8th ABIM Meeting, Basel, Switzerland

Workshop on microbial pesticides

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DG SANCO

Health and Consumers

OECD/KEMI/EU WORKSHOP ON MICROBIAL PESTICIDES

17 – 19 June, Saltsjöbaden, Sweden

OECD BioPesticides Steering Group
&
OECD Task Force on Biocides

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KEMI
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Swedish Chemicals Agency

OECD
BETTER POLICIES FOR BETTER LIVES

Structure of this presentation

- Background
- Structure of the workshop
- Conclusions and recommendations
- Way forward

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Regulating microbials: a challenge!

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Why a Workshop

- Micro-organisms for use as pesticides are regulated in a similar way as chemical pesticides.
- However the biological properties of living micro-organisms differ from the properties of chemical pesticides.
- Therefore it was desirable to reconsider the regulatory requirements for microbial pesticides.

Previous workshops

- Microbiological Plant Protection Products – Workshop on the Scientific Basis for Risk Assessment; 26-28 October 1998, Stockholm, Sweden.

- Workshop on the Regulation of Biopesticides: Registration and Communication Issues; 15-17 April 2008, EPA, Arlington, USA.

Aim of the Workshop

- To advance issues around both agricultural and non-agricultural microbial pesticides and their assessment from a scientific, technical and regulatory perspective.
- To develop recommendations for OECD, its member countries and other stakeholders.
- To identify pragmatic approaches for risk assessment of micro-organisms.

Workshop structure

- It lasted 2.5 days starting on Monday 17 June till Wednesday 19 June mid-day.
- The workshop was structured in plenary and break-out group sessions.
- Four break-out groups: addressing topics from human health or environmental perspective.

Workshop structure

Around 80 participants from Member countries, COM, EFSA, research/academia and biopesticides industry (IBMA, BIAC).

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Outcome of the Workshop

- Micro-organisms are living organisms with biological properties that can die, survive or proliferate.
- As living organisms micro-organisms respond to the environment in different ways.

"Biology is the difference!"

Overall recommendations

- Take note of valuable experiences in the assessment of chemicals.
- Improve the interpretation of the data requirements with detailed guidance for the assessment of the biological aspects.
- Micro-organisms are living organisms; improve related exposure scenarios.

Workshop issues (1)

1. Identification, incl. QA & contaminants
2. Secondary metabolites
3. Technical equivalence
4. Growth temperature
5. Mode of action
6. Genetic transfer
7. Analytical methods

Workshop issues (2)

8. Efficacy testing
9. Sensitization
10. Exposure
11. Residues
12. Persistence
13. Effects on bees/pollinators
14. Natural exposure versus PPP application

Workshop issues (3)

15. Sewage treatment
16. Earthworms
17. Labelling
18. Test methods
19. Justification for information/rationale
20. Procedural/regulatory issues

Identification, incl. QA & contaminants

- Prepare issue papers on particular biological properties (e.g. growth temperature).
- Develop issue papers on individual taxonomic groups.
- Use marker approach for identification at strain level as well as fate quantification.
- Use "most appropriate justified" technology for identification.

Secondary metabolites

Develop an OECD guidance document with a clear decision tree:

- What level of evidence needed?
- Usefulness of information on related species and strains.
- Consideration of biology of micro-organisms.
- Does the product contain metabolites or are they formed after application.
- Potential of effects of secondary metabolites in non-target organisms (birds and mammals).

Growth temperature

- Cannot be an absolute parameter for not conducting infectivity studies.
- Can be used to bridge from one strain to another strain with limited data.

Persistence

- Use population dynamics to study persistence in the environment.
- Reconsider decision-making criterion: "*microbial level has to decrease to the background level within one year*".
- Related to natural occurrence (background level).

Earthworms

- Not required unless microbial is not naturally occurring in the soil.
- Is acute study long enough to address infectivity/pathogenicity?
- Lack of effects: Earthworms have a highly developed immune system.

