



Netherlands Food and Consumer
Product Safety Authority
*Ministry of Agriculture,
Nature and Food Quality*

The development of the EPPPO standard on low-risk products

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IX. Symposium on Plant Protection
and Health in Europe

19-11-2019





Outline

- › Introduction Netherlands Food and Consumer Product Safety Authority (NVWA)
- › Introduction EPPO
- › EPPO Standard PP1/96(1) 'Principles of efficacy evaluation for low-risk plant protection products'



Netherlands Food and Consumer Product Safety Authority (NVWA)

- › Independent agency in the Ministry of Agriculture, Nature and Food Quality

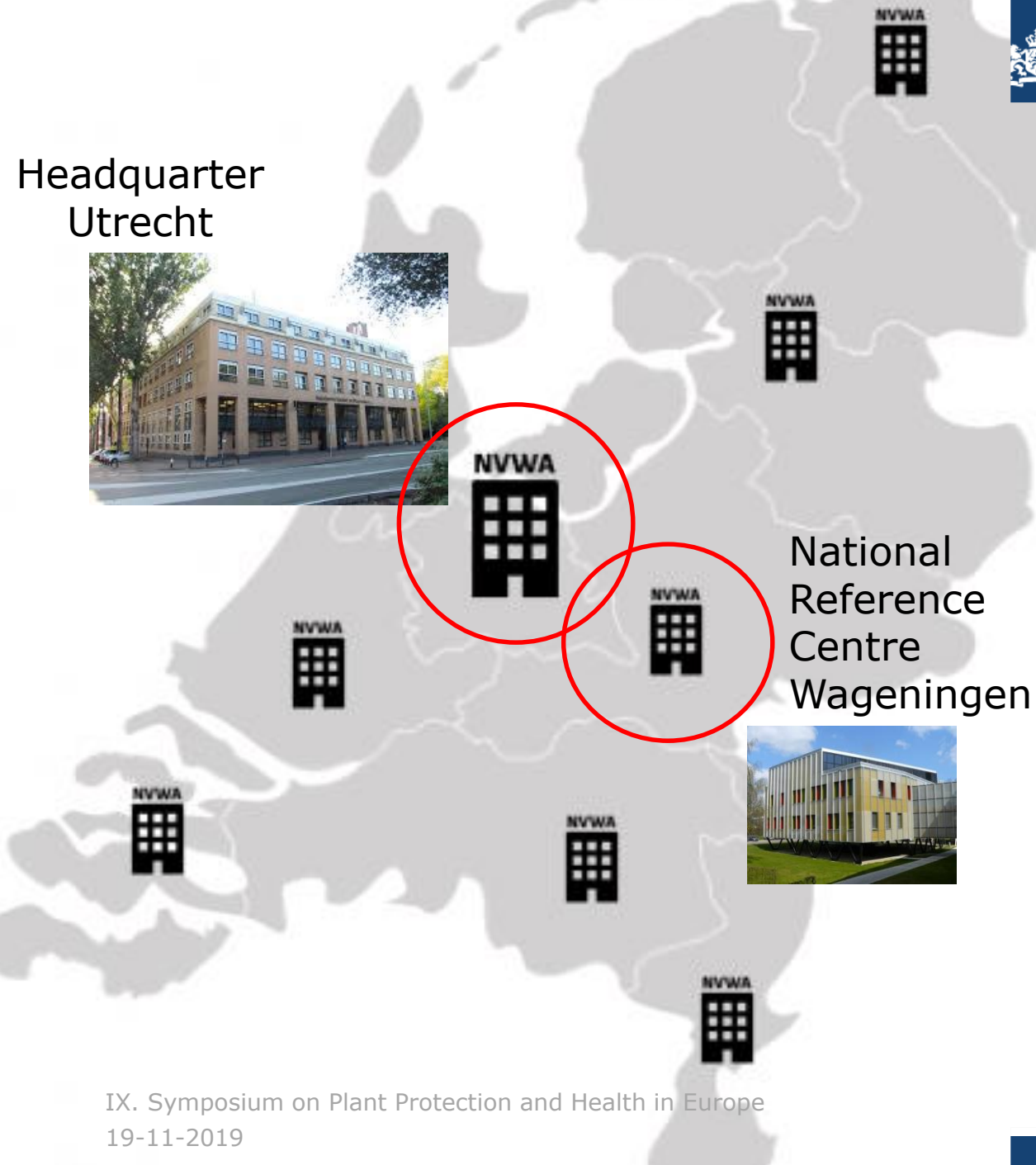


- › Delivery agency for the Ministry of Health, Welfare and Sport





Headquarter
Utrecht



2.583 employees

- Utrecht
- Groningen
- Zwolle
- Wageningen
- Zwijndrecht
- Yerseke
- Eindhoven
- Echt



Vision Netherlands Food and Consumer Product Safety Authority (NVWA)

Improving food and product safety, animal welfare and plant health through maximum compliance with (inter)national legislation and regulations, and optimum risk management.



