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PP 1/296 (2) Principles of efficacy evaluation for plant protection products based on low-risk substances

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

Specific approval and amendment: First approved in 2017-09.

First revision approved in 2025-09 mainly to refer to products based on low-risk substances rather than low-risk products.

1 | INTRODUCTION

This Standard describes the principles for determining the requirements for an efficacy evaluation of plant protection products based on low-risk substances (also referred to as low risk or lower risk substances) in a registration procedure.

It is anticipated that active substances such as micro-organisms[1] (including certain viruses[2]), botanicals (plant extracts) and semiochemicals may be included in this low-risk category. It should also be noted that certain chemical active substances of synthetic origin may be categorized as low-risk. For the assessment of products based on micro-organisms and plant defence inducers, EPPO Standards PP 1/276 *Principles of efficacy evaluation for microbial plant protection products*, and PP 1/319 *General principles for efficacy evaluation of plant protection products with a mode of action as plant defence inducers* should be of use. For the assessments of mating disruption pheromones, PP 1/264 *Principles of efficacy evaluation for mating disruption pheromones* should be of use.

In the EU, 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) as well as in Commission Regulations (EU) 2017/1432 of 7 August 2017 and (EU) 2022/1438 of 31 August 2022, amending Regulation (EC) 1107/2009. Non-EU EPPO countries may have other definitions of low-risk active substances.

The efficacy assessment of products based on low-risk active substance is necessary to ensure that growers use only sufficiently effective products to secure yield quantity and/or quality benefits, and that only minimum amounts of plant protection products (PPP) are used to limit environmental and human risks. It is also important that appropriate label recommendations are developed to optimize product effectiveness.

This Standard aims to harmonize the requirements for the efficacy evaluation of PPP based on low-risk substances to facilitate their placement on the market. The efficacy evaluation of low-risk substances may be flexible regarding the variability or level of effectiveness and less supporting efficacy data may be acceptable e.g. when literature and information on mode of action, is available.

For plant protection products based on low-risk substances, a more specialized approach may be used compared to other PPPs because they often have different properties and modes of action. Plant protection products based on low-risk substances may be highly specific to the pests that they affect, and require specific environmental conditions to reach optimal effectiveness. Many such products may be appropriately used as part of an integrated pest management (IPM) programme.

Although there are various areas to be addressed, several of these (e.g. succeeding crops) may be tackled by 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 are important valid sources of information for describing and

[1]A microorganism other than a virus may be considered a low-risk active substance unless its susceptibility to at least two classes of antimicrobial agents has not been demonstrated (Commission Regulation EU 2022/1438 of 31 August 2022).

[2]A virus may be considered a low-risk active substance unless it is a baculovirus with demonstrated adverse effects on non-target insects or a non-virulent variant of a plant pathogen with demonstrated adverse effects on non-target plants (Commission Regulation EU 2022/1438 of 31 August 2022).

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

explaining the mode of action and properties of the product as well as its efficacy.

The objective of this Standard is to provide a framework outlining the minimum efficacy data requirements needed to demonstrate that a plant protection product based on a low-risk substance is sufficiently effective (and crop safe) to allow authorisation. EPPO Standard 1/214 *Principles of acceptable efficacy* states that, because of the risk attached to the use of PPPs, it is necessary to decide if the benefits from the use of the PPP outweigh any disadvantages. The net result should be sufficient to demonstrate an overall benefit to the use of the PPP which may relate directly to pest control and/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 (amended in Commission Regulation (EU) 2017/1432 of 7 August 2017 and in Commission Regulation (EU) 2022/1438 of 31 August 2022) and low-risk plant protection products should meet the criteria defined in Article 47.

The diversity in crop protection claims and modes of action of plant protection products based on low-risk substances is high. Some principles and concepts can be applied to all products, but other aspects of the efficacy evaluation and the scope of extrapolations largely depend on the active substance mode of action. The following categories of plant protection products based on low-risk substances 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 (see section 9.1);
2. Low-risk (bio)chemicals, substances derived from animals, botanicals, minerals, extracts from micro-organisms, with an indirect mode of action (see section 9.2);
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 and allelochemicals.[4,5]

[4]For mating disruption pheromones, a specific EPPO Standard is available (PP 1/264 *Principles of efficacy evaluation for mating disruption pheromones*).
[5]See also EU Guidance document SANTE/12815/2014 rev. 11 (January 2024) *Guidance document on semiochemical active substances and plant protection products*.

As some active substances may have multiple modes of action, where these are claimed for the PPP under evaluation, the relative importance of the different modes of action should be described (where possible). This should also be taken into account when designing and describing trial methodology.

