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EPPO STANDARD

EPPO Standard on Efficacy Evaluation of Plant Protection Products

PP 1/257 (3) Principles of efficacy extrapolations for minor uses

Specific scope: This Standard describes the principles of extrapolation regarding the efficacy of plant protection products intended for minor uses. It provides guidance for regulatory authorities and applicants in the context of the registration of plant protection products for minor uses. It also provides detailed lists of acceptable extrapolations. The Standard does not cover Plant Growth Regulators (PGR) and plant defence inducers (PDI).
Specific approval and amendment: First approved in 2007–09.
Revision to reflect changes due to the new Regulation EC 1107/2009 approved in 2014–09.
Revision to include reference to the EPPO Database on PPP Data Extrapolation in 2026-09.

1 | INTRODUCTION

The aim of this Standard is to provide guidance on principles of extrapolation regarding the efficacy of plant protection products intended for minor uses. The text refers to extrapolation possibilities which provide guidance for applicants and regulatory authorities to seek and grant authorizations in the absence of specific data (or with reduced data), whilst ensuring efficacy of the extrapolated use. Extrapolation possibilities are developed and available on the EPPO Database on PPP Data Extrapolation[1] subsequently referred to as 'the extrapolation Database'. The extrapolation possibilities are maintained and updated separately from this Standard by the EPPO Panels on Efficacy Evaluation and the Expert Working Group for the Extrapolation Database and are published in the extrapolation Database to accompany this Standard.

These principles and examples of extrapolations (given in the extrapolation Database) provide a harmonized framework to support regulators, but it is important to ensure that expert judgement and regulatory experience are employed when using them.

PGR and PDI are outside the scope of this Standard because there can be significant variations in physiological responses of crops to a PGR or a PDI and extrapolation is generally not possible.

[1]The EPPO Database on PPP Data Extrapolation https://extrapolation.eppo.int/.

2 | BACKGROUND

Minor uses are those uses of plant protection products (defined in relation to crops and pests) in which either the crop is considered to be of low economic importance at a national level (minor crop), or the pest is of limited importance on a major crop (minor pest). It should be noted that a minor use in one country may be a major use in another country, and it is for each country to define what its minor uses are.

The availability of plant protection products to growers of minor crops is becoming increasingly limited. Given the low quantity of a plant protection product that would be used for a certain minor crop, agrochemical companies find it difficult to justify the registration costs. The requirement to generate a considerable amount of data makes the authorization process very expensive. However, minor crops are of substantial economic importance in many countries. For minor use authorization, it is therefore preferable to explore other possibilities for determining the efficacy of a plant protection product than those based on the amount of data normally required.

3 | EFFICACY REQUIREMENTS[2]

Extending an existing registration to a minor use, the two most important aspects of efficacy evaluation are the demonstration of direct efficacy against the target pest (effectiveness), and demonstration of safety to the crop.

For major uses, efficacy data are mainly obtained in trials set up according to the principles of good experimental practice and performed by official or officially recognized organizations. Data from other sources may be used to supplement this data. For minor uses, however, it is important to minimize the burden of efficacy trials. Therefore, in order to simplify and speed up the

[2]EC (2009) Regulation (EC) No 1107/2009 regulates the placing of plant protection products on the market and contains special provisions for the application and authorisation of so called minor uses. According to Article 51 no data on efficacy for minor uses are required. However, EPPO Standard PP 1/224 *Principles of efficacy evaluation for minor uses* recommends registering and using a product which has an acceptable level of efficacy.

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process the following information may be used, as far as possible:

- Comparison and extrapolation from the original registered uses;
- Use of data from a limited number of efficacy trials;
- Use of data from other sources.

This Standard deals specifically with comparison and extrapolation from original registered uses.

For minor uses, additional data for minimum effective dose is not usually required because determining the minimum effective dose is less important than for major uses.

Data available from the original registered uses can be studied to assess the likely direct efficacy of minor uses. This assessment can be aided by extrapolation: certain groups of pests or crops are considered to be more or less equivalent in relation to the efficacy of plant protection products.

