



Workshop Efficacy Requirements and Evaluation of Plant Protection Products based on Low-Risk Active Substances, Ede (NL), 2016-04-06/07

CONCLUSIONS and RECOMMENDATIONS

On 6th and 7th of April 2016, more than 100 representatives from 20 countries representing industry, competent authorities and consultants discussed the efficacy requirements for plant protection products based on low-risk active substances. Efficacy has been a bottleneck for placing these products on the market in Europe because the efficacy requirements are similar to those for conventional chemical plant protection products. The overall conclusions and recommendations of the workshop are listed below. The individual conclusions and recommendations of the separate working groups can be found in Appendix 1.

Overall conclusions:

1. An assessment of efficacy of plant protection products based on low-risk active substances is necessary. However, the requirements for efficacy can be lower compared to conventional plant protection products. The number of (field) trials may be reduced if data from other sources is available (literature, preliminary data, etc.). The evaluation should be simple and already existing flexibility should be used;
2. Lower and more variable effectiveness of plant protection products based on low risk active substances compared to the effectiveness of conventional plant protection products is acceptable. Any benefit of the product compared to the untreated control should be shown;
3. There is a strong need for harmonization of requirements with regard to efficacy evaluation of plant protection products based on low-risk active substances in order to accelerate the authorization of such plant protection products;
4. 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;
5. Differentiated label claims for plant protection products based on low-risk active substances are a controversial issue and need further discussion. No consensus was reached during the workshop.

Overall recommendations:

1. Guidance on efficacy requirements and evaluation of plant protection products based on low-risk active substances for Competent Authorities/NPPOs and applicants should be developed by EPPO;
2. A 'pre-pre- submission' meeting of applicants with authorities where e.g. data requirements can be discussed in an early stage of product development is necessary and should be available in all Member States. Member States should be in close contact to achieve harmonization on data requirements;
3. A good description of the mode of action should be available and applicants should be critical (realistic) about their own data.

At the end of the workshop the outcomes were presented to the EU Commission and EPPO.

APPENDIX 1: Individual conclusions and recommendations of the separate working groups

Conclusions and recommendations of groups A-D

1. Acceptable effectiveness levels and types of label claims

Conclusions:

- The required number of efficacy trials for plant protection products based on low-risk active substances can be reduced and need not necessary to be only GEP trials;
- There is a strong need for harmonization between Member States;
- Use of extrapolation possibilities related to the mode of action of the product should be optimized;
- Use of data from other (EU or EPPO) zones is acceptable;
- There was a major discussion, but no consensus reached on differentiated label claims. The label claim should be related to mode of action and description of optimal conditions for efficacy (such as temperature or relative humidity);
- There should be a difference with untreated control¹.

Recommendation:

- Develop (EPPO) guidance on the acceptable level of effectiveness of products based on low-risk active substances to improve harmonization between Member States.

2. Dose justification

Conclusion:

- To justify minimum effective dose, field trials may be not relevant/necessary depending on the mode of action. Instead dose can be addressed in preliminary trials or scientific reasoned cases.

Recommendation:

- Develop (EPPO) guidance on data requirements for minimum effective dose depending on the mode of action.

3. Data requirement: what is the minimal amount of information required to carry out a meaningful efficacy evaluation?

Conclusions:

- Trial data is necessary to be able to evaluate and demonstrate the effectiveness of products based on low-risk substances.
- GEP trials are preferred, but other trial data can be acceptable if it is scientifically sound and in line with relevant and available EPPO Standards. The applicant should give a clear justification for the use of alternative (trial) data.

Recommendations:

- The number of (field) trials may be reduced if data from other sources is available (literature, preliminary data, etc.). Suggestions on number of trials were: 3-4 trials or minimum number of trials in EPPO Standard PP 1/226 *Number of efficacy trials* (Minor uses 3 (range 2-6));
- A 'pre-pre-submission' meeting of applicants with authorities where data requirements can be discussed is necessary;
- There is a need for an EPPO example on data requirements for plant protection products based on low-risk substances.

¹ EPPO PP 1/214 *Principles of acceptable efficacy*: The primary criterion of acceptable efficacy is that the product should show results that are significantly superior to those recorded in the untreated control, i.e. that the use of the product is better than no use. The product should show a consistent, well-defined benefit to the user.

