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EPPO STANDARD

EPPO Standard on Efficacy Evaluation of Plant Protection Products

PP 1/225 (3) Minimum effective dose

Specific scope: This Standard describes the criteria, as well as the experimental procedures, for determining the minimum effective dose of a plant protection product.
Specific approval and amendment: First approved in 2003–09.
Revision mainly to reflect zonal assessment approved in 2012–09.
Revision approved in 2026–09.

1 | INTRODUCTION

For the purposes of this Standard, the 'minimum effective dose' of a plant protection product is the dose that is the minimum necessary to achieve the desired effect across the broad range of situations in which the product will be applied.

Where the product is proposed for use under diverse conditions, there may be situations that warrant the use of different doses, for example, in situations with different cropping practices or crop structures, or variation in the inherent sensitivity of the target pest. Thus, for a specific target, it may be possible to justify a number of specific 'minimum effective doses' under defined conditions, which should be established using the principles outlined in this Standard. When a dose range is requested, both the highest and lowest doses should be justified.

In the interests of reducing exposure to plant protection products in the environment, to the person(s) applying the product or to the end-users of the crop (either humans or domestic animals), it is important to ensure that the minimum dose required to achieve the desired effect is applied.

In addition, within the European Union, the legislative framework requires that dose rates lower than the recommended one should be included in trials in order to establish whether the recommended rate is the minimum necessary to achieve the desired effect (EC, 2013).

The objective of this guideline is to give applicants and national registration authorities a basis for considering the determination of the minimum effective dose. The intention is to detail the minimum requirements necessary to ensure a consistent approach when justifying the requested dose.

2 | DETERMINATION OF THE MINIMUM EFFECTIVE DOSE

To establish that the recommended dose of a plant protection product is the minimum necessary to achieve the desired effect, trials should demonstrate that the recommended dose provides one or more of the following:

- A higher level of effectiveness compared to the lower dose;
- A longer persistence of action compared to the lower dose;
- A more consistent effectiveness under various conditions compared to the lower dose;
- A balance between the positive and negative effects provided by the recommended dose (e.g. growth regulator or herbicides).

It is recognized that the selection of the recommended dose, and thus the justification that this is a minimum effective dose for a desired effect, may be a compromise based on expert judgement and on the results from a number of trials. In addition, the potential for resistance, the safety of the product to the crop, and other aspects of efficacy should be considered (see EPPO Standard PP 1/214 *Principles of acceptable efficacy*). Appropriate justification for the choice of the intended dose should be provided.

Where more than one active substance is included in a product, justification of both the ratio of active substances and the rate of the product is normally required. Particular attention should also be paid to the rationale behind the inclusion of each active substance in the product. It may be necessary, for example, to explain the benefit over the individual active substances (e.g. resistance management) in addition to a justification of the product dose. EPPO Standard 1/306 *General principles for the development of co-formulated mixtures of plant protection products* is particularly relevant when considering mixtures of plant protection products.

Where a composition or formulation change is considered biologically significant and increases effectiveness (See PP 1/307 *Efficacy considerations and data generation when making changes to the chemical composition or*

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formulation type of plant protection products), minimum effective dose should be demonstrated.

For plant protection products based on low-risk substances, microbials or semiochemicals, it may be possible to deviate from the principles above, see the following EPPO Standards for examples:

- PP 1/296 *Principles of efficacy evaluation for plant protection products based on low-risk substances*,
- PP 1/276 *Principles of efficacy evaluation for microbial plant protection products*,
- PP 1/314 *Evaluation of mating disruption techniques against Lepidopteran pests in grapevine, pome and stone fruits under field conditions*,
- PP 1/323 *Evaluation of mating disruption techniques against Lepidopteran pests in grapevine, pome and stone fruits under semi-field conditions* and
- PP 1/334 *Evaluation of mating disruption techniques against Lepidopteran pests in vegetable and ornamental crops under protected conditions.*

Due to risk assessment considerations, there may be situations where minimum effective dose has been determined, but subsequently this dose has to be reduced. Any reduced dose should be demonstrated to be effective and offer a meaningful benefit within the plant protection strategy for the relevant crop(s) (see Standard PP 1/214 *Principles of acceptable efficacy*).

3 | EFFICACY TESTING TO ESTABLISH THE MINIMUM EFFECTIVE DOSE

3.1 | Preliminary tests

During the early development of a plant protection product, initial dose-ranging trials, possibly in laboratory or semi-field situations, provide an indication of the likely recommended dose. Data from such trials can then be used in refining the doses to be applied in subsequent field trials to test the effectiveness of the product. These trials focus on doses around the dose necessary to deliver the required level of effectiveness and enable a recommended dose to be proposed.

3.1.1 | Direct efficacy (effectiveness) trials

To provide sufficient information to substantiate the direct efficacy (effectiveness) of a product, a number of trials, making up a trial series, would normally be conducted in which at least the proposed recommended dose is tested. This trial series will include a relevant range of climatic, agricultural, epidemiological and edaphic conditions and appropriate standards as reference products (preferably the same if available in all countries). EPPO Standards PP1 *Efficacy evaluation of plant protection products* provide more detailed instructions on the design and conduct of efficacy trials for individual host/pest combinations. For further guidance, refer to EPPO Standards PP 1/181 *Conduct and reporting of efficacy evaluation trials, including good experimental practice*, and PP 1/152 *Design and analysis of efficacy evaluation trials.*

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate effectiveness should include at least two lower dose(s) (preferably including around 60 and 80% of the recommended dose) to that which would be recommended. In addition, it may also be useful to include trials with a higher dose than the recommended one. The number of trials in which a lower dose is included should be sufficient to cover the range of situations in which the use is proposed and demonstrate differences in control (or effect for growth regulators) between the lower dose(s) and the recommended dose. At least some trials within the series should demonstrate a statistically significant difference between the lower dose(s) and the recommended dose. Alternatively, the overall trial series should reveal a clear or consistent numerical trend in the dose–response relationship, supporting the determination of the minimum effective dose. Where the recommended dose can be identified as the minimum effective dose from preliminary tests and efficacy trials, with lower doses meeting the criteria, no additional trials are necessary to establish that the dose recommended is the minimum necessary for efficacy.

Where situations have been identified that allow reduced rates to be employed without compromising the desired effect, they should appear as recommendations on the label, e.g. where reduced rates are giving satisfactory control of specific weed species or pathogens, or where reduced persistence is acceptable, or on particular soil types where a lower dose is fully effective and gives no danger of reduced sensitivity or resistance.

4 | MULTIPLE TARGET PESTS AND MULTIPLE DOSE RECOMMENDATIONS

Many plant protection products are used to control a range of target pests on one crop or crop group and for a common application timing. In such situations, it would be impractical and unnecessary to provide evidence for the minimum effective dose for all target pests. Information is required for a range of targets which are considered to be the most important, and for which control provides the major agricultural benefit. It should be noted that where the proposed use is across a substantive geographical area such as an authorization zone

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(as defined in PP 1/278 *Principles of zonal data production and evaluation*), the major target species and/or the major crop may vary and there may be differences in population pressures. Therefore, particular consideration should be given to trials location.

For some target pests with broad spectrum of host crops, trials may be provided on representative crops and extrapolation could be used for other crops (see PP 1/257 *Efficacy and crop safety extrapolations for minor uses* and PP 1/331 *Principles of efficacy extrapolations for major uses*).

REFERENCE

EC (2013) Commission Regulation No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.