effects on Insect Pollinators
- Residue Chemistry Expert Group
- RNAi



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.

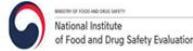




SEMINAR on “Bioinformatics and regulation of microbial pesticides”



Bioinformatics in the spotlight



Foodborne pathogens & whole genome sequencing

JOINT CONFERENCE 26-28 March 2019

#FoodSafetyWGS2019



Food and Agriculture Organization of the United Nations

Search

Home / News / CPM-13 side session on gene sequencing and molecular technologies

CPM-13 side session on gene sequencing and molecular technologies

INSIGHTS

POLICY FORUM

GLOBAL HEALTH

Threats to timely sharing of pathogen sequence data

The Nagoya Protocol may impose costs and delays

Genomics & Microbiome Analysis

to identify the next generation biopesticides

Marcus Meadows-Smith
CEO
BioConsortia, Inc.



Global Engage

6TH PLANT GENOMICS & GENE EDITING CONGRESS: ASIA

Co-located with the **MICROBIOME FOR AGRICULTURE CONGRESS: ASIA**

29-30 JULY 2019 – KUALA LUMPUR, MALAYSIA



Bioinformatics

- The seminar on “**Bioinformatics and regulation of microbial pesticides**” was held on 24 June 2019 and was attended by 56 people.
- **Bioinformatics** combines biology, computer science, information engineering, mathematics and statistics to analyse and interpret biological data.





Seminar on Bioinformatics and Regulation of Microbial Pesticides

- **Genome sequence, bioinformatic tools and databases** are routinely used in different research and development sectors.
- These technologies are now starting to be used in the area of microbial biopesticides and could **potentially enrich the toolbox of evaluators** for microbials.
- Discuss **the usefulness and benefits** of this technology in the **regulatory decision process** for microbials. **How to interpret results** from this technology?



What is the added value of bioinformatic analysis within the current regulatory approach?

- Whole Genome Sequencing (WGS) data need careful interpretation. **Additional information** (biology) and **further analysis** may be needed.
- Diversity of bioinformatics tools: need to establish **quality system** for the WGS process; results need to be **reproducible**.
- We have to distinguish between: What information is **nice** to know and what information do we **need** to know.
- WGS information can be used to **address certain data requirements** for the registration of microorganisms (especially identification, characterisation, AMR).
- We also have to consider the **expression level** of genes.



Conclusions (I)

- **Harmonize** at an international level the type of data required and the way these data should be evaluated.
- **Learn** from what is happening in other sectors (e.g. food and feed additives).
- **Training** on new methods may be needed as the expertise within regulatory authorities to analyse all the available data may be limited.

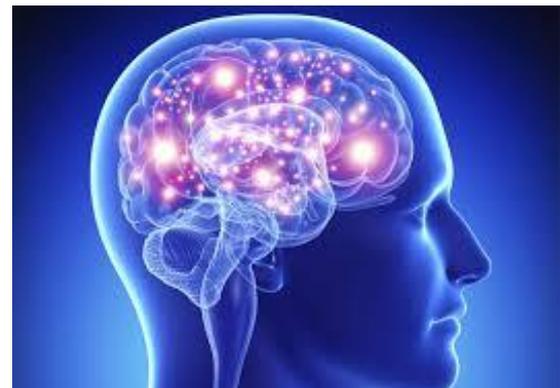




Conclusions (II)

- **No new data requirements are envisioned**; WGS should not become a standard data requirement.
- Use the technology to make risk assessment **more appropriate**.
- **Possible case-studies** how bioinformatics can be used to facilitate the registration of microbial biopesticides should be identified.

“The capacity of our brain to analyse all the available data and information may be the limiting factor.”