4 | PRINCIPLES OF EXTRAPOLATION

EPPO Standard PP 1/224 *Principles of efficacy evaluation for minor uses* describes the principles for determining requirements for efficacy evaluation regarding authorizations of plant protection products for minor uses and should be considered in connection with this Standard. It refers to extrapolation as one of the possibilities for demonstrating efficacy.

Many extrapolations will be applicable across Europe. However, differences may exist between different regions, e.g. the northern and the southern part of Europe. This has been considered for the extrapolations which are included in the extrapolation Database for effectiveness/crop safety of plant protection products. However, it is important that extrapolations are considered and verified by national experts to take account of local conditions, such as different agronomic practices or resistance to plant protection products. This Standard supports national experts in their review.

Extrapolations may be used to allow an existing authorization to be extended to include additional crops or pests in the absence of specific data. Extrapolation may also allow a more reduced data package than normally would be required to support another use, as specified in EPPO Standards PP 1/224 *Principles of efficacy evaluation for minor uses* and PP 1/226 *Numbers of efficacy trials*. However, the present Standard does not address reduced data for an authorization of a plant protection product for a major use, but only for minor use authorizations.

The extrapolations included in the extrapolation Database are based on an examination of biological and chemical evidence that justifies assumptions of efficacy without a full set of supportive data. The extrapolation Database is not exhaustive. When an extrapolation is not listed, it does not mean that it may not be acceptable.

For purposes of acceptance of trial data for the registration of plant protection products, the EPPO region has been divided into four agro-climatic zones; see EPPO Standard PP 1/241 *Guidance on comparable climates*. From this perspective, extrapolations are possible within the same agroclimatic zone. Between zones, extrapolation may also be appropriate if the conditions are deemed to be comparable to those in that country (or in special cases, regions of countries) where the product is already authorized. For crops grown in protected situations there may be greater scope to extrapolate because the environmental conditions are controlled and less variable.

The effects of climate on pest/crop interrelationships should also be taken into account. However, climate is only one factor that may affect the effectiveness and crop safety of a product in addition to other factors (agronomic, edaphic, target-related) when establishing the relevance of data generated within different member states.

Extrapolations may only be accepted for the extension of use of a given plant protection product used at the same or a similar dose, applied under similar conditions (e.g. timings, growth stages, application methods, soil conditions). Extrapolations cannot automatically be reversed, i.e. permission to extrapolate from situation A to situation B does not automatically permit extrapolation from situation B to A. Extrapolation is hampered by potential variability in pest/crop/product interactions. However, the scope for extrapolation may be extended as data and experience with a certain plant protection product increase. Extrapolation may be limited when a certain plant protection product is known to be effective for a rather specific set of conditions. The less specific this set, the greater the scope for extrapolation.

The accompanying extrapolation Database is based on the principle that certain crops can be considered equivalent in relation to effectiveness or crop safety and can be grouped together in crop groups. A crop group contains all crops for which an extrapolation can be performed from an indicator crop (for a particular plant protection product), regarding either:

- Effectiveness against a particular pest
- Safety for a particular crop.

Indicator crops are those crops which can be considered representative of effectiveness or crop safety for their crop group and for which a set of data is or should be available. Within a crop group there might be some crops for which certain pests are considered to be more

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difficult to control and therefore collecting some additional evidence is recommended while extrapolating from an indicator crop. It should be noted that it is commonly preferable to have data on several of the crops within the crop group, but data on the indicator crop should also be available.

If effectiveness of a plant protection product has been adequately demonstrated against a major pest or a range of related pests for a particular crop group, it may be possible to extrapolate to other related pests in other crop groups.

4.1 | Effectiveness extrapolations for plant protection products other than herbicides[3]

A decision-support scheme for extrapolations for fungicides and insecticides is given in Appendix 1. This scheme can also be used for bactericides, acaricides, molluscicides and nematicides.

4.1.1 | Key factors which may be relevant for extrapolation

4.1.1.1 | *Crop*

Crop morphology, botanical family, cropping system, growth pattern. It should be noted that closely related species may still differ significantly in growth pattern, leaf surface or the parts of plant that are harvested. Extrapolation may be relevant from a major economic crop, but in some circumstances a more challenging situation for control may be found in a minor crop.

