

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

PP 1/278(1)

Efficacy evaluation of plant protection products Evaluation biologique des produits phytosanitaires

Principles of zonal data production and evaluation

Specific scope

This standard describes the principles to be considered when designing a trials series for the generation of efficacy data to support an authorization of a plant protection product across a substantive area or region, such as across one or more distinct geographic areas or countries. That is beyond the scope currently considered by existing EPPO PP1 General Standards (e.g. PP 1/226 *Number of efficacy trials*).

Specific approval and amendment

First approved in 2012–09.

Introduction

This standard aims to provide information to facilitate the preparation of a dossier to support an authorization of a plant protection product across a substantive area. For simplicity, such an area is referred to as an ‘authorization zone’ throughout this standard. An authorization zone can be defined as a substantive area or region used for administrative purposes in which authorization is sought, covering one or more distinct geographic areas or countries. Across such an area, there may be variations in climate, agronomy, and pest biology, as well as sensitivity to plant protection products.

It is important to note that this term is not a defined area but an area chosen by the applicant over which authorization is sought. It may also be a zone as defined under EC Regulation 1107/2009 (EC, 2009). Note however, that in the context of EPPO Standards PP 1/241 *Guidance on comparable climates*, and PP 1/269 *Comparable climates on global level* a ‘climatic zone’ is defined as an area in which agroclimatic conditions may be considered comparable.

In order to develop a trials programme to demonstrate the efficacy of a plant protection product across an authorization zone, there are a number of factors and principles that should be considered. This Standard identifies those factors and explains the principles to enable the provision

of an appropriate dataset, so that there can be reasonable confidence in the performance of the product and its crop safety profile within and across requested authorization and climatic zones. Similarly, this Standard provides an indication to those evaluating such a zonal dataset as to whether the performance of the product is maintained across the conditions in the zone.

This standard should be read in conjunction with EPPO Standard PP 1/181 *Conduct and reporting of efficacy evaluation trials, including good experimental practice*, which provides information on the conduct and reporting of data from trials series.

The current Standard is mainly designed for:

- The person/s responsible for writing the protocols for trial series or relevant studies (e.g. oenological tests, germination tests, taint tests).
- The person/s responsible for setting up the trials.
- The person/s responsible for assembling and submitting the biological dossier, who are advised on the successive points to be considered.
- The national authorities (e.g. EU Zonal Rapporteur Member State) that are responsible for assessment of registration dossiers and which have to ensure that the data in the dossiers has been obtained following EPPO Standards and in accordance with Good Experimental Practice (GEP).

A series of examples of data requirements to support specific pest-crop-zone combinations are presented with explanations as appendices to this standard¹.

Overriding principles of the zonal approach

The key requirement for an applicant in proposing a submission to cover a large area such as an authorization zone is to understand and address all the factors within the area that have the potential to influence performance of the plant protection product. These include climatic and edaphic conditions, and agronomic and crop husbandry practices, as well as influences arising from the target pest and from the properties and mode of action of the active substance and the plant protection product. The applicant should address these factors either by ensuring that there are specific data to demonstrate efficacy under the different conditions, or there is a reasoned case to justify why the data available are directly relevant to those conditions. A list of key factors is detailed below and comments regarding their impact and how they might be addressed in a submission are presented.

The benefit of such an approach is that it provides the potential for a reduction in the dataset relative to that which might otherwise be required for the generation of a data package on a country by country basis. Similarly, a single but potentially more complex dataset presented in a single biological efficacy dossier means a single evaluation may be relevant for multiple countries within the zone.

Situations where a zonal approach may not be relevant

While there may be considerable benefit from the generation of data and their evaluation at a zonal level, there is merit in maintaining the opportunity for more local targeted information in the use of plant protection products. However, in some cases it may be necessary to consider specific local conditions, or requirements for local risk mitigation requirements. For example, some aspects of resistance risk can be presented and evaluated at the zonal level, with risk management considered at the national level. In such circumstances the zonal efficacy submission may be accompanied by some country specific information, presented separately in what are currently termed in the EU as 'national addenda'.²

¹The case study appendices are available on the EPPO website at: http://www.eppo.int/PPP/PRODUCTS/zonal_efficiency/zonal_efficiency.htm. The number and distribution of trials will vary depending on the authorization zone and the intended use. Expert judgement should be applied in all cases.

²An EU SANCO guidance document which specifically addresses the issue of core data and national addenda is presently under development, entitled: 'Guidance document on the composition of Core and National dossier to be submitted for claiming authorization of plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market'.

