



Netherlands Food and Consumer
Product Safety Authority
Ministry of Economic Affairs

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

*Workshop Efficacy Requirements and
Evaluation of Plant Protection Products
based on Low-Risk Active Substances,
The Netherlands, April 6 & 7 2016*





Reduction of data requirements

- Within the legal framework
- Common grounds with approach for minor uses
- Value assessment
- Extrapolation possibilities



European legislation: Regulation No 1107/2009

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 non-target organisms**'.

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, that product shall be authorised as a low-risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment. This plant protection product shall also meet the following requirements:

It is sufficiently effective



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!