Efficacy requirements of Plant Protection Products based on Low-Risk Active Substances

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Outline

- Reduction of data requirements
- European legislation
- Minor use approach
- Value assessment
- Extrapolation possibilities
Reduction of data requirements

- Within the legal framework
- Common grounds with approach for minor uses
- Value assessment
- Extrapolation possibilities
Article 4(3) of the Regulation requires that a plant protection product shall be a) ‘sufficiently effective’ and b) ‘shall not have any unacceptable effects on the plants or plant products’.

Article 47

Placing on the market of low-risk plant protection products

1. Where all the active substances contained in a plant protection product are active substances as referred to in Article 22, the plant protection product provided no specific risk mitigation measures, and no mitigation measure is needed following a risk assessment. This plant protection product shall also meet the following requirements:
Sufficiently effective, what is meant?

- Guidance on microbials: EPPO 1/276 and OECD working document
- **Level** of effectiveness of microbials is more variable compared to conventional PPP
- What about other products based on low risk substances?
- Minimum acceptable **level** of effectiveness?
- Label claim on **level** of effectiveness or label claim as low risk product?
Minor Use approach

- Products for minor crops/uses can be authorized without efficacy data (art 51) or with reduced efficacy data
- Feasible to have a reduced efficacy package for products that pose a low risk to the environment and human health
- EPPO guidance on minor uses (PP 1/224) and extrapolation tables
- Lower number of trials, data from other sources and extrapolation
Value assessment

• System and experiences will be presented by Pat Curry from Canada

• Could this be of use for the efficacy evaluation of PPP based on low risk substances?
Extrapolation possibilities

Direct MOA

versus

Indirect MOA
Mode Of Action

Direct MOA: Pest related

Indirect MOA: Crop related

Pest and crop related
Direct MOA

- Toxic
- Parasitic
- (Mating) disruption
- Repellent
Extrapolation possibilities

One pest species

One crop

All crops
Indirect MOA

- Induction of defence system
- Root colonisation
Extrapolation possibilities

One pest species

One crop

Group of pests
Topics to be discussed

1. Acceptable effectiveness levels and types of label claims;
2. Dose justification;
3. Data requirement: what is the minimal amount of information to do a meaningful efficacy evaluation? What kind of information?;
4. Extrapolation possibilities/ justification of extrapolation;
5. Quality of dossiers/ role of applicant;
6. Usefulness of Value assessment.
To make this workshop a success:

- Active participation of all participants is needed
- Think out of the box, be creative
- Think in solutions and not in problems

- Have a good workshop!