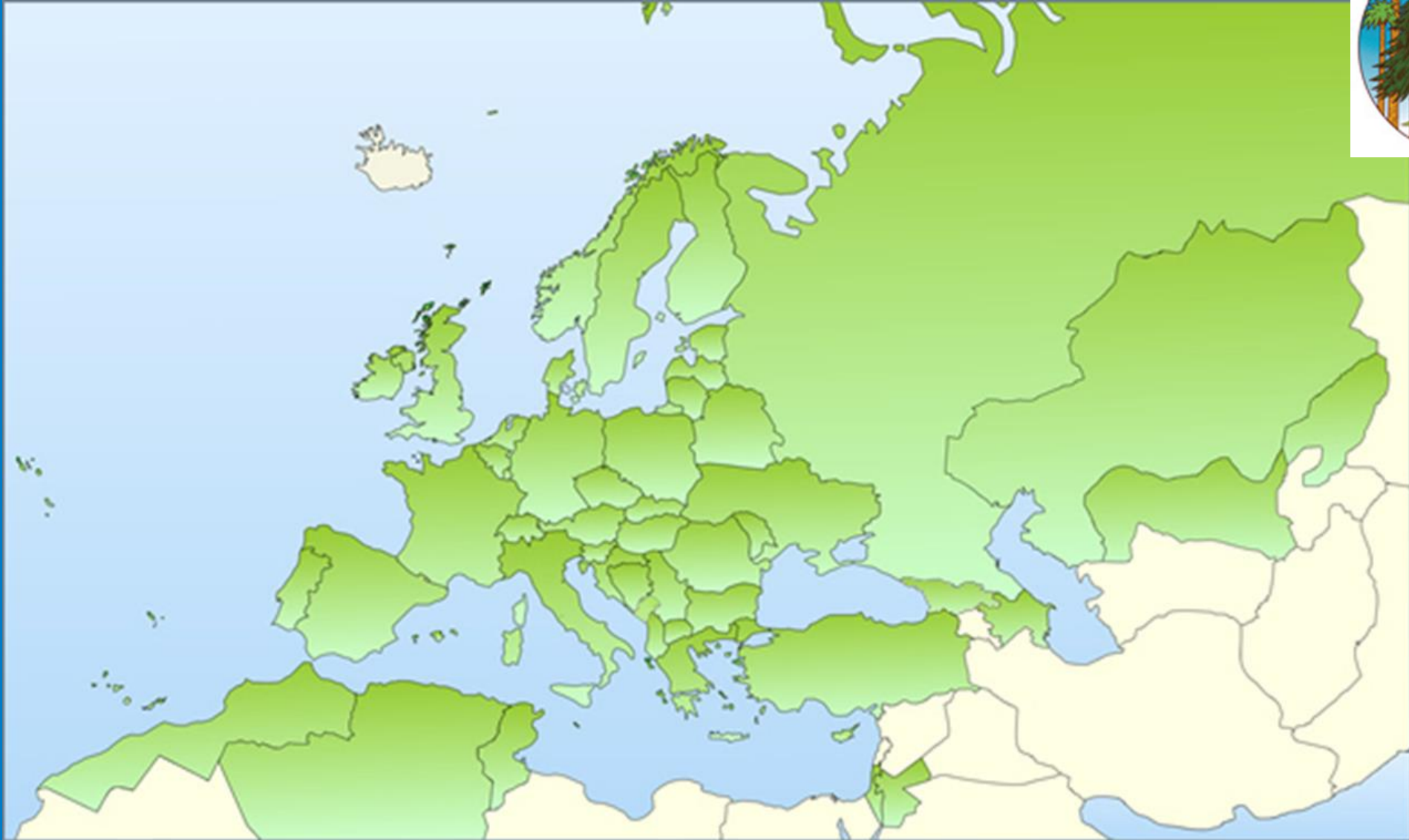


European and Mediterranean Plant Protection Organization (EPPO)



- › Intergovernmental organization responsible for cooperation in plant health within the Euro-Mediterranean region
- › Founded in 1951 by 15 European countries
- › Objectives: protect plants, by developing international strategies against the introduction and spread of pests which are a threat to agriculture, forestry and the environment, and by promoting safe and effective pest control methods.

52 member countries





EPPO activities on PPP (1)



- › Development of EPPO standards in the area of efficacy evaluation of PPP
- › Technical work is carried out by several Panels (groups of experts) under the supervision of the EPPO Working Party on PPP
- › EPPO regularly organizes Conferences and Workshops on themes related to plant protection (e.g. efficacy requirements and evaluation low risk PPP in The Netherland in 2016)



LAST UPDATE

The database was last updated in November 2019 with the new and revised Standards that were approved by EPPO Council in September 2019.

General Standards

PP 1/264(2) Principles of efficacy evaluation for mating disruption pheromones (REVISION)

Revision of PP 1/271(3) Guidance on efficacy aspects of comparative assessment (REVISION) – following the [EPPO Workshop on Comparative Assessment of Plant Protection Products](#) (Lisbon, 2018-10-24/25)

Specific Standards

PP 1/314 Evaluation of mating disruption techniques against Lepidoptera pests in grapevine, pome and stone fruits under field conditions (NEW)

PP 1/315 *Aculops lycopersici* on tomato (NEW)

PP 1/316 Leaf and plant hoppers on grapevines (NEW)

PP 1/317 *Xanthomonas arboricola* pv. *pruni* on stone fruit (NEW)

PP 1/318 *Pseudomonas syringae* pv. *syringae* and pv. *morsprunorum* on stone fruit (NEW)

PP 1/074(3) Scales on citrus (REVISION)

Extrapolation tables approved to accompany EPPO Standard PP 1/257 Efficacy and crop safety extrapolations for minor uses are available on the [EPPO website](#)



EPPO Standard PP1/96(1) 'Principles of efficacy evaluation for low-risk plant protection products'

- › Reason for development
- › Process of development -> workshop 2016
- › General principles, data requirement and extrapolation possibilities

