

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PP 1/224 (2)

Efficacy evaluation of plant protection products Evaluation biologique des produits phytosanitaires

PP 1/224 (2) Principles of efficacy evaluation for minor uses

Specific scope

This Standard describes the principles for determining requirements for efficacy evaluation for minor uses of plant protection products in a registration procedure.

Specific approval and amendment

First approved in 2003–09.

Revision to reflect changes due to the new Regulation EC 1107/2009 approved in 2014–09.

Introduction

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 national level (minor crop), or the pest (minor pest) is not important on a major crop.¹ It should be noted that a minor use in one country may be major use in another country, and it is for each country to define what its minor uses are. Lists of major or minor crops are available in many countries, including those based only on criteria to establish maximum residue limits (where consumption of plants and plant products as food is the key issue).

For the purposes of this Standard, the minor uses that are of interest are those for which the volume of plant protection products that would be used at a national level is insufficient for an applicant to wish to seek registration. Registration of plant protection products is a complex system needing the generation of a considerable amount of data. The financial cost of producing the data is so high that the crop protection industry increasingly gives priority to seeking registration for products to be used on the main crops and against the main pests, with the consequence that fewer plant protection products are being proposed for registration for minor uses. Furthermore, the process of re-evaluation of old active substances is removing more and more useful products from the market. As a consequence, for many minor uses, there are few or no products available, or else the products registered are not satisfactory (because of insufficient efficacy, development of resistance,

etc.). Other methods to protect the crops often do not exist or are not sufficiently effective. Growers urgently need products to protect often high-value crops grown on small areas, or to control pests which are only incidentally of economic significance. There is widespread interest in EPPO countries in designing a simpler process to provide products for minor uses. The most widely accepted solution is to facilitate the extension of an existing registration to include a minor use.

EU legislation² sets a framework to achieve that objective but, in general terms, leaves to each Member State the definition of the minor-use concept and its practical application.

EPPO recommends that a pre-requisite to register and use a product is that it should have an acceptable level of efficacy (EPPO Standard PP 1/214 *Principles of acceptable efficacy*), in order to ensure that products with little benefit in plant protection do not cause an unnecessary burden to the environment. The level of efficacy should be demonstrated by the submission of trial data covering the crops to be protected and the pests to be controlled, or by suitable extrapolation (EPPO Standard PP 1/257 *Efficacy and crop safety extrapolations for minor uses*). In principle, an equivalent amount of efficacy data should be provided when a registration is extended to a new use. However, for the reasons given above, it is preferable to develop a special procedure for minor use registration, with different requirements for efficacy data. The present document is intended

¹The concept of minor use applies in an equivalent manner to plant growth regulators.

²Regulation (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 *Extension of authorisations for minor uses* no data on efficacy for minor uses are required.

to provide general principles on efficacy evaluation for minor uses. It does not cover other minor-use requirements, such as residue and ecotoxicological studies, which have to be addressed by the applicant and considered by the appropriate authority.

Efficacy requirements

Efficacy is defined as the direct effect (effectiveness) on the pest or on the modification of plant growth (growth regulators) together with other indirect effects such as those on the crop being protected, on succeeding or adjacent crops, on natural enemies, or on the development of resistance (see EPPO Standard PP 1/213 *Resistance risk analysis*). The method of assessment of efficacy for minor uses should, in principle, follow the lay-out of specific EPPO Standards relating directly to a particular crop/pest combination, and also some general Standards (e.g. phytotoxicity). In 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, and the absence of phytotoxicity on the minor crop. The other elements of efficacy are generally adequately covered by the existing registration dossier.

Demonstration of effectiveness

For major uses, efficacy data is mainly obtained in trials correctly 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 that data. For minor uses, however, it is important to minimize the burden of efficacy trials. Therefore, in order to simplify and speed up the 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.

Comparison and extrapolation³ from the original registered uses

Data available from 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. Some countries have prepared lists of crops and pests for use in extrapolation which can be the basis for the registration of products for minor uses.

³EPPO extrapolation tables are published as 'Extrapolation tables for effectiveness/crop safety of plant protection products (insecticides/fungicides/herbicides) to accompany EPPO Standard PP 1/257) *Efficacy and crop safety extrapolations for minor uses*'. www.eppo.int

The elaboration of such lists can be difficult as it should be based on present scientific knowledge and, as far as possible, practical experience. Considerable expertise is needed and this seems to vary from country to country. In some countries only a few examples of already accepted extrapolations are provided as guidance to the applicant. Numerous factors may have to be taken into consideration, for example whether and how the climate, edaphic factors and agronomic conditions, which may be different between the registered use and the proposed extension to a minor use, will influence efficacy. Similarly, the differences between protected crops and outdoor crops, and between autumn/winter and spring sown/planted crops, may need to be considered. A convincing case has to be made for a valid extrapolation from one to another of those situations.