4.1.1.2 | *Disease/pest*

Taxonomic relationship, biology, life cycle, behaviour, plant parts attacked, damage caused. Closely related species may have significant differences. A given pest species may behave differently between crops. For example, different generations of a pest may cause different types of damage so care is needed with extrapolation between crops, or similarities in feeding behaviour of insects may make extrapolation across a range of pest groups appropriate, but the biology of the individual pest is still important.

4.1.1.3 | *Product*

Mode of action, timing, frequency, method of application, preventative or curative treatment, systemic or non-systemic, formulation, dose, extent of existing database, existence of regional differences in susceptibility to plant protection products.

[3]These other plant protection products include bactericides, acaricides, molluscicides and nematicides.

4.1.1.4 | *Agronomic*

Growing conditions (field or protected) and cultivation techniques, growing systems, soil type (particularly for soil treatments). Generally, protected situations are considered less challenging than field situations, particularly for foliar applications.

4.1.1.5 | *Seed treatment*

Extrapolation between seed treatments of different crops is normally more acceptable when the seeding density and thousand grain weight is similar.

Furthermore, different sizes of seeds between different crops may lead to different dilution effects which may mean that extrapolation is not possible.

Other factors of importance, for which similarity is necessary, are sowing period, time of appearance of pest, application technique, seed skin (rough surface or smooth surface). Substantial differences in growth rate can lead to different dilution effects for systemic plant protection products and extrapolation may not be possible if this is the case.

4.2 | Effectiveness extrapolations for herbicides

A decision-support scheme for extrapolations for herbicides is given in Appendix 2.

Specific principles which may be relevant for extrapolation between crops for the same target weed:

- When considering the acceptability of an extrapolation, account should be taken of timing of weed control, time/ method of sowing/planting, competitiveness of the crop, time/method of harvesting and ease of separating crop and weed seeds;
- When effectiveness of a herbicide has been adequately demonstrated against a major weed species or a range of species from a particular plant family, it may be possible to extrapolate to a related weed species;
- Extrapolation may be possible from the control of a particular weed outdoors to the same species under protected conditions, since conditions are less variable and weeds under protection tend to be more sensitive. However, effectiveness under protected conditions cannot be extrapolated to outdoor use as weeds grown outdoors are usually hardened off and therefore less sensitive to herbicides;
- The effectiveness of soil-acting herbicides against weed species in the field cannot be extrapolated to use in container plants or plants in artificial substrate. This is due to the likelihood of different effects of different growing media on effectiveness.

Extrapolation from one weed species to other weed species is generally not possible, because of differences

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in the sensitivity of weed species to herbicides. However, when trials are carried out with several weed species from the same group of weeds (e.g. annual dicotyledonous or annual grasses), extrapolation is possible to the whole group. This does not mean that all weeds in this group are susceptible. The susceptible weeds may be mentioned on the label.

4.2.1 | Key factors which may be relevant for extrapolation

4.2.1.1 | *Crop*

Crop morphology, competitiveness of the crop, growth habit, growth pattern. It should be noted that closely related species may still differ significantly in growth habit. Time/method of sowing/planting, cropping system, time/method of harvesting and ease of separating crop and weed seeds.

4.2.1.2 | *Weed*

Taxonomic relationship, biology, life cycle, behaviour, growth stage. Closely related species may have significant differences.

4.2.1.3 | *Product*

Mode of action, time of application, frequency, method of application, aerial or soil treatment, formulation, dose, spray volume, extent of existing database, regional differences in susceptibility of weeds to plant protection products might exist.

4.2.1.4 | *Agronomic*

Growing conditions and cultivation techniques, growing systems, field or protected, soil type (particularly for soil treatments).

4.3 | Crop safety

Phytotoxicity is particularly relevant with certain products (such as herbicides), some types of application (such as soil or seed/plant treatments), and for specific crops such as ornamentals. Phytotoxicity can vary considerably between different crop species, cultivars of the same crop and between different plant protection products. Extrapolation is possible in some situations but should be well reasoned in order to ensure crop safety. It may be based on comparison between the minor crop and crops on which the product is already approved. If an extensive database on crop safety for the plant protection product is available, crop groups may be developed. On the other hand, extrapolation may not be possible where use of the product has resulted in crop damage on some crops or cultivars, where crops concerned are significantly different, or when a crop is known to be particularly sensitive.

