

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



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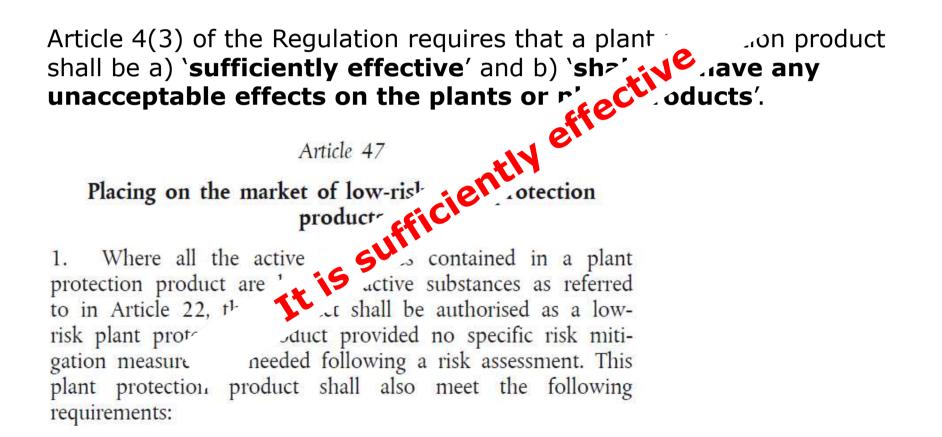


#### Reduction of data requirements

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



#### European legislation: Regulation No 1107/2009



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#### 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







# Direct MOA

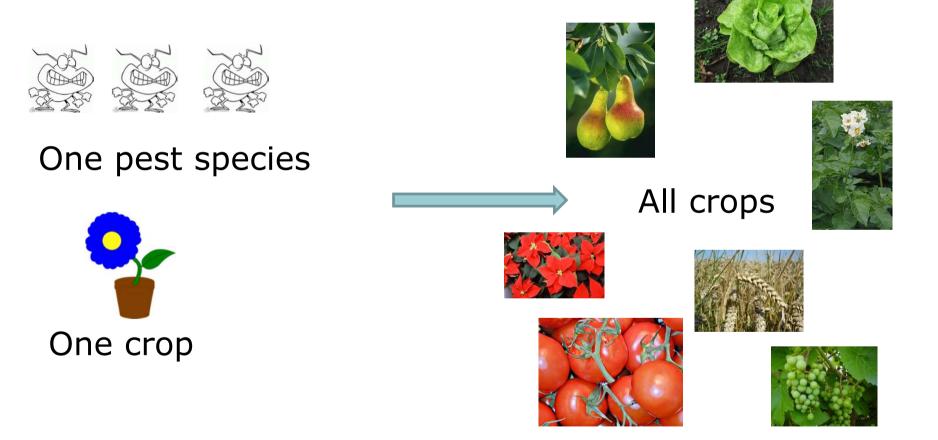


• Toxic 🐼

- Parasitic
- (Mating) disruption
- Repellent



### Extrapolation possibilities





# Indirect MOA



- Induction of defence system
- Root colonisation



# Extrapolation possibilities



#### One pest species





#### 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!