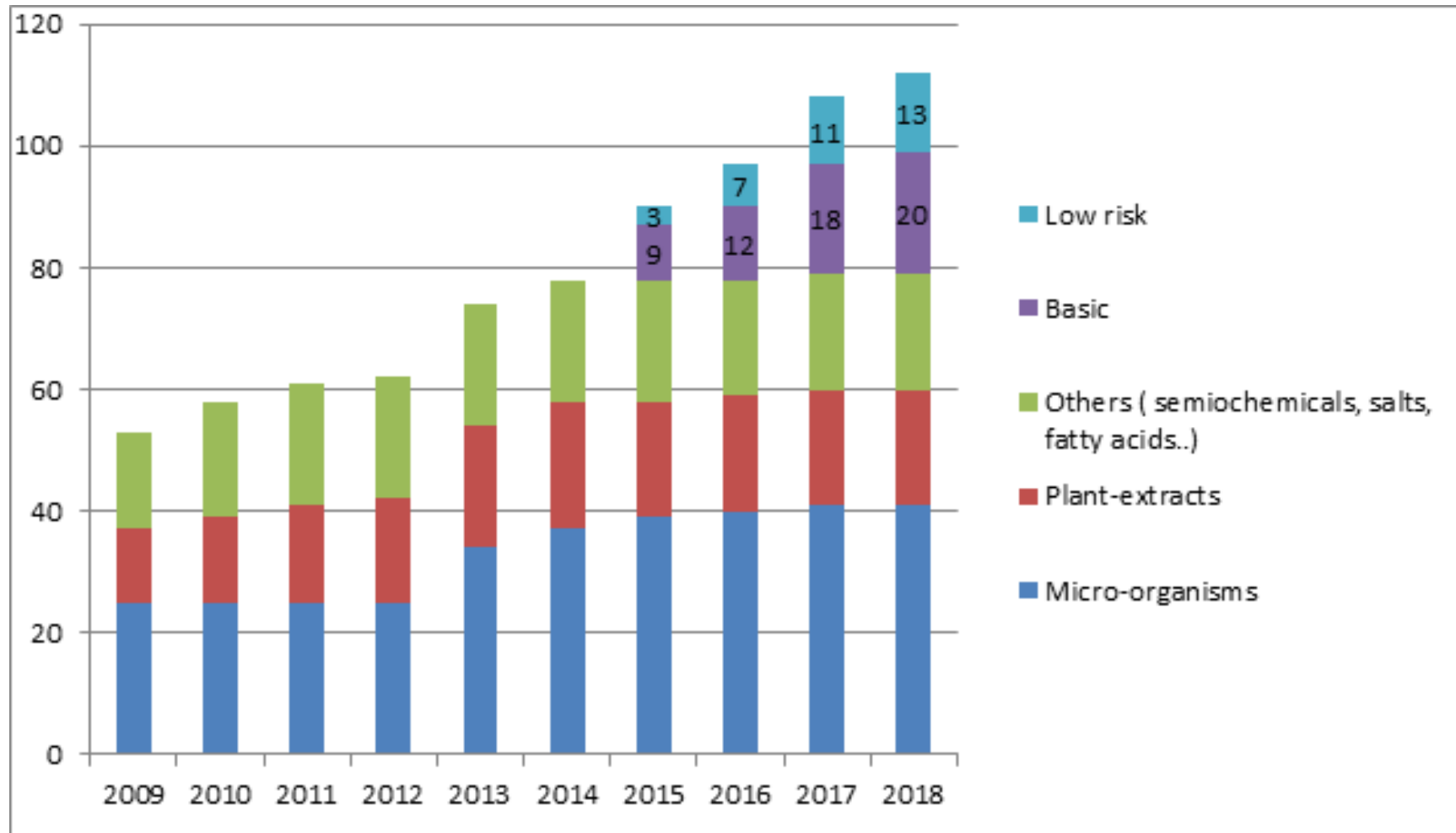


Reason for development of the standard

- › Directive 2009/128/EC aims to achieve a **sustainable use** of pesticides
- › Stimulates different products proved to have a **lower health and environmental risk** than conventional pesticides
- › More development on **low risk substances** and **products** in EU and worldwide
- › The current, 'chemistry based', requirements are not always helpful
- › Efficacy requirements were seen as a **hurdle** for registration of PPPs based on low risk active substances



Availability of Low Risk Substances



Source: EC DG Sante
Unit E.4 – Pesticides
and Biocides



ctgb



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

- > Organised April 2016 in The Netherlands
- > Jointly organized by the NVWA, the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), IBMA and EPPO
- > 113 participants from 19 EPPO countries, Canada, the EU COM, EU MUCF, manufacturers of biocontrol solutions, agrochemical companies and consultancy firms
- > Plenary lecture session and working group sessions (five groups)
- > https://www.eppo.int/MEETINGS/2016_meetings/wk_low_risk_substances



Conclusions workshop (1)

- > An assessment of efficacy of PPPs based on low risk active substances is **necessary**. However, the requirements for efficacy can be **lower** compared to conventional PPPs.
- > **Lower** and **more variable effectiveness** of PPPs based on low risk active substances compared to the effectiveness of conventional PPPs is **acceptable**. Any benefit of the product compared to the untreated control should be shown.