In addition to or to assist extrapolation, it may be possible to assess crop safety while obtaining data for residues or effectiveness for a particular plant protection product.

4.3.1 | Specific principles for extrapolation for crop safety

The general principles for extrapolation in this Standard apply also in cases of extrapolation for crop safety. In addition, the following specific principles are important:

- The method of application for the crops involved in the extrapolation should be similar;
- Availability and interpretation of evidence of crop safety (or of phytotoxicity) from standard pre- and post-emergence pot tests and glasshouse varietal screens should be treated with care. Conditions in a glasshouse can affect the structure of plant surfaces, as well as pest biology, thereby changing the crop safety of a product.

In addition to these specific principles the following key factors may be relevant for extrapolation for crop safety:

- Taxonomic relation to the crop for which the product is already approved;
- Similarity in morphology of the crops concerned;
- Availability of adequate crop safety data showing a good margin of safety for the crop(s) from which extrapolation is required and across a range of cultivars.

4.3.2 | Crop safety extrapolations for plant protection products other than herbicides[4]

As a general principle, insecticides and fungicides are expected to have low phytotoxic activity with limited adverse effects on the treated crop. The extent of extrapolation within or between crops is largely dependent on the use of the product, known sensitivity of the treated crop and/or growth stage, and the extent of existing knowledge.

Evidence may be available from standard pre- and post- emergence pot tests and glasshouse varietal screens. Such preliminary data provides a very useful baseline of inherent crop safety properties for a particular active substance. Following this, trials using the relevant formulation will provide assessments of phytotoxicity in both efficacy trials on the main target crops, and possibly

[4]This includes bactericides, acaricides, molluscicides and nematicides.

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data from specific crop safety trials. Where relevant for major crops, these should also include some evidence on yield effects. Using this combination of glasshouse and field data, information can be built up on a range of uses and possibly formulation types. As existing knowledge builds up, the scope for extrapolation to other crops in the absence of further crop safety data becomes greater.

Where there are significant differences between the current use and a proposed extrapolation, particularly regarding dose and formulation, additional data may be required. However, even in these circumstances there may be evidence of inherent crop safety at high doses, or across a range of formulation types, which could be used as evidence in making a reasoned case. Other factors such as timing, application method, growing conditions and crop morphology will also need to be addressed, either by a reasoned case or further limited data. For insecticides and fungicides with a robust database indicating inherent crop safety across a range of conditions and crops, additional data may only be required in very specific circumstances, e.g. for a new crop of known particular sensitivity.

Given the above, the suitability of extrapolation from a crop safety perspective will need to be considered on a case-by-case basis for a particular product, making full use of existing knowledge. Nevertheless, some general comments on crop safety for particular crop groups are provided in the EPPO Database on PPP Data Extrapolation (under crop safety, fungicides and insecticides) as well as, where known, information on the more sensitive crops and/or crop stages. These are particularly appropriate as test plants because they represent a 'worst case' and provide greater scope for extrapolation. They could be used as indicator plants in crop groups for crop safety extrapolations to be developed in the future, as experience in crop safety extrapolations develops.

4.3.3 | Crop safety extrapolations for seed treatment

See Section 4.1.1.5.

4.3.4 | Crop safety extrapolations for herbicides

Crop safety is particularly an issue in the case of herbicides. Specific principles are not available and extrapolations have to be considered on a case-by-case basis.

If a herbicide is demonstrated as only effective against monocotyledonous species, it may be possible to extrapolate crop safety between dicotyledonous crops, and vice versa. However, this will depend on the information available on the active substance.