3 | GENERAL PRINCIPLES OF EFFICACY ASSESSMENT OF PLANT PROTECTION PRODUCTS BASED ON LOW-RISK SUBSTANCES

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

- The effects of PPP treatment in fulfilling the claims made on the proposed label, in order to positively improve 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 PPP 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 plant protection products based on low-risk substances GEP should be followed, but non-GEP trial data (published papers[3] and laboratory studies) 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. To support the registration of a plant protection product based on a low-risk substance the following efficacy parameters should be considered:

- effectiveness (direct efficacy) against pest/weed/pathogen to support any claim of effectiveness including the label claim:
  - a justification of the recommended dose(s)
- resistance risk
- 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 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, improvement of effectiveness and/or sustainability of IPM programme).

Taking into account the positive and negative effects of the low-risk plant protection product, the net overall result should reflect a benefit to the use of the plant protection product, and be appropriate to the agronomic setting in which the product will be used. Moderate levels of effectiveness may be acceptable, e.g. (i) when the pest pressure is low and the objective is to keep the pest below damage thresholds, (ii) when a product will be used as a component of an IPM programme (iii) in situations such as organic farming, or (iv) where the product contributes to managing other issues such as resistance. It may be necessary to clearly specify the circumstances in which the product is to be used e.g. only for low pest infestations.

4 | DEMONSTRATION OF EFFECTIVENESS (AND CROP SAFETY)

To demonstrate the effectiveness of plant protection products based on low-risk substances, less data are generally required than for conventional chemical 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, that is, under field or glasshouse conditions. However, additional data from small scale laboratory and growth chamber studies may form a vital component of the overall information package provided to support authorization. Laboratory studies can 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 relevant to 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 plant protection products based on low-risk substances. Factors such as temperature, humidity, soil and leaf moisture, plant growth stage, edaphic conditions, etc. may affect the effectiveness of the products in a variety of different ways. Where appropriate, the conditions necessary for these 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 made available to the user – generally in the form of a product label. This information may be derived from laboratory studies, field trials or any valid relevant published paper.[6] 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 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 plant protection products based on low-risk substances 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 papers) indicating the basis for the proposed dose (and concentration in the formulation when relevant). Studies indicating population levels

[6]As defined in footnote 4.

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, and a range of doses may be appropriate.

For semiochemicals the effective dose can be reduced with continual usage of the PPP 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. 11, January 2024, *Guidance document on semiochemical active substances and plant protection products*).

4.2.3 | Assessment of effectiveness

Data are required to demonstrate that use of the plant protection product based on a low-risk substance according to label directions can provide a benefit to the user. These data are generated in field or glasshouse trials on treated crops and target pests, and performed according to the appropriate EPPO Standards, 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. Trials of use within IPM spray programmes would best resemble the conditions of practical use of the product. The minimum number of direct efficacy trials (in an area of similar conditions) required for plant protection products based on low-risk substances 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').

Data over 2 years' should normally be provided. However, with acceptable justification, 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, and reflect performance across relevant EPPO zones.

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 demonstrate both acceptable efficacy and to provide the user with robust 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 negatively impacting on effectiveness.

TABLE 1 Minimum number of direct efficacy trials (in an area of similar conditions) required for plant protection products based on low-risk substances.

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

[a]See Section 9 'Extrapolation'.

5 | EFFICACY DATA

5.1 | Effectiveness 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 plant protection products based on low-risk substances. 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. Compared with conventional chemical PPPs the testing conditions and protocols for plant protection products based on low-risk substances might need adjustments. These could include, (i) an increase in the number of replicates, (ii) an increase in sampling size, (iii) a lowered inoculum concentration (in the case of artificial infection), (iv) an increase in the number of applications, and/or (v) specific requirements to timings to ensure that a significant level of control is more likely to appear. Another possible option is to provide evidence that the inclusion of the product into a standard IPM spray program significantly improves the effectiveness of a standard spray program See also EPPO Standard PP 1/337 (1) *Principles of effectiveness evaluation of Plant Protection Products in a plant protection programme*.

Normally a reference product should also be included. If not available, justification should be provided. Due to the variability of the conditions under which PPPs are used, the inclusion of a reference product 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 product based on a low-risk substance, preferably one with a comparable mode of action. For a product based on a low-risk substance 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 chemical product may be included. Note that a product based on a low-risk substance 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 nonchemical 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 appropriate reference product(s) or nonchemical control system are used may be acceptable, but should only be considered in exceptional circumstances (e.g. pheromones or 'long-season' target pests, which are usually controlled by applying several different PPPs with different mode of actions in combination and/or alternation). Interpretation of performance, particularly where it is variable and/or moderate, is more difficult without a suitable reference for comparison, and so the majority of the content 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 determine whether resistance is likely to occur during practical use of a product based on low-risk substances. Resistance may be of less relevance for substances with multiple modes of action or pheromones, but it should be addressed.