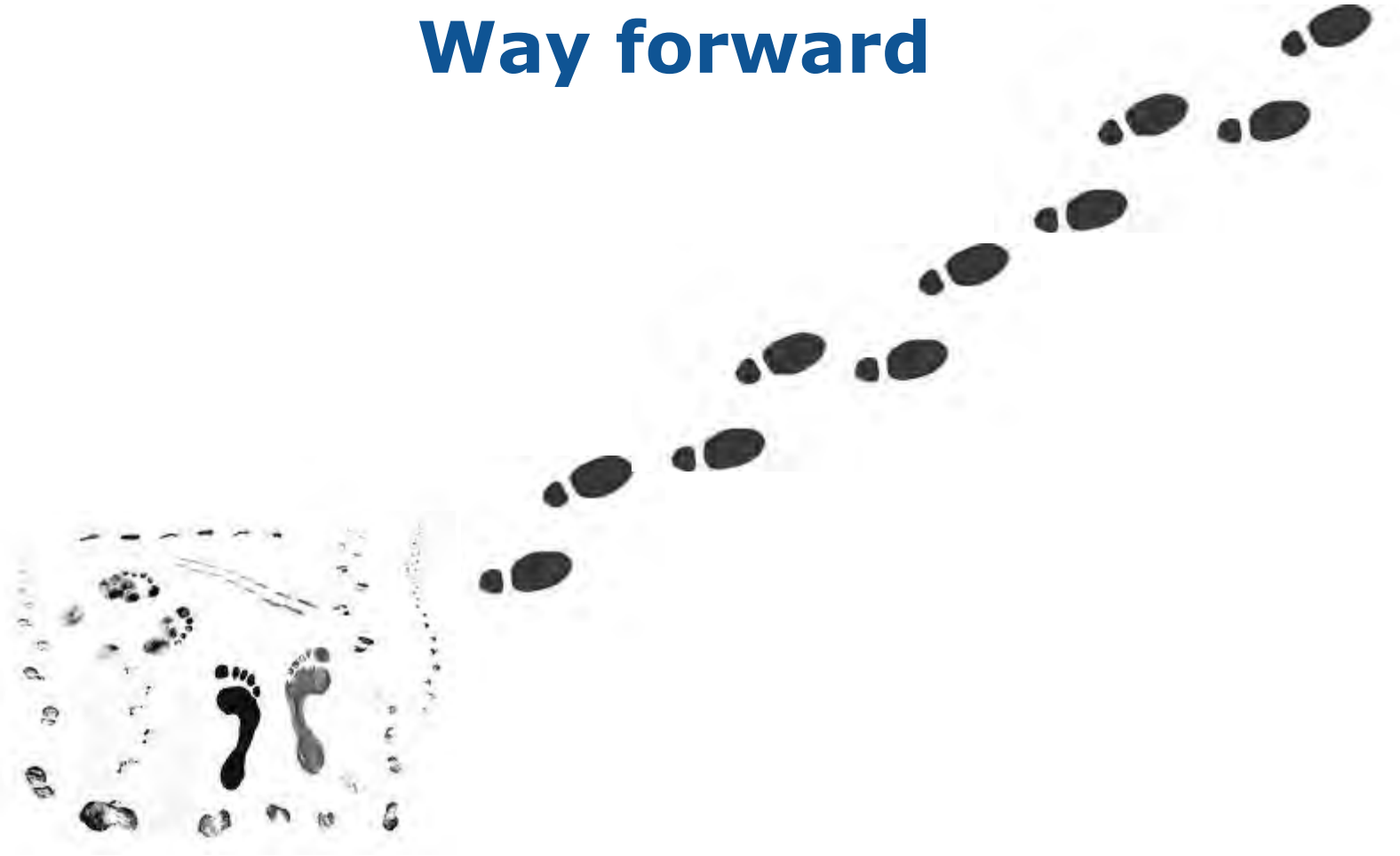
Test methods

- Test methods for chemicals should be evaluated and adapted for micro-organisms.
- Biology of the micro-organism should be considered when designing tests (e.g. duration of test).
- Develop priority list for development of new/amended test guidelines for microbials (based on OECD-BPSG questionnaire).

Procedural/regulatory issues

- Encourage EFSA involvement in developing GD.
- Use risk assessments from other areas.
- Provide a list of test methods and GD how to address each item of the data requirements.
- "Regulatory toolbox" on micro-organisms?

