PROGRESS TOWARDS GLOBAL HARMONISATION OF REGULATION AND ASSESSMENT OF BIOPESTICIDES

20-22 October 2014, ABIM, Basel

OECD BioPesticides Steering Group

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OECD
BETTER POLICIES FOR BETTER LIVES

OECD

OECD: The Organisation for Economic Co-operation and Development

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.

Overview

Macro-organisms

Microbial Pesticides

Semiochemicals/
Pheromones

Botanicals/
Plant extracts

Macro-organisms

- Update of 2007 survey is considered necessary.
- New survey about the regulation of macro-organisms for pest and disease control in OECD countries has been circulated.
- Deadline: 1 December 2014.

Overview

Macro-organisms

Microbial Pesticides

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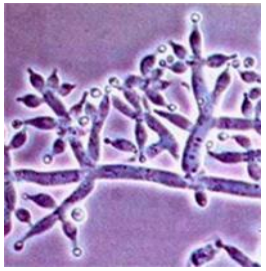
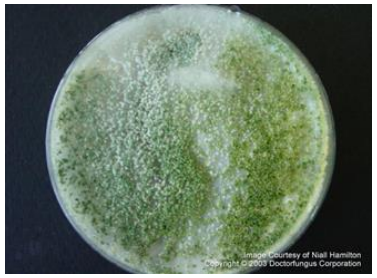
Trichoderma spp.

- The report of Seminar on "*Trichoderma spp.* for the use in Plant Protection Products: similarities and differences", has been published (OECD Series on Pesticides No. 74, 2013).

- One of the recommendations of the seminar was to develop an OECD Guidance on *Trichoderma spp.* which should:
  - address questions raised by regulatory authorities;
  - take into account the EFSA-conclusions on *Trichoderma* (data gaps, areas of concern) and
  - clarify a number of issues for the applicants.





Guidance Document on micro-organisms

Such guidance could cover a number of areas including:

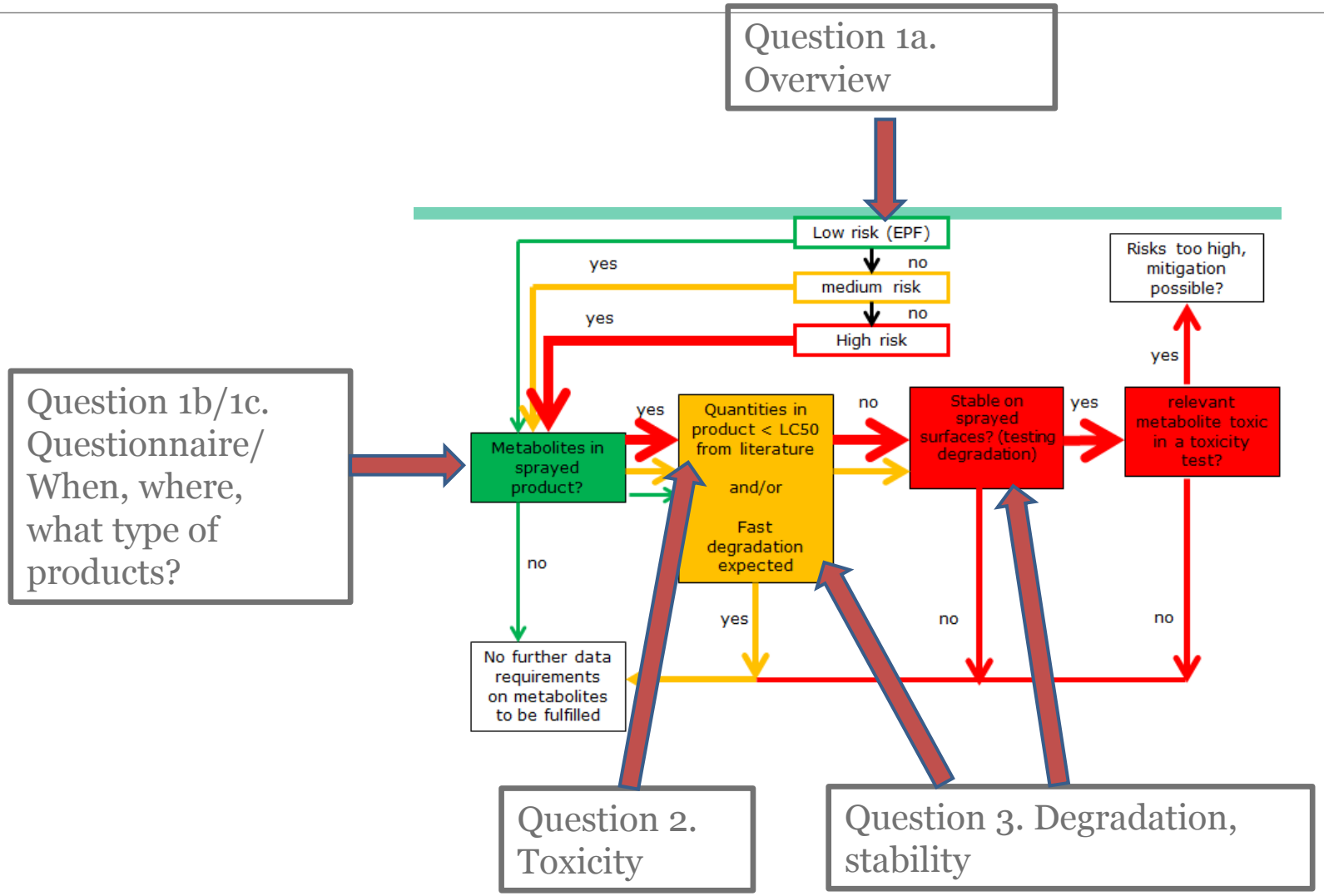
- definitions and categorization (e.g. as biopesticide, biostimulant, fertilizer, plant growth regulator ... - and the regulatory impacts);
- information needed for regulatory purposes;
- taxonomy;
- different modes of action of the species;
- methods to detect the various strains, including microbiological/ chemical and molecular methods;
- fate and behaviour, including persistence in soil;
- effects on soil microflora (on bacterial and fungal communities);
- Etc.

→ General guidance; use *Trichoderma* as an example

Secondary metabolites

- Goal: Assessment of secondary metabolite production, hazard and risk in the manufacture and use of biopesticides.
- Output should form the basis for a future OECD Guidance Document on this topic.
- Possible topic for BPSG 2015 seminar.
- Focus is on entomopathogens only.
- Project lead by J. Scheepmaker from RIVM (NL).

All answers given in this project give input to the design of a risk assessment scheme for metabolites.



Secondary metabolites – Question 1

Identification of relevant biocontrol agents with the potential to produce secondary metabolites.

1a: Review the literature on related species and strains known to be used as biocontrol agents. Which metabolites are specific to the species/genus/family?

1b: Identification of technical grade active ingredient (TGAI) known or suspected to contain secondary metabolites.

1c: The microorganisms' biology and production of metabolites; where, when, what precursors?

Secondary metabolites – Question 2

Determination of the toxicity of TGAIs identified as containing or producing secondary metabolites.

Key questions:

- Will there be exposure to metabolites?
- Are these metabolites present in the TGAI?
- If they are, what will be the actual concentrations in the field application?

Secondary metabolites – Questions 3 and 4

Question 3

Review degradation of metabolites in the environment, considering the stability of the metabolite.

Question 4

Investigate what level of evidence is required to show that no secondary metabolites of concern are formed (this may include consideration of where the metabolite is formed, its concentration, the metabolite's intrinsic toxicity);

In the case that metabolites are formed, investigate ways of selecting which metabolites should be considered for risk assessment.

DRAFT - GD on equivalence

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 (SANCO/12823/2012)

- In the EU micro-organisms are approved at strain level.