For fungicides, if a product can control a pathogen in a variety of situations, it may control a related pathogen in a comparable situation. If a product can be used against a pathogen on one crop, it may perhaps be used against it on other crops. In some cases, it may be possible to extrapolate in this way without supporting data. Nevertheless, it should be stressed that the epidemiology of a pathogen can be different on different host plants.

For insecticides and acaricides, it is sometimes possible to generalize the use of a product to a whole group (e.g. aphids or mites) within which several species can be controlled, without supporting data for each species. Similarly, there are pest species which can attack several host plants and it can be argued, in these cases, that efficacy on other hosts should be considered equivalent. Data showing that a product can control many insects or mites feeding in the same situation on the plant may also justify extrapolation for the same timing for treatment.

For herbicides, the composition and characteristics of the weeds present in a crop are the key factors influencing efficacy, but the crop also plays an important role. The required level of weed control varies according to the crop, the cropping system, the timing of treatment and its relation with sowing/planting time.

Efficacy trials

Data from efficacy trials may be needed when extrapolation cannot be used to support the registration of a product for a minor use. The trials should be performed according to the appropriate EPPO Standard, by official or officially recognized organizations and following good experimental practice. The number of trials needed should be reduced to a minimum. In general, 2–3 trials could be acceptable, but each case should be considered individually. Trials in different locations and years may be useful, according to the relative importance of the problem, subject to the total number of trials allowed. See also EPPO Standard PP 1/226 *Numbers of efficacy trials*. In general, trials set up in other countries should be accepted, provided that a case for comparability is presented and agreed.

Under certain circumstances, trials may also be performed, under official supervision, by farmers and other commercial users ('user-derived evidence').⁴ Data obtained in this way may be used to support an application for registration of a minor use, but this option is only appropriate to some situations where very good control and supervision of the trials can be assured. Data from this type of trial, properly conducted, may, however, be preferable to data supported only by the type of information described below under 'Other sources'.

Other sources

The comparison between registered uses and minor uses can, in certain cases, be supported by data obtained from bibliographic references, provided that comparability could be demonstrated. Comparability should be based on dose rates and on number and timing of treatments. The comparison should also consider the pest complex and crop practices in the country, the behaviour of the pest (specific or polyphagous) and the relative abundance of pest populations. Efficacy data obtained in growth-room or laboratory trials can also be used to give some indication of likely effectiveness in the field. The registration of a given minor use in another country may support an application for registration, provided that comparability between national conditions can be demonstrated.

Phytotoxicity (crop safety)

Phytotoxicity can be a very important aspect of overall efficacy when dealing with minor crops. It is particularly relevant with certain products, such as herbicides, and some types of application, such as soil or seed/plant treatments. Factors to consider with respect to phytotoxicity are the plant species and, in some cases, cultivar, together with the type of plant protection product and its mode of application (e.g. dose rate, water volume, timing). 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. Other data, such as that obtained from the database of the product can help. Information on phytotoxicity can also be obtained from trials other than efficacy trials, such as those set up for obtaining residue data, where crop safety assessments can be made. The occurrence of damage by the product on other crops (including succeeding crops), particularly on sensitive crops/plants, or in favourable conditions (e.g. plant growth stage, climatic con-

ditions), could require the setting up of specific trials on phytotoxicity. In this case, conditions to prevent phytotoxicity on the crop should be taken into account in considering extension of the registration.

Obligations of the applicants

As with other types of uses, applicants should make the necessary application for the registration of a named plant protection product (already registered for other uses) for a defined minor use. Thus, they have to prepare a dossier of information. In submitting the dossier on efficacy, the applicant should establish that the use is really a minor one. The applicant should then adequately demonstrate that the product has satisfactory efficacy for the proposed minor use. This should be done by the methods described in this Standard.

Obligations of the registration authorities

The registration authorities should recognize the importance of facilitating registration for minor uses in order to provide farmers with as wide a range of products as possible to protect their production. They should prepare guidance on extrapolation, or reference lists which could be the effective basis for extrapolation. The procedures for registration of plant protection products for minor uses in relation to efficacy should be established by each registration authority and they should be made easily available to applicants or other authorities. It would be useful to maintain a database⁵ of minor uses for which registration has been obtained. With regard to these efficacy requirements, registration authorities should adopt a more flexible approach for minor uses than for other applications, and should be prepared to consider efficacy data whose form and content may not correspond with the normal dossier for registration. They should, however, be convinced by the application that the use of any product will represent an overall benefit, and that any risks, especially concerning crop safety, will be minimal.

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* L309, 1–50.

⁴There is good experience of such user-derived evidence in certain EPPO countries.

⁵The EU Minor Uses Database (EUMUDA) is the database of the EU Technical Working Group on Minor Uses (TWG) and the EU Commodity Expert Groups on Minor Uses (CEG).