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European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes PP 1/296 (1)

Evaluation biologique des produits phytosanitaires
Efficacy evaluation of plant protection products

PP 1/296 (1) Principles of efficacy evaluation for low-risk plant protection products

Specific scope

This Standard describes the principles for determining the requirements for an efficacy evaluation of low-risk plant protection products in a registration procedure. Low-risk plant protection products are products with low risk to human and animal health and the environment.

Specific approval and amendment

First approved in 2017-09.

1. Introduction

This Standard describes the principles for determining the requirements for an efficacy evaluation of low-risk plant protection products in a registration procedure. It is based on addressing the data requirements as specified by EC Regulation 1107/2009 (EC, 2009) and refers extensively to relevant EPPO Standards.

Low-risk active substances are active substances which have been approved and listed as having low risk to human and animal health and the environment. Criteria for low-risk active substances are defined in EC Regulation 1107/2009 (EC, 2009) and Commission Regulation (EU) 2017/1432 of 7 August 2017 amending Regulation (EC) 1107/2009. Non-EU EPPO countries may have other definitions of low-risk active substances. It is anticipated that active substances such as micro-organisms[1], botanicals (plant extracts), semiochemicals and baculoviruses[2] may be of low risk. It should also be noted that certain active chemical substances may be categorized as low-risk.

Important reasons to assess efficacy are to ensure that growers use only sufficiently effective products to secure yield quantity and/or quality benefits, and that they use only minimum amounts of plant protection products to reduce environmental and human risks. It is also important to develop recommendations on the label that optimize the effectiveness of a product.

Low-risk plant protection products contain only active substances that are of low risk and do not require specific mitigation measures following a risk assessment. Applicants are advised to confirm the low-risk status of a plant protection product with the relevant authority before submission.

There is a strong need for harmonization of requirements for the efficacy evaluation of low-risk plant protection products to facilitate their placement on the market. The efficacy evaluation may be flexible regarding the variability or level of effectiveness and less supporting efficacy data may be needed.

For low-risk plant protection products, a more specialized approach may be used compared to other plant protection products because they often have different properties and modes of action.

Low-risk products may be highly specific on the pests that they affect. Some require specific environmental conditions to reach optimal effectiveness. Many such products may be appropriately used as part of an integrated pest management system as promoted by the Sustainable Use Directive (Directive 2009/128/EC).

It should be noted that although there are various areas to be addressed, for a number of aspects (e.g. succeeding crops) it may be possible to use reasoned cases in lieu of actual data (e.g. based on the mode of action, natural occurrence etc.). In doing so, reference may be made to laboratory studies and any relevant published data[3]. Both of these

[1]A micro-organism may be considered to be of low risk unless at strain level it has demonstrated multiple resistance to anti-microbials used in human or veterinary medicine.

[2]A baculovirus should be considered of low risk unless at strain level it has demonstrated adverse effects on non-target insects.

[3]Any relevant technical and/or scientific reports.

are important valid sources of information for describing and explaining the mode of action and properties of the product as well as its efficacy.

The objective of this document is to provide a framework for the minimum efficacy data requirements needed to demonstrate that a low-risk plant protection product is sufficiently effective (and crop safe) for authorization. EPPO Standard 1/214 *Principles of acceptable efficacy* states that, because of the risk attached to the use of plant protection products, it is necessary to decide if the benefits from the use of the plant protection product outweigh any disadvantages. The net result of the positive and negative effects should be a sufficient overall benefit in order to justify the use of the plant protection product. The data should demonstrate a benefit in use, and this may relate directly to pest control or aspects of yield quality and/or quantity.

2. Description of the different types of low-risk plant protection products

Low-risk active substances are defined in EC Regulation 1107/2009 (and amended in Commission Regulation 2017/1432 of 7 August 2017) and low-risk plant protection products should meet the criteria in Article 47.

The diversity in crop protection claims and modes of action of low-risk products is high. Some principles and concepts can be applied to all products, but other aspects of the efficacy evaluation and the scope of extrapolations depend strongly on the mode of action. The following categories of low-risk plant protection products are used throughout this document:

1. Low-risk (bio)chemicals, substances derived from animals, botanicals, minerals, extracts from micro-organisms or of synthetic origin, with a direct mode of action;
2. Low-risk (bio)chemicals, substances derived from animals/botanicals, minerals, extracts from micro-organisms, with an indirect mode of action;
3. Low-risk micro-organisms with a direct mode of action (e.g. insect and fungal pathogens, baculoviruses);
4. Low-risk micro-organisms with an indirect mode of action (e.g. acting through population regulation processes such as competition for space or resources, host plant defence induction, endophytes);
5. Semiochemicals including pheromones[4,5].

