



OECD Harmonisation

—

Activities of the BPSG

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OECD

- A few words about OECD
- OECD Work on (Bio)Pesticides



OECD

OECD: The Organisation for Economic Co-operation and Development



OECD

- Started after **World War II**;
- Transformed in **1961** into the Organisation for Economic Co-operation and Development with trans-Atlantic and then global reach;
- Today the OECD has **34 member countries**;
- **More than 70** developing and transition economies are engaged in working relationships with the OECD (Brazil, China and India).

What is OECD?

A forum in which governments work together to:

- Co-ordinate and harmonise **policies**;
- Discuss issues of **mutual concern**;
- Work together to respond to **international problems**.

A provider of **comparative statistics** and **economic and social data** with more than 250 publications per year.

How do pesticides fit in all this?

One of the fields in which OECD is actively involved is the **sustainability of agriculture**.



OECD – Working Group on Pesticides

The OECD work on **agricultural pesticides** aims to help member countries:

- improve the efficiency of **pesticide control**;
- share the work of **pesticide registration and re-registration**;
- minimise non-tariff **trade barriers**;
- **reduce risks** to human health and the environment.



OECD – Working Group on Pesticides

Working Group on Pesticides:

- Registration Steering Group (RSG)
- Risk Reduction Steering Group (RRSG)
- **BioPesticides Steering Group (BPSG)**



OECD - BPSG

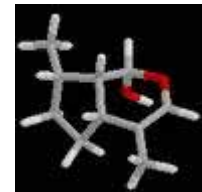
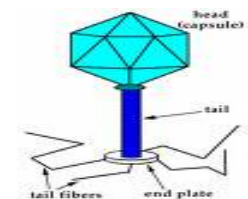
The BioPesticides Steering Group (BPSG) was established by the WGP in 1999 to help member countries:

- to harmonise the methods and approaches used to **assess biological pesticides** and
- to improve the efficiency of **control procedures**.

OECD - BPSG

Biological Pesticides:

- Macro-organisms
- Microbial biopesticides
- Semiochemicals
- Plant extracts/Botanicals



OECD - BPSG

The first tasks of the BPSG consisted of:

(i) reviewing regulatory **data requirements** for three categories of biopesticides; and

(ii) developing **formats for dossiers and monographs** for microbials, and pheromones and other semio-chemicals.



FDA and EPA Requirements

	Current EPA Requirements	Current FDA Requirements
Pre-Market Animal Safety Study	Guideline No: 870.7200 Title: Companion Animal Safety Number of Animals: 4 per sex per dose Level of Concern: 5K Other: Harmonized with previous FDACVM Guidance #33	Guideline No: 185 (VICH GL43) Title: Target Animal Safety for Veterinary Pharmaceutical Products Number of Animals: 4 per sex per dose Level of Concern: 5K Other: International harmonization
Pre-Market Clinical Trials	None	Guideline No: 65 (VICH GL8) Title: Good Clinical Practice Number of Animals: ~200 (where 1/2 are positive control). Represents populations of actual pets rather than only test beagles. Informs labeling and contributes to the overall approval decision.
Post-Market Surveillance	Aggregate summary reporting of summary numbers of adverse effects under FIFRA Section 6(x)(2). Generally only used to trigger a more detailed review.	Ten veterinarians and other professional staff evaluate detailed adverse events, particularly for new products. Findings may result in changes to product, label, insert, and communication with vets and the public.

OECD – Publications (1)

Registration requirements:

- for **pheromones** (Series on Pesticides, No. 12, 2001);
- for **microbial pesticides** (Series on Pesticides, No. 18, 2003);
- for **invertebrate biocontrol agents/IBCA**s (Series on Pesticides, No. 21, 2004).



OECD – Publications (2)

Dossier

- OECD Dossier Guidance for Microbials, 2003
rev. August 2006.
- OECD Dossier Guidance for Pheromones and other
Semiochemicals, 2003

Monograph

- OECD Monograph Guidance for Microbials, 2003
rev. August 2006.
- OECD Monograph Guidance for Pheromones and other
Semiochemicals, 2003.



OECD - BPSG

The BPSG then decided to concentrate its efforts on science issues that remain as barriers to harmonisation and work-sharing.



OECD – Publications (3)

“Working Document on the Evaluation of Microbials for Pest Control”

This document is essentially a set of **examples/case studies** aimed at helping the regulatory authorities to deal with these issues in the assessment of (microbial) biopesticides.

