Workshop on efficacy requirements and evaluation of plant protection products based on low-risk active substances

Ede (NL), 2016-04-06/07

REPORTING DOCUMENT FOR WORKING GROUPS

Theme B
Low risk micro-organisms with direct mode of actions

Participants Group B

	Organisation, Country
Ms Ivonne Elberse	National Plant Protection Organization, Netherlands
Mr Ricci Manuele	Bayer CropScience, Italy
Ms Kars Ilona	Bejo Zaden, Netherlands
Mr Marco Jegerings	Loxia Consulting, Belgium
Ms Sarah Van Beneden	Biobest Belgium, Belgium
Ms Katharina Sokoll	TSGE Consulting, Germany
Ms Céline Vase	Redebel Regulatory Affairs SCRL, Belgium
Ms Alice Gilleman	Redebel Regulatory Affairs SCRL, Belgium
Ms Barry Kortenhoff	Ctgb, Netherlands
Mr Alexandru Paica	RESEARCH - DEVELOPMENT INSTITUTE FOR PLANT PROTECTION, Romania
Ms Pat Croft	Chemicals Regulation Directorate UK, United Kingdom
Mr Martin Hommes	Julius Kühn Institut (JKI), Institute for Plant Protection in Horticulture and Forests, Germany
Ms Catherine Golden	ELEPHANT VERT, France
Ms Karine Grosbeau	ELEPHANT VERT, France
Mr Bart De Winter	DCM Corporation, Belgium
Ms Edith Ladurner	CBC (Europe) S.r.l., Italy
Ms Lise Deleuran	Department of Agroecology, Aarhus University, Denmark
Mr Tonnie Engels	Linge Agroconsultancy, Netherlands
Ms Flora Limache	Novozymes France, France
Mr John T O'sullivan	BioAtlantis Limited, Ireland
Mr Paul Sopp	Fargro Ltd, United Kingdom
Ms Roma Gwynn	Biorationale, United Kingdom
Mr Jésus Jiménez Ruiz	National Instiute of Agricultural and Food Research and Technology, Plant Protection Products Unit

1. Acceptable effectiveness levels and types of label claims.

- What minimum level of effectiveness is acceptable for the different themes? What is seen as an acceptable /minimal level of control?
- What information is essential to be able to evaluate if the level of control is acceptable?
- Is it feasible to have a label claim on the level of efficacy on the label (e.g. moderate control or suppression)? What are the advantages and disadvantages of differentiated label claims?
- What tools are available to accelerate the introduction of plant protection products based on low-risk substances, e.g. waiving the evaluation of phytotoxicity?

Group B - Acceptable effectiveness levels

- Harmonisation necessary (efficacy levels accepted byMS currently differ)
- Acceptable level: significant better than untreated
- Clear claim / justify the claim (in case of low efficacy)
- Differentiation / phrases for different % control (no numbers!)?
- Label should include good description of the conditions for good performance
- Can data justify to consider EU as one zone?
- One year instead of 2 year trials?
- Minimum number of issues in National addenda
- Harmonise language: some MS require correspondence / national data in MS language (instead of English)

2. Dose justification

- What information on minimum effective dose is necessary for low risk (bio)chemicals/botanicals/ minerals?

- Does the EPPO Standard PP 1/276 (1) give sufficient information on data requirements for minimum effective dose for microbials?

- Does the OECD guidance give sufficient information on data requirements for minimum effective dose for microbials?

Group B - Dose justification

- Min. effective dose in general **not** relevant/necessary
  → instead dose can be adressed in preliminary trials

- Harmonisation in dose expression is a problem (LWA, set dose, %)
  Note: there will be a workshop in Vienna in 2016 on this topic

3. Data requirement: minimal amount of information to do a meaningful efficacy evaluation?

- In general: what information is required to do a meaningful efficacy evaluation?

- Are (field) trials on efficacy always required? If not, is it possible to make clear guidance when it is and when it is not required?

- Are GEP trials necessary in case an applicant can demonstrate that trials are performed under scientific sound methods and in a reproducible form?

Group B - Minimal amount of information

- At least the required number of efficacy trials (up to 6) , under worst case conditions (extrapolate whenever possible between zones)

- Trials from one year (with wide geographical spread) would be favourable esp. to smaller companies

- Effort should be made to harmonise extrapolation for major uses

- GEP: yes, is a guarantee for independency / standardisation. But other (accredited) trials could be acceptable
- Harmonisation for mutual recognition

4. Extrapolation possibilities/ justification of extrapolation.

- Can the approach for minor uses also be useful for the evaluation of plant protection products based on low-risk active substances?

- Is there agreement on the proposed extrapolation possibilities for microbials and are there other/similar ways of extrapolation for other mode of actions?

- How should harmonisation on extrapolation take place (EPPO guidance, other)?
- What about worst case scenario (e.g. low temperature for a microbial) and extrapolation to other scenario's? Is that possible provided dependency on critical factors is well explained on mode of action?
- What extrapolation possibilities exist when the mode of action is not exactly known?
- Is trial data generated in one climatic EPPO zone of use for other climatic EPPO zones? What about trial data generated outside the EU?

Group B - Extrapolation

- Minor use approach: yes
- Several MS have extrapolation lists of indicator crops / pests → harmonsation would be useful
- Make a reasoned case, provide justification
- List for minor crops per zone?

5. Quality of dossiers/ role of applicant.

- How can the quality of the efficacy dossiers be improved?
- Do applicants need extra guidance on quality of dossiers?
- Is it always possible to provide extensive information on the mode of action of the product?

Group B - Quality of dossier

- Dossiers sometimes of poor quality (data gaps, no justifications, poor data summaries, poor set-up of trials): stimulate (pre)PSM, consultants

- Extra /improved guidance is needed (esp. for small companies).

- Mode of action: often very complex, sometimes remains unknown.
  Information can be helpful to facilitate evaluation (also may justify reduced data set).

6. Usefulness of Value assessment.

- Can the approach of value assessment be useful for the (efficacy) evaluation of plant production products on low-risk active substances?
- Does this approach fit to current legislation or is adjustment needed?
- Do national (or zonal) conditions need to be considered in a value assessment?

Group B - Value assessment

- New section 3 already has a paragraph for additional (value) information.

- Harmonisation needed for evaluators how to carry out value assessment.