As some active substances may fall into more than one category, it is important that the applicant clearly describes the mode of action of the active substance. Where multiple modes of action are claimed the relative importance of the different modes of action should be described, if possible. This should also be taken in account when designing and describing trial methodology.

[4]For mating disruption pheromones a specific EPPO Standard is available (PP 1/264 *Mating disruption pheromones*).

[5]See also EU Guidance document SANTE/12815/2014 rev. 5.2 (May 2016) *Guidance document on semiochemicals active substances and plant protection products.*

3. General principles of efficacy assessment of low-risk plant protection products

EPPO Standard PP 1/214 *Principles of acceptable efficacy* considers that efficacy can be a balance between the following points:

- The positive effects of treatment in performing the desired plant protection activity to fulfil the claims made on the proposed label, in order to achieve improvement in the quantity and/or quality of the crop;
- Any negative effects, such as reduction of quality or quantity of yield, phytotoxicity, taint, transformation processes, damage to beneficial organisms, damage to succeeding or adjacent crops, development of resistance;
- Other aspects of efficacy which, depending on the product, can be either positive or negative; these include effects on non-target pests, the length of time for which the plant protection product continues to be active, its ease of use, and compatibility with cultural practices and other crop protection measures.

Efficacy data are mainly obtained from trials set up according to the principles of good experimental practice (GEP) and performed by official or officially recognized organizations (see EPPO Standard PP 1/181 *Conduct and reporting of efficacy evaluation trials, including good experimental practice*).

For low-risk plant protection products GEP should be followed. However, non-GEP trial data may be acceptable if it is scientifically sound and in line with other applicable EPPO Standards. When deviating from GEP and/or EPPO Standards, the applicant should give a clear justification for the use of alternative (trial) data. Valid data from other sources, e.g. published papers[3] and laboratory studies, may be used to supplement this data.

To support the registration of a plant protection product the following efficacy parameters should be considered:

- Effectiveness (direct efficacy) against pest/weed/disease to support the any claim of effectiveness including the label claim:
  - a justification of the recommended dose(s)
- Resistance risk
- Absence of adverse effects on treated plants or plant products:
  - phytotoxicity (evidence of safety to the treated crops)
  - yield and quality of yield (including evaluation of possible occurrence of taint and effects on transformation processes)
  - plants or plant products used for propagation
- Observations on other undesirable or unintended side-effects:
  - impact on succeeding crops and adjacent crops
  - effects on beneficial (e.g. arthropods, micro-organisms) and other non-target organisms
- Evidence of biological compatibility (lack of antagonism) if tank mix is recommended

- Contribution to sustainable agriculture including compatibility and function within an IPM programme (such as preventing or delaying the development of resistance against existing plant protection products).

The net result of the positive and negative effects should be a sufficient overall benefit to plant protection in order to justify the use of the product. The level of benefit from the use of a product should be appropriate to the agronomic setting in which the product will be used. Moderate effectiveness may be acceptable, e.g. when the pest pressure is low, when a product will be used as a component of an IPM programme, in some specific situations such as organic farming or where the product will make a particular contribution to managing other issues such as resistance.

4. Demonstration of effectiveness (and crop safety)

To demonstrate the effectiveness of low-risk plant protection products, less data is generally required than for conventional plant protection products. In general, the evaluation of efficacy is carried out by means of trials under field or protected conditions; however, other (trial) data or information may be acceptable (see Section 3). The applicant should provide a comprehensive and detailed description of the mode(s) of action of the active substance(s) in the product (e.g. mechanism, target species and stage). This may be particularly important where it relates to the specificity of activity or the effect of environmental factors on the performance of the product, or where there is a claim of a low resistance risk.

4.1. Use of preliminary data (non-GEP)

Effectiveness should normally be evaluated under conditions that replicate the practical use of the product; this means, in general, evaluation of trials under field or glasshouse conditions. However, additional data from carefully designed small-scale laboratory and growth chamber studies may form a vital component of the overall information package provided to support authorization. Laboratory studies provide data on the mode of action, the susceptibility of target pests or hosts, including different life stages (where appropriate), dose–response behaviour and the effect of environmental, agronomic and other factors on the product. Appropriately conducted studies provide key supporting information which support the subsequent number of larger-scale (including GEP) field studies required, and assist in the interpretation of trial data.