Conclusions workshop (2)

- > **Extrapolation** possibilities related to e.g. mode of action and the use of data from other EU or EPPO zones should be **further explored** and where relevant guidance should be developed.
- > A good description of the **mode of action** should be available and applicants should be **critical** (realistic) about their own data.
- > Net result of positive and negative effects should be a **sufficient overall benefit** to plant protection.



Objective of the EPPPO standard

- › Provide a **framework** for the minimum efficacy data requirements needed to demonstrate that a low-risk PPP is **sufficiently effective** for authorization.





Dose justification

- Information demonstrating that the proposed dose provides a beneficial effect
- Field-generated data may not be necessary
- MOA, any relevant biology, preliminary studies, relevant published papers



Effectiveness

Minimum number of direct efficacy trials in an area of similar conditions required for low-risk PPP

	Fully supportive results required
Major pest (group) on major field crop (group)	6
Major pest; protected conditions	4
Other uses	3



Decision on acceptable efficacy

- › Product should show results that are significantly superior to those recorded in the UTC
- › Moderate levels of control or more variable control than might be expected for a conventional chemical PPP
- › Provided the level of effectiveness is beneficial (stand alone or in a programme) this may be acceptable
- › The contribution of the proposed use to agricultural sustainability is considered in the evaluation of low-risk products



Extrapolation possibilities

Direct MOA: Pest related

Insect and fungal pathogens
Baculoviruses



versus

Indirect MOA: Crop related

Induction of defence system
Root colonisation





Direct MOA -> crop may be of less relevance



Key factors to be considered:

- Crop morphology
- Cropping system
- Growing condition
- Competitiveness of the crop





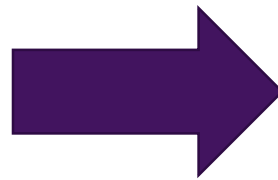
Extrapolation possibilities



Major pest species



Major crop



Other major and minor crops





Indirect MOA -> pest may be of less relevance



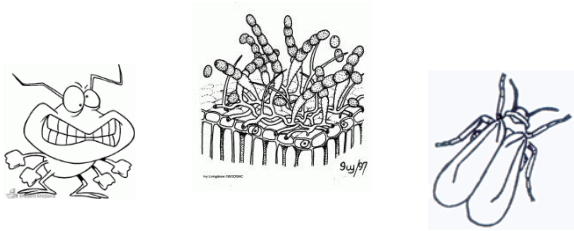
Key factors to be considered:

- Life cycle of the pest
- Taxonomic relationship
- Plant part affected
- Growth stage