OECD Environment, Health and Safety Publications, Series on Pesticides No. 43, 2008

Working Document - Chapters

1. **Taxonomic identification** of micro organisms in MPCP;
2. **Genetic toxicity** assessment of microbial pesticides;
3. **Exposure** (operators, bystanders, consumers)
4. Microbial **metabolite residues in food**;
5. **Efficacy** evaluation of microbials.



Chapters

Chapters

Workshop on the Regulation of Biopesticides

“Workshop on the Regulation of Biopesticides: Registration and Communication issues” 15-17 April 2008, EPA, Arlington, USA; *OECD Environment, Health and Safety Publications, Series on Pesticides No. 44, 2009*

The objectives of the workshop were met:

- To collect input to resolve science issues;
- To improve communication and information exchange.



BPSG Workplan 2009 - 2012

- Resolve **science issues** associated with registering biopesticides:
 - microbial contaminants limits;
 - environmental safety evaluation;
 - storage stability;
 - etc.
- Promote **communication** and **information exchange** on Biopesticides :
 - organise seminars.



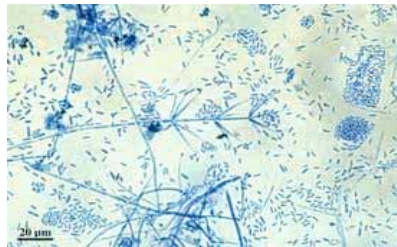
OECD – Publications (4)

Most recent publications:

- Issue Paper on **Microbial Contaminant Limits** for Microbial Pest Control Products (OECD Series on Pesticides No. 65, 2011)
→ *SANCO/12116/2012 – rev. 0, September 2012*
- Guidance to the **Environmental Safety Evaluation** of Microbial Biocontrol Agents (OECD Series on Pesticides No. 67, 2012)
→ *SANCO/12117/2012 – rev. 0, September 2012*

OECD – Seminars (1)

1. *Report of Seminar on “Identity and Characterisation of micro-organisms”*, OECD Series on Pesticides No. 53, 2010.



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2. *Report of Seminar on “The fate in the environment of microbial control agents and their effect on non-target organisms”*, OECD Series on Pesticides No. 64, 2011.



OECD – Seminars (2)

3. *Report of Seminar on “Characterisation and Analyses of Botanicals for the use in Plant Protection Products”,* held on 30 March 2011; Publication in preparation



4. *Report of Seminar on “Trichoderma spp. for the use in Plant Protection Products: similarities and differences”,* held on 11 June 2012; Publication in preparation

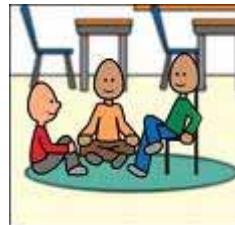


Seminar Structure

Presentations on:

government, research and stakeholder
experience and perspectives,

followed by discussion after each set of
presentations.



BPSG Workplan 2013 – 2016 (1)

- Develop guidance on **botanicals/plant extracts**;
- Develop guidance on *Trichoderma*;
- Develop guidance on '**equivalence check**' for different sources of micro-organisms;
- Prepare checklist for **pre-submission meetings**;
- Continue development of "**issue papers**" on:
 - storage stability;
 - pheromones.

BPSG Workplan 2013 – 2016 (2)

- Review the regulatory status of **invertebrates** used for pest control;
- Coordinate implementation of harmonised study **templates** for biopesticides;
- Make an inventory of available **test methods** and develop a guidance regarding the use of existing OECD Test Guidelines for microbials.

BPSG Workplan 2013 – 2016 (3)

- **Workshop** on microbiological plant protection products: joint OECD-EU workshop (June 2013)
- Possible topics for **seminars**:
 - **application techniques** for microbials (especially in relation to exposure and releases into the environment);
 - **secondary metabolites** for bio-pesticides (particularly with respect to environmental area);
 - **Straight-Chained Lepidopteran Pheromons** (SCLPs): formulations/dispensers/exposures.

Conclusion

- The BPSG has achieved a lot of progress towards harmonisation and work sharing through the development of **guidance** and **working documents**, the 2008 **Workshop** and subsequent **seminars**.
- The BPSG will continue to facilitate the **evaluation** and **assessment** of biopesticides and promote **harmonisation** and **work sharing** for the next period from 2013-2016.

Thank you for your attention



Any questions?