4.2 Effectiveness trials

4.2.1. Effect of environmental and agronomic factors on product performance

A wide range of factors may affect the performance of low-risk products. Factors such as temperature, humidity, soil and leaf moisture, plant growth stage, edaphic conditions, etc. may affect the behaviour of low-risk products in a range of different ways. Where appropriate, the conditions necessary for the low-risk products to perform optimally (e.g. in the case of a micro-organism: to survive, reproduce, colonize, compete with or infect target organisms) should be determined, and where possible advice given to the user, for example on a product label. This information may be derived from laboratory studies, field trials or any valid relevant published paper.[3] For some low-risk (bio)chemicals and botanicals environmental and agronomic factors may be of less importance.

4.2.2. Dose justification

In the interests of reducing the exposure of humans, animals and the environment to plant protection products to humans studies are usually necessary to demonstrate that the recommended dose is the minimum necessary to achieve the desired effect (see EPPO Standard PP 1/225 *Minimum effective dose*). For low-risk plant protection products information demonstrating that the proposed dose provides a beneficial effect may suffice. Whilst an appropriate explanation for the proposed dose is required, the provision of field-generated data may not be necessary. Such explanations should refer to the mode of action and any relevant biology, and may also include preliminary studies (including relevant published papers3) indicating the basis for the proposed dose (and concentration in the formulation when relevant). Studies indicating population levels over time can also provide useful information.

For those micro-organisms that are capable of reproducing (and which may therefore multiply), the concept of a minimum effective dose may be more difficult to determine practically and a range of doses may be appropriate.

For semiochemicals the effective dose can be reduced with continual usage of the plant protection product for multiple seasons – therefore establishing a minimum effective dose is inappropriate. In most cases there is no clear dose–response relationship. However, a rationale for the chosen dose should still be provided, and this may include preliminary laboratory (or glasshouse) studies examining emission rates (e.g. pheromone release doses), effects on biology etc. (EU Guidance document SANTE/12815/2014 rev. 5.2, May 2016, *Guidance document on semiochemicals active substances and plant protection products*).

4.2.3. Assessment of effectiveness

Data is required to demonstrate that use of the low-risk product according to the instructions for use can give a benefit to the user. This data is generated in field or glasshouse trials on the treated crops and target pests as appropriate and performed according to appropriate EPPO Standards, where applicable, by official or officially recognized organizations. These trials allow the efficacy of the product to be assessed under conditions as near as possible to the conditions of practical use of the product. The minimum number of direct efficacy trials in an area of similar conditions required for

Table 1. Minimum number of direct efficacy trials in an area of similar conditions required for low-risk plant protection products

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

*See Section 9 'Extrapolation'.

low-risk plant protection products is given in Table 1. It may be possible to use data generated from field trials on crops or pests other than those for which registration is proposed, or from small-scale trials, to reduce the number of trials conducted on a specific crop or against a specific pest (see Section 9 'Extrapolation').

Two-years' data should normally be provided, but where justified, with additional information to ensure robust field performance including distribution of trials across relevant EPPO zones, trial data from 1 year may be considered sufficient. Data should provide a clear picture of what a product can achieve under the described conditions.

Applicants are advised to liaise with relevant registration authorities as early as possible in the registration process to discuss specific data requirements. The aim is to generate sufficient data to both demonstrate acceptable efficacy and to provide the user with instructions for use that will enable them to achieve the benefits described on the label in most cases. Where the data indicates that there are significant inconsistencies in the performance of a product, the reasons for these inconsistencies should be explained. The instructions for use should enable the user to identify the conditions under which the product will provide optimal performance, and any factors that may have an impact on effectiveness.

5. Efficacy data

5.1. Efficacy trials

Trials should follow the guidance set out in both the general and specific EPPO Standards (PP 1 series). However, it is recognized that deviations from the guidance may be required in some cases to account for the specific properties of low-risk plant protection products. Where this is the case, applicants should provide detailed descriptions and explanations of the methodologies used. The explanation may require the methodology to be related to the mode of action and potential factors affecting its effectiveness under field conditions. All trials should include an untreated control to indicate both initial pest pressure and subsequent development during the duration of the trial. The primary criterion of acceptable efficacy is that the product should show results that are significantly superior to those recorded in the untreated control.