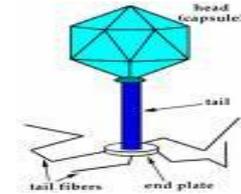


Current Activities and Future Plans of the OECD-Expert Group on Biopesticides



Biological Pesticides:

- **Macro-organisms**
 - Predators, parasites & nematodes
 - **Not usually regulated as PPPs**
- **Microbial pesticides**
 - Viruses, Bacteria & Fungal Pathogens
- **Semiochemicals**
 - Pheromones, Plant volatiles
- **Botanicals**
 - Botanicals & Other Natural substances





- Working Document on the **Risk Assessment of Secondary Metabolites of Microbial Biocontrol Agents** (OECD Series on Pesticides No. 98, 2018)
- Report of Seminar on: **Test Methods for Micro-organisms** (OECD Series on Pesticides No. 100, 2019)
- OECD **Series on Pesticides**:
 - 29 out of 100 are related to Bio-Pesticides
 - 12 out of the last 20 publications



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

Replaces & 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 Activities (I)

Overview Document/Manual on Microbials with the structure of the (chapters of the) data requirements with reference to OECD publications and other relevant documents from EU, USA, CAN and other jurisdictions (**webpage based**).

Table of contents [micro-organisms](#):

- ▶ Chapter 1: Identity
- ▶ Chapter 2: Biological Properties
- ▶ Chapter 3: Data on Application/Efficacy
- ▶ Chapter 4: Analytical Methods
- ▶ Chapter 5: Effects on Human Health
- ▶ Chapter 6: Residues in or on Treated Products, Food and Feed
- ▶ Chapter 7: Fate and Behaviour in the Environment
- ▶ Chapter 8: Effects on Non-Target Organisms



OECD-EGBP Activities (II)

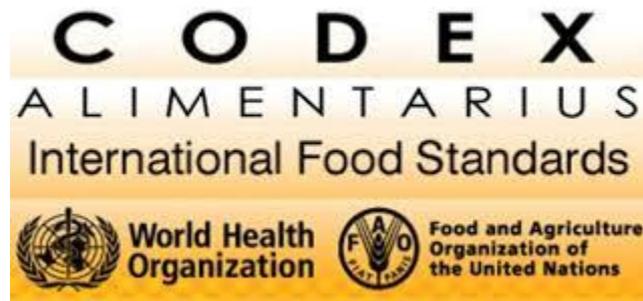
- Scoping Document on **Test Methods for Micro-organisms** to identify the key areas for further work on test methods and guidelines
 - Tiered approach for mammalian toxicity testing of microbials
 - Justifications for not providing mammalian toxicity studies with microbial PPPs
 - Comparing study guidelines for avian toxicity testing of microbials
 - Impact of microbial pesticides on earthworms