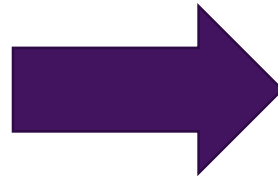




Extrapolation possibilities



**Limited number
of major pest
species**

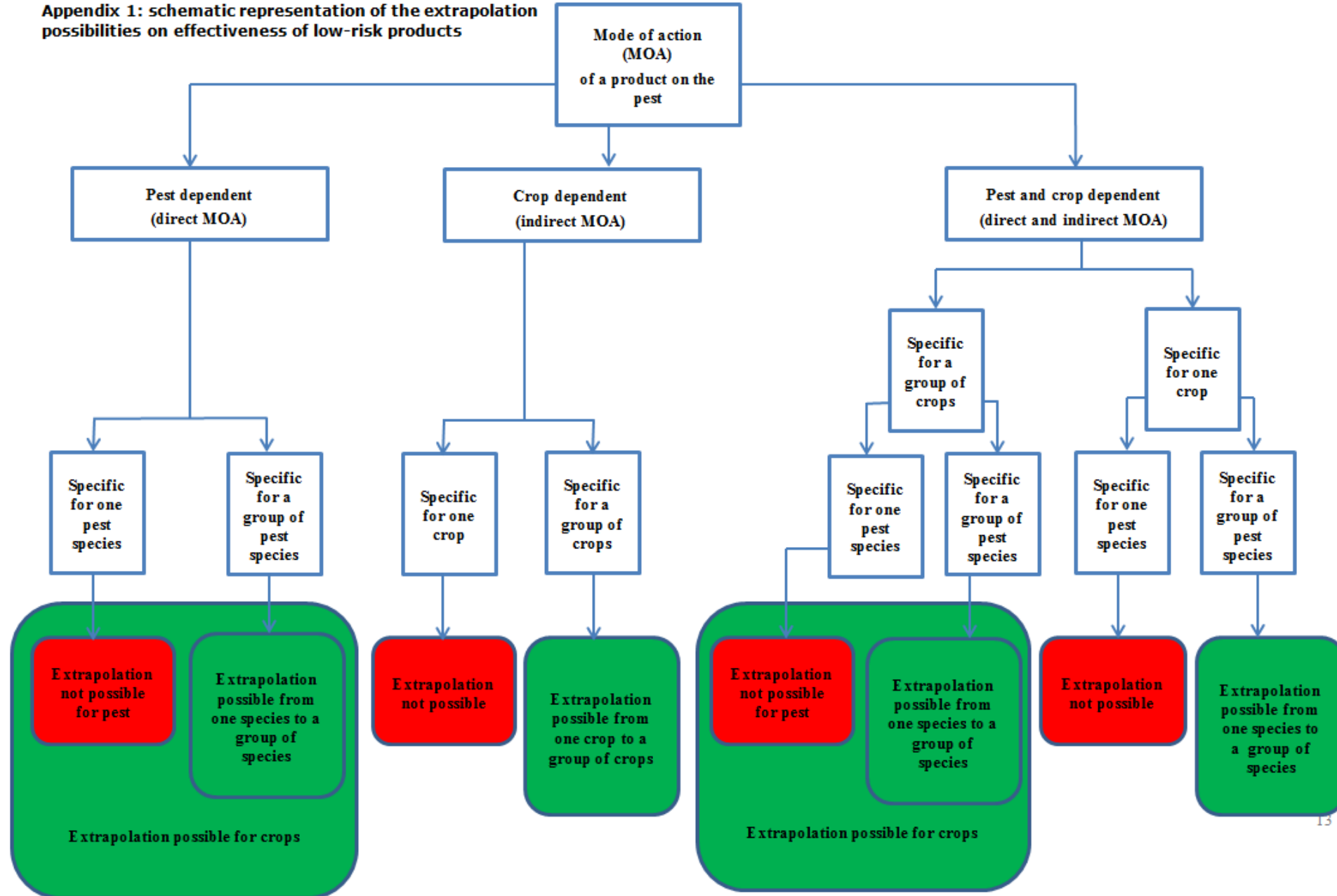


Group of pests



One major crop

Appendix 1: schematic representation of the extrapolation possibilities on effectiveness of low-risk products





From **START** to finish



- > Workshop **April 2016** in The Netherlands
- > Formation Expert Working Group on low-risk substance **September 2016**
(DK, SE, DE, UK, FR, ES, NL, IBMA, MUCF, EPPO)
- > First teleconference **November 2016**
- > Two more teleconferences in **January** and **March 2017**
- > **May 2017** Country Consultation – Working Party PPP
- > Approved **September 2017**





Further developments

- › New standard on Plant Defence Inducers



Questions?