Normally a reference product should also be included. If not available, justification should be provided. Because of the variability of the conditions under which plant protection products are used, the inclusion of a reference allows a meaningful evaluation of efficacy under the conditions of the trial and permits comparison between different trials in a series.

Wherever possible the reference product should be an existing authorized low-risk product, preferably one with a comparable mode of action. For a low-risk product to be used as a reference the conditions of use that affect performance (temperature, humidity, etc.) need to be similar to the test product and compatible with the crop production requirements.

Where the use of an appropriate low-risk reference product is not possible, an alternative conventional product may be included. Please note that the low-risk product does not need to show the same level of efficacy as the conventional reference product, but the latter is used to be able to assess the quality of the trial. If no such reference products exist, a non-chemical control option, such as a physical or cultural method, deemed to be satisfactory in practice may be beneficial for interpretation of the data.

Trials in which no reference product or non-chemical control system is used may be acceptable, but these should only be considered in exceptional cases. Interpretation of performance, particularly where it is variable and/or moderate, is more difficult without a suitable reference for comparison, and so the major part of any submitted data package should be based on trials where such comparisons are available.

5.2. Development of resistance

EPPO Standard PP 1/213 *Resistance risk analysis* indicates which information should be provided to indicate whether resistance is likely to occur during practical use of the low-risk product. Resistance may be of less relevance for substances with multiple modes of action or pheromones.

Many existing resistance management approaches (e.g. alternation) are appropriate or can be adapted for strategies for use with low-risk plant protection products.

5.3. Adverse effects on treated crops

5.3.1. Phytotoxicity

Crop safety trials are normally required for low-risk products with herbicidal activity. However, for plant growth regulators and specific herbicides, phytotoxicity should also be addressed by appropriate observations made in the effectiveness trials. Only if adverse effects are observed may further investigation of effects at 2N doses and/or further crop safety trials (in the absence of the pest) be required. Where effects *are* observed, the symptoms should be accurately described. For other products (e.g. with fungicidal or insecticidal activity) phytotoxicity can usually be addressed

by appropriate observations at each assessment made in the effectiveness trials.

EPPO Standard PP 1/135 *Phytotoxicity assessment* gives detailed information on how assessments should be performed. Further guidance on the circumstances where further testing may be required is given in EPPO Standard PP 1/226 *Numbers of efficacy trials*. Assessments made in phytotoxicity trials can establish crop safety and provide useful support for reasoned cases addressing succeeding or adjacent crops.

5.3.2. Yield (quantity and quality)

EPPO Standard PP 1/226 *Number of efficacy trials* and the specific EPPO Standards provide guidance on the circumstances where yield assessments (total yield or components of yield) are required. Effects on the quality of the treated produce should be assessed, although specific trials are not usually required, with assessments being made in the effectiveness studies. The types of relevant observations are described in EPPO Standard PP 1/135 and in specific PP 1 EPPO Standards. Depending on the nature of the proposed product and its formulation, observations on the visual appearance of treated produce may be appropriate.

For certain crops there may be a need to address taint and effects on transformation processes. EPPO Standards PP 1/242 *Taint tests* and PP 1/243 *Effects of plant protection products on transformation processes* give further guidance on making relevant cases, and where data may be required.

5.3.3. Effects on plant parts for propagation

EPPO Standard PP 1/135 *Phytotoxicity assessment* includes a decision-making table which identifies those circumstances where data may be required. For low-risk plant protection products a reasoned case may suffice in lieu of data, which should include reference to any phytotoxicity assessments.

5.4. Observations on other undesirable or unintended side-effects

5.4.1. Damage to succeeding or adjacent crops

EPPO Standard PP 1/207 *Effects on succeeding crops* provides guidance on whether and how information should be obtained on possible long-term effects resulting from treatment with a plant protection product. Such information will generally only be required if the micro-organism or active substance survives in the soil in the long term, and there is evidence to suggest that there may be an adverse effect on seed germination or plant growth.

EPPO Standard PP 1/256 *Effects on adjacent crops* provides guidance on whether (and how much) information should be obtained on effects on field crops grown adjacent to a field crop treated with that product. Small-scale screening tests against a range of appropriate plant species may be sufficient to demonstrate the safety of formulated products to adjacent crops. Alternatively, reference may be made to the phytotoxicity assessments made in the effectiveness trials.