Commenting by OECD-EGBP by 31 October 2019



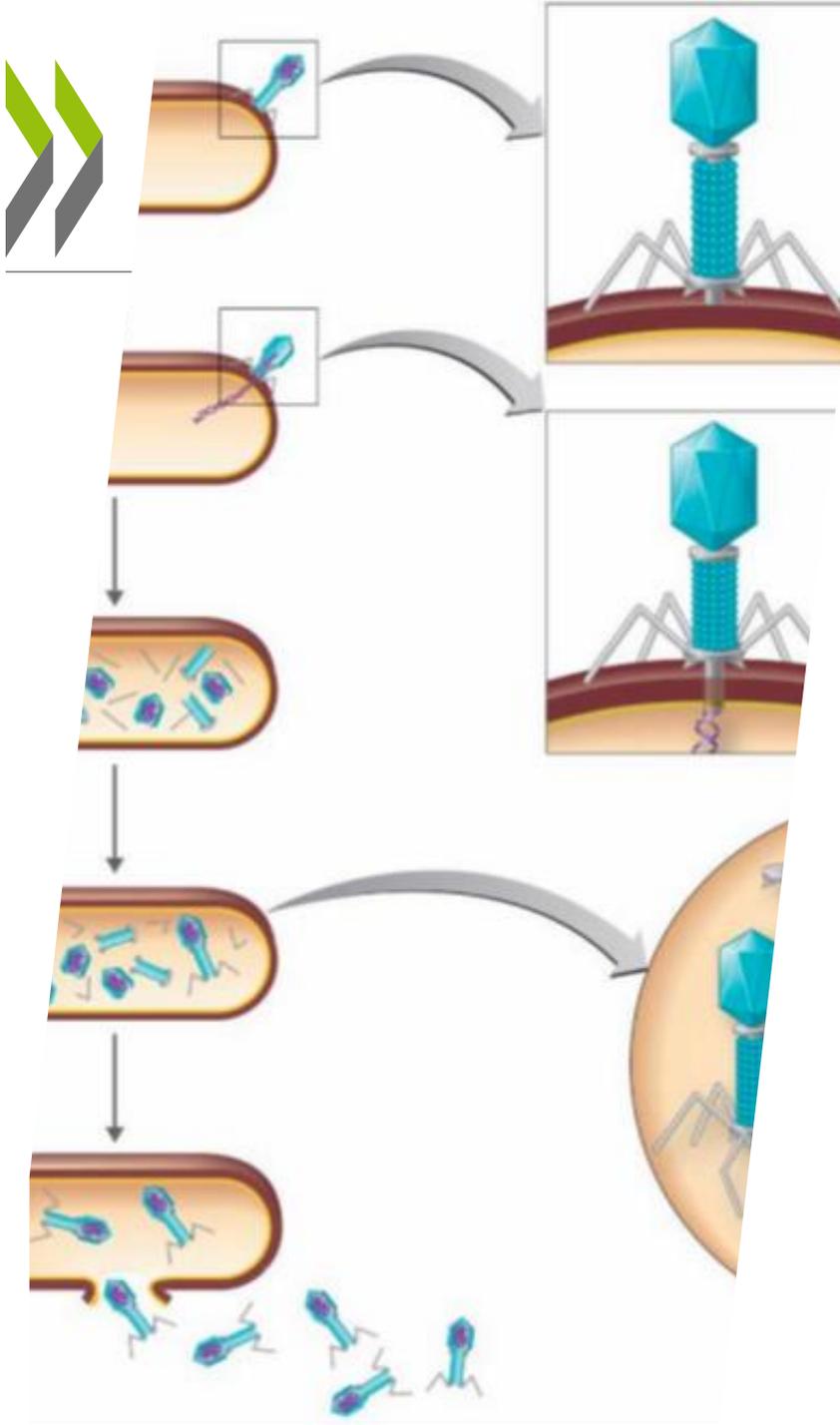
OECD-EGBP Activities (III)

- **Consensus documents** that deals with Niche Uses of Highly Specific Biocontrol Agents:
 - Issue paper on **Bacteriophages** (see next slides)
 - Issue paper on **Baculoviruses**
- Participate in a Codex project on compounds of **low public health concern** that could be **exempted** from the establishment of **Maximum Residue Levels**



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.





Bacteriophage

Draft Working Document for the regulatory framework for the micro-organism group, bacteriophage is in preparation:

- **Micro-organisms** in general can be approved for plant protection and there is **guidance available** for this.
- Bacteriophage are a group of microorganism that are viruses specifically parasitic on bacteria only, which can be considered a **niche use**.
- **Currently available guidance does not directly address bacteriophage.**
- The strain concept is not applicable to bacteriophage and they should be **approved at species level** (as for baculoviruses),
- The draft working document is intended to provide guidance to **both industry and regulatory authorities.**

Commenting by OECD-EGBP by 31 October 2019



Conclusions

EGBP contributes to the following core elements of the OECD Programme on Pesticides and Sustainable Pest Management:

- Continued efforts towards **harmonisation** of the regulatory system and **work sharing**
- **Reduction** of risks arising from pesticides
- **Large number of publications** provides a comprehensive foundation for, and guidance to, OECD members, non-members and industry

Work sharing and Cooperation between EU and OECD leads to a more harmonized regulatory framework for biopesticides.



Thank you for your kind attention – Any questions?

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