4. Extrapolation possibilities/ justification of extrapolation

Conclusions:

- Depending on the mode of action of the product, extrapolation from data on one pest in one crop to the same pest in other crops and/or from one pest species to another pest species should be possible. Bridging or justification is necessary;
- Data from worst case circumstances (efficacy envelope²) can be used for extrapolation to less critical situations;
- Good quality of data and science are key.

Recommendations:

- Create one EU zone for products based on low-risk substances ;
- Create an efficacy envelope with zonal labels.

5. Quality of dossiers/ role of applicant

Conclusions:

- A good description of the mode of action should be available;
- A good draft Registration Report (Concise summary) should be written.

Recommendations:

- A pre-pre-submission meeting should be available in all Member States;
- Be critical (be realistic) about your own data;
- Training of applicants by the competent authority.

6. Usefulness of Value assessment

Conclusions:

- New section 3 of the dRR already gives room for additional (value) information, including benefits other than efficacy (e.g. under paragraph 3.5.3.).
- Guidance for evaluators on how to carry out value assessment is needed.

Recommendations:

- Harmonized requirements on value assessment need to be established.
- There is a separate Registration Report format for micro-organisms available which is still section 7. This format should be updated in accordance with the format for conventional plant protection products.

Conclusions and recommendations of group E (policy group)

Is assessment of efficacy for plant protection products based on low-risk substances needed?

Conclusion:

- Plant protection products based on low-risk substances can have lower requirements for efficacy compared to conventional plant protection products.

Recommendation:

- Clear guidance on (data) requirements and what information may be included in the efficacy dossiers is needed.

What should be demonstrated by the applicant to show efficacy for low-risk products? In the regulation it is indicated that a low-risk product should be sufficiently effective (Art 47, 1d). What is seen by policy makers as 'sufficiently effective'?

² Similar concept as the risk envelope approach, but needs further exploration.

Conclusions:

- The data package should show any benefit of the product;
- Sufficiently effective: when any benefit compared to the untreated control is demonstrated.

Is the differentiated approach of Chemical Regulation Directorate (different levels of control indicated on the label) helpful, or wanted? What are the advantages and disadvantages of such a differentiated label.

Conclusions:

- The main objective of a label claim is to manage expectations for the growers;
- Some member states already use this (DE, DK, LT, AT), it should be adopted across the EU;
- No consensus reached on type of label claim; further discussion needed.

Recommendation:

- As label claims for plant protection products based on low-risk substances are a controversial issue, further discussion is needed.

Could a Value Assessment as applied in Canada be a tool to execute a more appropriate efficacy assessment of products based on low-risk substances?

Conclusions:

- Value Assessment as applied by some Member States, needs to be harmonized and applied at zonal level.

Recommendations:

- Keep the efficacy evaluation simple and make use of existing flexibility;
- Develop a new EPPO Standard on principles on efficacy requirements and evaluation of plant protection products based on low-risk active substances, based on existing EPPO standards;
- Detail which other types of information can be used to support the claim (e.g. product performance, benefits, scientifically sound efficacy trials, laboratory trials, historic use, growers' needs).

A zonal evaluation of a plant protection product based on a low-risk substance should be finalised in 120 days. How can the efficacy evaluation contribute to shorten the assessment time?

Conclusions:

- Improved dossiers for efficacy;
- Special expertise to evaluate plant protection products based on low-risk active substances products;
- Zonal co-operation/work-sharing.

Recommendations:

- Countries should install 'green teams'³ if they have the capacity;
- Early pre-submission meetings help to develop good quality dossiers;
- Limit efficacy requirements (prove 'any' benefit).

Which tools are available to accelerate the introduction of plant protection products based on low-risk substances?

Conclusion:

- One EU-zone for plant protection products based on low-risk substances.

³ A team of specialists on evaluation of plant protection products based on low-risk substances.

Other conclusions, not specific for plant protection products based on low-risk active substances:

Minor crops and minor uses

- Revise the definition of minor use -> create a harmonized list of minor uses;
- One single assessment of 'minor use' throughout EU;
- Harmonized crop grouping system/ extrapolation from 'major' to 'minor' and 'minor' to 'minor'.