5.4.2. Effects on beneficial and other non-target organisms

Observations of any adverse effects on natural enemies in the treated crop should be made. Reference may be made to data or information provided in the ecotoxicology risk assessment.

5.5. Interaction with other crop protection measures

Microbial products and other low-risk products may be influenced by other plant protection products, especially fungicides. Given that other plant protection products, and especially fungicides, may be used prior to or subsequently on the crop, and that the application equipment may have previously been used to apply fungicidal products, the impact of previous or subsequent use on the effectiveness of the proposed product should be considered, as should any requirements for using specific application equipment if contaminants in a sprayer are likely to have an impact on performance. Appropriate information to address the risk of other plant protection products, and particularly fungicide use, should be presented.

6. Contribution to IPM and sustainable agriculture

The contribution of the proposed use to agricultural sustainability is considered in the evaluation of low-risk products. Any agronomic benefits that are expected to result from the registration of the proposed use may be included in the dossier. A description of the product's fit within a cropping system and its benefits in relation to alternatives may be provided, for example compatibility within an IPM system.

7. Decision on acceptable efficacy

In general, the principles laid out in EPPO Standard PP 1/214 *Principles of acceptable efficacy* should be followed for low-risk plant protection products. The principles refer to various factors influencing the determination of what is 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. It is important that users are provided with valid information on the likely performance of the product and given guidance, for example on the label, on how best to use the product so that it will perform as effectively and consistently as possible.

Low-risk plant protection products may in some cases deliver moderate levels of control or more variable control than might be expected for a conventional chemical plant protection product. However, provided the level of

effectiveness is beneficial (stand alone or in a programme) this may be acceptable.

Low-risk products may have further advantages in the following areas:

- Use over a wider range of growth stages of the crop (e.g. short or no pre-harvest intervals and reduced residues);
- Greater compatibility with cultural practices or other plant protection measures (e.g. IPM, organic farming);
- Lower probability of resistance or important as part of a resistance management strategy;
- Fewer undesirable effects (e.g. on beneficial organisms);
- No need for specific mitigation measures.

8. Label recommendations (where relevant for member countries)

Low-risk plant protection products may provide a sufficient level of control to reduce pest damage. In some cases, these products may deliver more moderate levels of control or more variable performance than a conventional chemical plant protection product. The effectiveness of some low-risk products, particularly those based on living micro-organisms, can be affected by environmental factors and/or by other plant protection products. To ensure that low-risk plant protection products are used optimally, it is critical to include recommendations for the user, for example on the label. These recommendations may address the following aspects:

- Product preparation and application: certain precautions may be required for pouring, mixing, applying (e.g. do not leave solution standing under sunlight, or apply only in the early morning or late evening).
- Use of the product in an IPM programme: recommendations on how to use the product in relation to: (i) the level of pest pressure and/or the pest cycle, (ii) partnership with other plant protection products [e.g. alternation, or block programme (sequence), or dose reduction of the partner plant protection product], and/or IPM methods, when relevant.
- Compatibility with other plant protection products with regard to mixing, when relevant, or with other plant protection products used in programme.

Examples of label claims are: 'Used as stand-alone product may provide sufficient control under low to moderate pest pressure, but may require additional intervention under high pest pressure as indicated by crop monitoring' or 'Control may be enhanced by use of additional control measures in an IPM programme'.

Alternatively, the label claim could be linked to the mode of action of the low-risk product, where the product does not directly act to control or suppress the target pest.

Any supplementary label statement(s) should be recommended by the applicant in consultation with the national competent authority early in the communication, for instance at pre-submission meeting(s).

9. Extrapolation possibilities for effectiveness

Extrapolation is based on the principle that certain groups of pests or groups of crops are considered to be more or less equivalent in relation to the efficacy of the low-risk plant protection products. EPPO Standard PP 1/257 *Efficacy and crop safety extrapolations for minor uses* describes the principles of extrapolation regarding the efficacy and crop safety of plant protection products intended for minor uses. These principles may also be used for uses of low-risk plant protection products. Extrapolation tables for minor uses have been developed and are available on the EPPO website (https://www.eppo.int/PPPRODUCTS/minor_uses/minor_uses.htm).

These extrapolation tables may also be used for major and/or minor uses of low-risk products.

