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 C:
Low Risk micro-organisms with indirect mode of actions

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?

It should be statistically significant from the negative control.

-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?

No agreement on having categories on label

advantage: sets reasonable expectation for product.

Disadvantage: not harmonised, might change in future.

Should also be same approach for chemicals.

-What tools are available to accelerate the introduction of plant protection products based on low-risk substances, e.g. waiving the evaluation of phytotoxicity?

Phytotoxicity is not just dependent on mode of action/active substance, but formulation dependent.

2. Dose justification

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

No new trials needed, beneficial to include data you have from development on why dose rate was chosen.

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?

can be reduced if data from other sources is available (literature, preliminary data, etc) Some trials needed to maintain value of low risk classification, 3-4 trials?

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

GEP Preferred, should be justified why not!.

Could discuss with authorities if type of product makes it impossible.

4. Extrapolation possibilities/ justification of extrapolation.

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?

Hard to write down exact guidance because it depends strongly on product/moa. Science and Mode of action based extrapolations must be possible.

a) Is trial data generated in one climatic EPPO zone of use for other climatic EPPO zones? What about trial data generated outside the EU?

For microbials, why have zones?

Good description needed in dossier why the proposed extrapolations (zone to zone) work.

If worst case is covered, other zones should be fine. Lower rates in other zones are not needed as there is no risk from the product.

5. Quality of dossiers/ role of applicant.

a) How can the quality of the efficacy dossiers be improved?

Clear statistics and summary tables required,

mode of action description is important.

a) Do applicants need extra guidance on quality of dossiers?

YES (small companies)

a) Is it always possible to provide extensive information on the mode of action of the product?

It is needed for extrapolation and reduced data

6. Usefulness of Value assessment.

Is value assessment defined as the Canadian approach, or in IPM context, or as justification for less data?

a) Can the approach of value assessment be useful for the (efficacy) evaluation of plant production products on low-risk active substances?

Low risk is value in itself, extra information can help.

a) Does this approach fit to current legislation or is adjustment needed?

yes

a) Do national (or zonal) conditions need to be considered in a value assessment?

(not discussed)