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

5.3 | Adverse effects on treated crops

5.3.1 | Phytotoxicity

Crop safety trials are normally required for herbicidal products based on low-risk substances. 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. Additionally, where control is variable or low, yield data may be required to show the benefit of the PPP as indicated in EPPO Standard PP 1/332 *Principles for recording yield data when evaluating the efficacy of fungicides and insecticides*. 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 plant protection products based on low-risk substances 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 PPP. 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 nontarget 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 products based on low-risk substances may be influenced by other PPPs, especially fungicides, which may be used before or after the use of the low-risk plant protection product. Additionally, application equipment that may have previously been used to apply fungicidal products or other contaminants may have an impact on the performance of low-risk plant protection products. Appropriate information to address the risk of interactions with other PPPs (particularly fungicides) should be presented.

6 | CONTRIBUTION TO IPM AND SUSTAINABLE AGRICULTURE

The potential contribution of a low-risk plant protection product to agricultural sustainability is considered in the evaluation of such products. Anticipated agronomic benefits arising from the use of the low-risk plant protection product may be included in the submitted dossier. A description of the product's compatibility 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 plant protection products based on low-risk substances. These 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, that is, that the use of the product is better than no use (see also Section 5.1). It is important that users are provided with valid information on the likely performance of the product and given label guidance on how best to use the product so that it will perform as effectively and consistently as possible.

Plant protection products based on low-risk substances may in some cases deliver low to moderate levels of control or more variable control than might be expected for a conventional chemical PPP. However, provided the level of effectiveness is beneficial (as a standalone product or in a programme) low to moderate levels of effectiveness may be acceptable.

Products based on low-risk substances may have additional advantages in the following areas:

- Use over a wider range of crop growth stages (e.g. short or no preharvest intervals and reduced residues);
- Better compatibility with cultural practices or other plant protection measures (e.g. IPM, organic farming);
- Lower probability of resistance developing, or offering positive contribution to a resistance management strategy;
- Limited undesirable effects (e.g. on beneficial organisms);
- No need for specific mitigation measures.

8 | LABEL RECOMMENDATIONS (WHERE RELEVANT FOR MEMBER COUNTRIES)

Plant protection products based on low-risk substances may provide a sufficient level of control to reduce pest damage. In some cases, these products may deliver more moderate levels of control and/or more variable performance than a conventional chemical PPP. The effectiveness of some plant protection products based on low-risk substances, particularly those based on living micro-organisms, can be affected by environmental factors and/or other PPPs. To ensure that these products are used optimally, it is critical to include comprehensive label directions for use. 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 in sunlight, or apply only in the early morning or late evening).

- Use of the product in an IPM programme: guidance is required on how to use the product in relation to: (i) the level of pest pressure and/or the pest cycle, (ii) partnership with other PPPs, for example, alternation, or block programme (sequence), or dose reduction of the partner plant protection product, and/or (iii) IPM methods (if relevant).
- Compatibility with other plant protection products relates to mixing (if relevant), or with other PPPs used in a control programme.

Examples of label claims:

– 'When used as a standalone product, sufficient effectiveness may be achieved in response to low or moderate pest pressure, but additional interventions may be required under high pest pressure (additional applications or intervention with conventional chemical products (as indicated by crop monitoring))'
– '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 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 similar in relation to the efficacy of the plant protection products based on low-risk substances. EPPO Standards PP 1/257 *Efficacy and crop safety extrapolations for minor uses* and PP 1/331 *Principles of efficacy extrapolations for major uses* describe the principles of extrapolation regarding the efficacy and crop safety of plant protection products intended for minor and major uses. These principles may also be used for uses of plant protection products based on low-risk substances. The EPPO Database on PPP Data Extrapolation (https://extrapolation.eppo.int/) provides detailed lists of acceptable extrapolations which may also be used for major and/or minor uses of products based on low-risk substances.

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 scenarios (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 science and data 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 agroclimatic zone. Between agroclimatic 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 considered. 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 fully explained in relation to biology. Extrapolations may only be accepted when a PPP 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 Standards PP 1/257 and PP 1/331, building on the key factors including mode of action and the proposed new extrapolations.

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 products based on low-risk substances, 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.

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, (i) crop morphology (e.g. waxy surface or dense canopy or leaf structure), (ii) cropping system, (iii) feeding area on the plant (e.g. root or leaf), (iv) growing conditions (e.g. field or protected), (v) application technique or timing, and (vi) 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 products based on low-risk substances 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: (i) the life cycle of the pest (e.g. targeting the same stage, biology), (ii) taxonomic relationship, (iii) plant part affected (e.g. root, leaf), (iv) type of damage, (v) application technique or timing, (vi) behaviour (e.g. secretive habit), and (vii) 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. Consequently, extrapolation is possible to other crops in which the same pest appears. Where semiochemicals 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.

REFERENCES

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 7 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. *Official Journal of the European Union L* 205, 59-62.

COMMISSION REGULATION (EU) 2022/1438 of 31 August 2022 amending Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards specific criteria for the approval of active substances that are micro-organisms. *Official Journal of the European Union L* 227, 2–7.

APPENDIX 1 - SCHEMATIC REPRESENTATION OF THE EXTRAPOLATION POSSIBILITIES FOR EFFECTIVENESS OF PPP BASED ON LOW-RISK SUBSTANCES