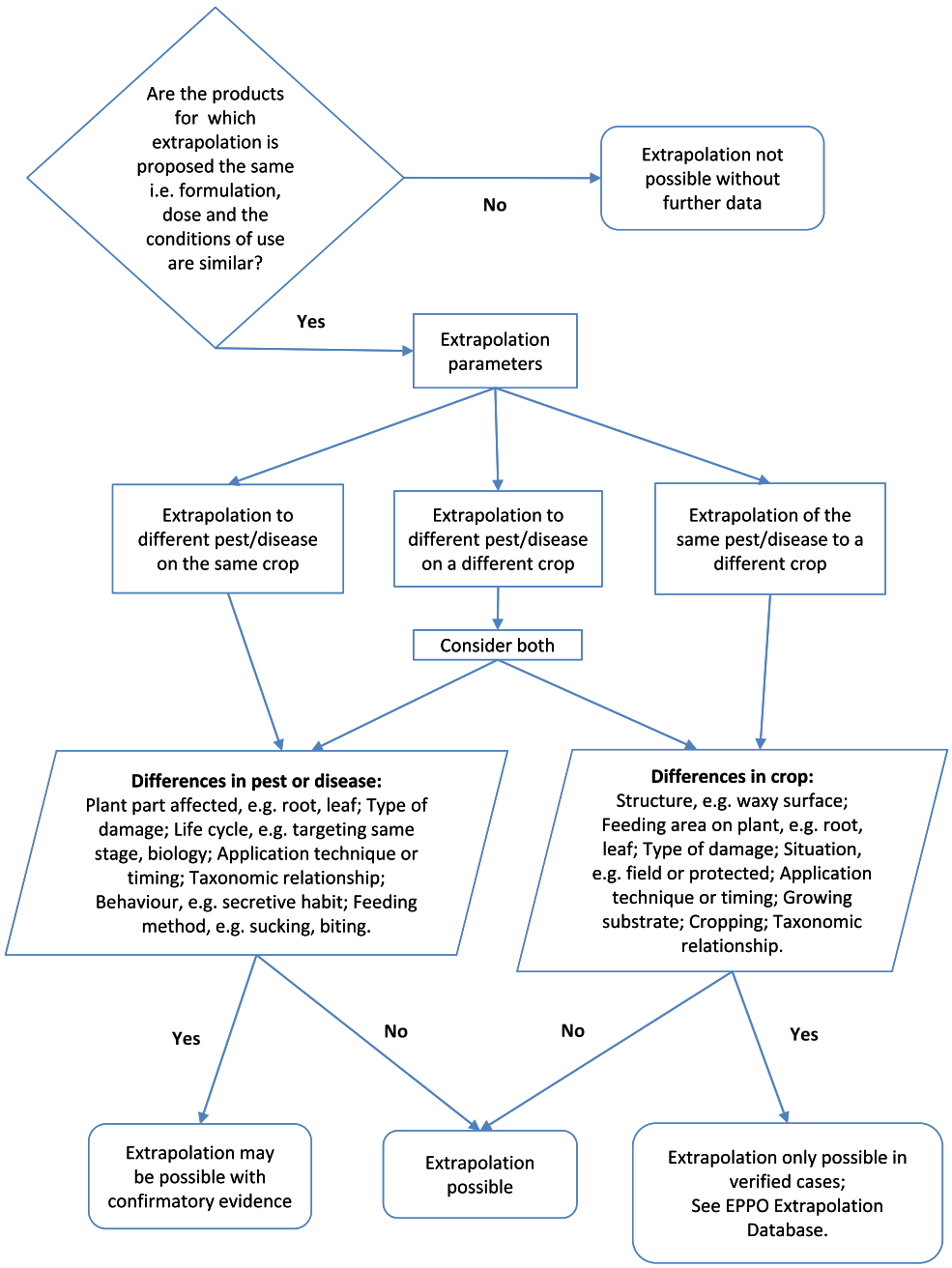
In the EPPO Database on PPP Data Extrapolation (under crop safety, herbicides) a list of possibilities for crop safety extrapolations is given, based on existing experience. This list is not exhaustive and can be extended as experience develops.

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.

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APPENDIX 1 - DECISION-SUPPORT SCHEME FOR EXTRAPOLATIONS FOR FUNGICIDES AND INSECTICIDES



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APPENDIX 2 - DECISION-SUPPORT SCHEME FOR EXTRAPOLATIONS FOR HERBICIDES