- Guidance Document is applicable for changes to the same strain only!

DRAFT - GD on equivalence

Technical equivalence with the approved (reference) source needs to be demonstrated in the following cases:

- Change of manufacturing plant (equipment and/or location),
- Scale up of fermentation vessel,
- Change of method of manufacture, including change of ingredients.

DRAFT - GD on equivalence

The aim is to ensure that the new source complies with the approved source of the technical grade active ingredient for the following parameters:

- Identity of the micro-organism;
- Content of the active micro-organism;
- Content of relevant metabolites/toxins;
- Composition of starting material for manufacturing (e.g. culture media);
- Content of microbial contaminants.

Criteria not fulfilled → Tier II assessment → risk to human health and the environment

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SCLPs

- Austria was asked to provide suggestions for an update of the OECD-12.
- It should be *clearly* stated which requirements are absolutely necessary and cannot be waived (e.g. concerning identity).
- In all cases references are required and must be accessible for the evaluators.
- More guidance for formulations other than solid matrix dispensers (e.g. sprayable microcapsule suspensions).

SCLPs

- In the OECD No. 12 it is stated that "application rates of up to 375 g SCLP/ha/year are generally understood to result in exposure levels which are comparable to natural emissions"
- However, the rationale for this assumption/value is based on a 'white paper'.
- This value should be reconsidered (in line with the EFSA-conclusion on Straight Chain Lepidopteran Pheromone; January 2014).
- Update *Guidance Document on the approval of new substances falling into the group of SCLPs* (SANCO/5272/2009).

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Botanicals/Plant Extracts

- OECD-seminar on "Characterisation and Analyses of Botanicals for the use in Plant protection Products" 30 March 2011; OECD Series on Pesticides No. 72, 2012.

- BPSG Workplan 2013 – 2016:
  Develop guidance on botanicals/plant extracts

- EU-expert group on "botanicals"




EU-expert group on "botanicals"

- EU Draft Working Document on Plant Extracts SANCO/10472/2003 – clearly needs to be updated.

- The intention is to prepare an EU Guidance Document, possibly to be 'upgraded' at a later stage to an OECD-document.

The following information has been taken into account:

- experience of other non-EU OECD countries (e.g. USA and Canada that have already some guidance in place),
- information from the EU Biocides guidance document,
- publications of EFSA (e.g. scientific opinions).

- Revised data requirements (identification, metabolism): "*For plant extracts, a different approach may be taken and adequately justified*".

Guidance Document on "botanicals" (1)

Based on the taxonomy and/or current knowledge of the botanical source three groups can be distinguished.

Group 1

- Botanical active substances that are known to have no unacceptable effects on humans, animals and the environment and are based on materials with known specifications e.g. food grade.

  → Not necessary to identify each component but demonstrate that each sample is comparable to the specification.

Guidance Document on "botanicals" (2)

Group 2

- Botanical active substances for which taxonomy and current knowledge indicates that the botanical active substance may contain components of possible concern for humans, animals and/or the environment.

  → In this case these components should be identified and quantified.

Group 3

- Botanical active substances that are not based on a material with an established specification.

  → Complete identification and characterisation is needed.

Guidance Document on "botanicals" (3)

- Guidance Document on botanicals has been 'noted' on 20 March 2014 and is applicable to applications submitted from 1 October 2014 onwards (SANCO/11470/2012).

- Circulated to OECD-BPSG: comments received from CAN and CropLife.

- Current document should be amended to address comments and align with different definitions used by regulators in other countries/regions.

- Explore possibly to upgrade the EU Guidance Document to an OECD-document.

Conclusions

- The BPSG has achieved a lot of progress towards harmonisation and work sharing through the development of guidance and working documents, the 2008 and 2013 Workshops and subsequent seminars.
- The BPSG and EU Working Group on Biopesticides will continue to facilitate in close cooperation with other stakeholders the evaluation and assessment of biopesticides and promote harmonisation and work sharing.

Thank you for your attention

Any questions?