Way forward



Guidance Documents (BPSG)

- Guidance document on secondary metabolites.
- Guidance document on 'technical equivalence'.
- Guidance document for validation of analytical methods.
- Develop methodology/models for exposure assessment for operator, bystander, worker and resident.
- Guidance Document on how to prepare a justification/'waiver'.

Outcomes of the workshop

- The report of the workshop, its conclusions and recommendations, including the presentations will be published as an OECD report.

- The workshop has increased mutual understanding by improving communication and collaboration.

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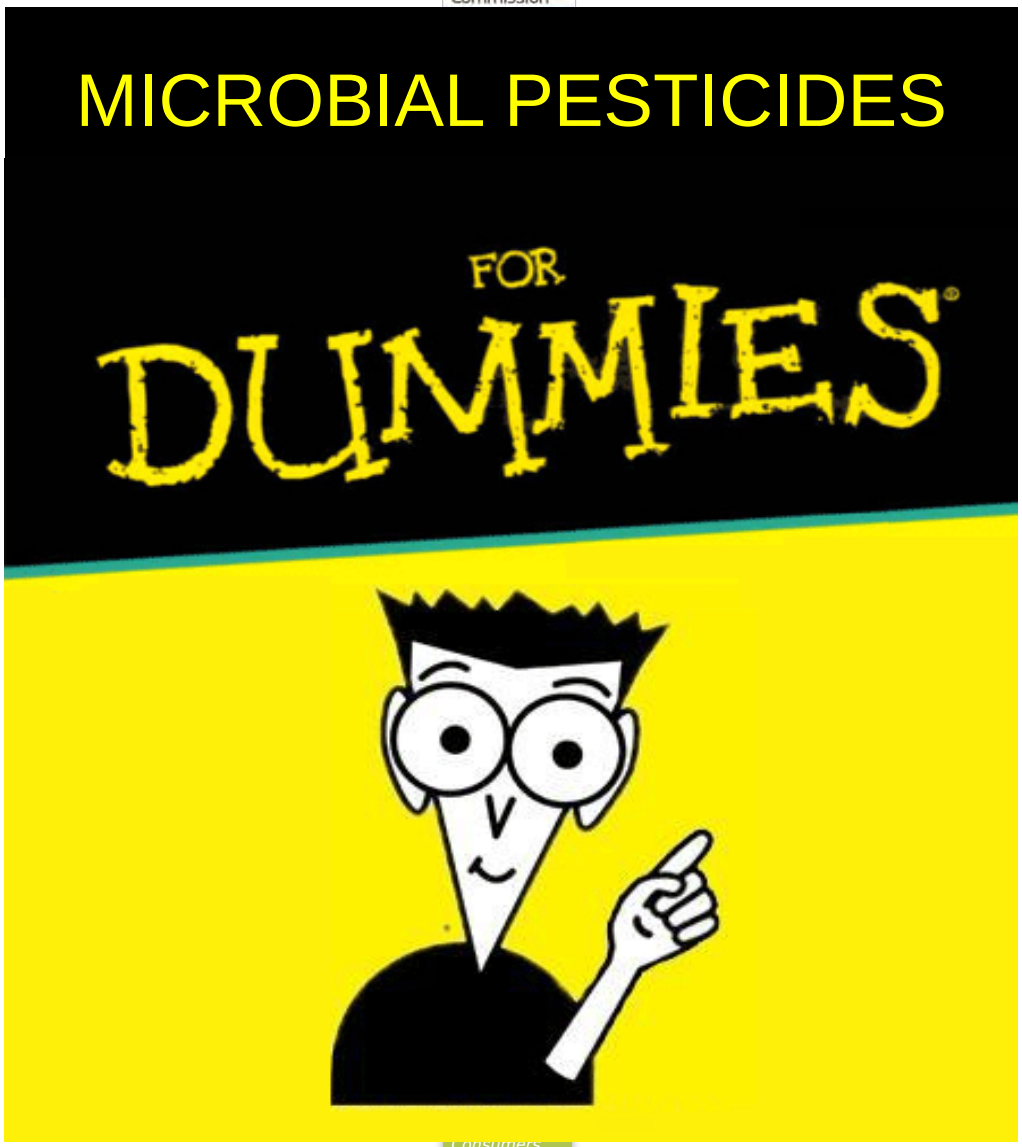

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Thank you for your attention

Any questions?