Depending on the mode of action of the product there may be scope to extrapolate between different crops and pests, resulting in a smaller efficacy data set. Trials across a limited range of proposed major crops and pests may be acceptable with appropriate descriptions and justifications. Data from worst-case circumstances (e.g. crop(s) with a dense canopy or leaf structure in case of a contact mode of action) can be used for extrapolation to less critical situations. Good-quality data and science are essential. A clear justification (e.g. of the importance of the tested pest, crop comparability, application time etc.) is always necessary.

The applicant should always provide appropriate justification and information to support the proposed extrapolation. For example, comparability of target biology may be a relevant factor, either in extrapolating to other target species or for the same target onto another crop. For crops, factors such as comparable growth habit, structure etc. should be considered.

Extrapolations are possible within the same agro-climatic zone. Between agro-climatic zones, extrapolation may also be appropriate if the conditions are deemed to be comparable. Such conditions include not only climate but other factors that may have an impact on effectiveness, such as edaphic and agronomic factors (e.g. application techniques) and target biology.

For crops grown in protected conditions there may be greater scope to extrapolate because the environmental conditions are controlled and less variable. However, it may still be important to consider the other factors above (e.g. the growing system).

The effects of environmental conditions on pest/crop interrelationships should also be taken into account. The effect of environmental conditions on the active ingredient itself may be important (e.g. in the case of a microbiological product). Extrapolations should be well explained in relation to biology. Extrapolations may only be accepted when a plant protection product is used at the same or a similar dose and applied under similar conditions (e.g. timings, growth stages, application methods, soil conditions).

Applicants need to provide robust scientifically justified argumentation to support extrapolations outside of EPPO PP 1/257, building on the key factors including mode of action and the proposed new extrapolations.

9.1. Direct mode of action on the pest

If a product has a direct mode of action which is pest dependent the crop may be of less relevance. Extrapolation from data on a major pest in a major crop to the same pest in other major and minor crops may be possible depending on the quality of the existing data.

Key factors to consider, in order to achieve extrapolation between crops for products with a direct mode of action (other than herbicides and plant growth regulators), are, for example, crop morphology (e.g. waxy surface or dense canopy or leaf structure), cropping system, feeding area on the plant (e.g. root or leaf), growing conditions (e.g. field or protected), application technique or timing and growing substrate. For herbicides and plant growth regulators crop morphology, competitiveness of the crop, growth habit, growth pattern and weed species present are key factors. Effectiveness trials can be conducted on a limited number of claimed major crops and extrapolation to other claimed major and minor crops may be possible.

9.2. Indirect mode of action

For low-risk products with an indirect mode of action the claimed pest may be less relevant. For example a product producing induced resistance may enhance the plant's resistance to additional diseases or insects. In this case efficacy trials can be conducted on a limited number of claimed pests and extrapolation to other claimed and relevant pests may be possible. Key factors to consider, in order to achieve extrapolation between crops for products with an indirect mode of action (other than herbicides and plant growth regulators), are: the life cycle of the pest (e.g. targeting the same stage, biology), taxonomic relationship, plant part affected (e.g. root, leaf), type of damage, application technique or timing, behaviour (e.g. secretive habit) and feeding method (e.g. sucking, biting). For herbicides and plant growth regulators taxonomic relationship, biology, life cycle, behaviour, weed species present and growth stage are key factors.

9.3. Semiochemicals including pheromones

Semiochemicals are often pest specific and act by modifying behaviour. The plant species is not relevant in relation to the product's performance. For that reason extrapolation is possible to other crops in which the same pest appears. In the case semiochemicals that have multiple targets, extrapolation to a group of related species is possible. EPPO Standard 1/264 has specific advice on mating disruption pheromones, and some of the general advice may also be relevant for other semiochemicals.

The flow chart in Appendix 1 gives a schematic representation of the extrapolation possibilities on effectiveness. Due to the large variation in modes of action for low-risk products, not all extrapolation possibilities may be covered by the flow chart. Alternative extrapolations may be proposed by the applicant. A clear justification is always necessary and may be supported by scientific literature and/or data.

Reference

EC (2009) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/414/EEC. *Official Journal of the European Union L* **309**, 1–50.

- COMMISSION REGULATION (EU) 2017/1432 of August 2017 amending Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances
- Annex 1 amending EC Regulation 1107/2009

Appendix 1 – Schematic representation of the extrapolation possibilities for effectiveness of low-risk products