Objectives of the applicant and evaluator

The objective of both the applicant and evaluator is to have a comprehensive dataset justifying the performance of the product across the range of conditions present in the authorization zone. This is achieved by ensuring that the range of conditions that might influence the performance of the product is, as far as practicable, identified and that trials are conducted to address efficacy under those conditions. It is not always essential to test in trials every possible combination of conditions; testing the extremes of conditions may be sufficient if it is reasonable to assume comparable performance in the intermediary conditions. However, regardless of conditions, some testing should occur in the major area of cropping where the pest is prevalent. Comparison of the results of the trials from the range of conditions can demonstrate whether performance is comparable. For example, if performance is tested in both the hottest and coldest conditions likely to be encountered, then testing intermediary conditions would only be required where performance was shown to be affected by temperature, and where in some temperatures performance was unacceptable.

Careful and appropriate analysis of the data from trials conducted under different conditions enables the applicant to determine whether the product performs effectively across the range of conditions, or whether certain conditions impair performance. Where performance is impaired it is important to address this; this may be by ensuring that National product labels accurately reflect the conditions in which appropriate performance can be achieved, and identify clearly the impact of different conditions on performance. The principles clearly stated in EPPO Standard PP 1/214³ *Principles of acceptable efficacy* and EPPO Standard PP 1/225 *Minimum effective dose* should apply, although the potential for variation in performance is increased because of a greater diversity of conditions across an authorization zone.

The applicant may consider that a different dose should be tested and if performance at the revised dose is satisfactory, it may be recommended for those conditions. See section titled Minimum effective dose.

The applicant should justify the relevance of the original dataset or provide additional confirmatory evidence to support the extension of use within the regulatory zone when authorization is subsequently sought for use/uses outside of that originally considered in the zonal authorizations.

³Expert judgment is needed to decide if any of these factors could have influenced the efficacy and whether the effect was an apparent increase or decrease of direct efficacy. In addition, the expert assessor may be able to recognize other possible influences on direct efficacy from an examination of the data set presented for registration; for example, mode of action, formulation, development of resistance may influence the trial results. By studying these factors, the expert may also be able to develop conditions and limitations of use that would improve direct efficacy, prevent negative effects or allow control of a pest or attainment of a protective purpose even under unfavorable conditions.

Use of ‘master labels’

The principle of the zonal approach to data production may be expected to result in a data set supporting a range of recommendations for use against different targets on different crops and across a broad range of situations and conditions. ‘Master label’ is defined in this standard as being only the recommendations and directions for use within the different zone(s) applied for [e.g. at least the content of the GAP table (s)], not a complete label including risk and safety phrases. As such a ‘master label’ on which all the proposed recommendations for use are made, including any limitations under certain conditions, may be drafted by the applicant. The proposed label directions relating to a particular target/use assist greatly in understanding the interaction of product performance and target biology, and in determining the validity of both the trials conduct and generated data. These aspects are listed in EPPO Standard PP 1/240 *Harmonized basic information for databases on plant protection products*.

The production of a ‘master label’ containing all the recommendations for use within the zone where authorization is to be sought is recommended. It should be made clear whether the recommendations apply to the whole requested authorization zone or where they only apply to either regions or even specific countries within that zone. As such, and given that authorization is generally granted at a national level, applicants (or evaluators) may identify components of the label relevant to individual countries, such that only appropriate recommendations are authorized on the national label.

National label

A number of recommendations in the ‘master label’ may not be relevant to every country within the authorization zone. For example certain pests or crops may not be present in 1 country or certain conditions encountered in part of an authorization zone may require different recommendations for use compared to other parts (e.g. a pest may only require 2 applications in some parts of an authorization zone but a much higher frequency of applications in other parts, or even a higher dose in some areas). Or any resistance management strategies may need to be specified for national situations. Therefore, a national label in the local language should be presented to the national authority, if the product is to be sold in that country. (For the purposes of any ‘core’ assessment, it may still be useful to consider a specific national use alongside any relevant data for the entire authorization zone on related pests/targets).

Understanding/identifying conditions across the authorization zone

The applicant should consider the product and its use and determine which factors may be important in influencing

performance. The applicant should then identify the conditions that are present and likely to affect performance across the authorization zone. This may best be done using published information or expert advice (e.g. from local extension services within the authorization zone). A map or maps showing the variation of important conditions may be relevant. For example EPPO Standard PP 1/241 *Comparable climates* identifies areas across the EPPO region where climate is considered comparable. Other maps for example showing distribution of pest species, soil types or areas where the crop is grown and on which use is sought, may be relevant and aid both the applicant and evaluator in understanding the distribution of conditions across an authorization zone.

Such maps may assist the identification of locations where it is appropriate for specific trials to be conducted such that the relevant conditions are encountered in the trials. The objective is to ensure that trials are sited across the range of conditions that are encountered and especially in the more challenging situations prevailing (e.g. situations of high target pressure), and in the major areas of cropping of the intended use. As indicated in the section below, the product and its use determine which factors may be important.

The factors to be considered in the design of a trials programme and the location of trials

The key objective of a zonal trials programme is to ensure that the range of conditions likely to be encountered across the authorization zone is adequately addressed by the data. Trials should therefore be sited in situations covering the range of conditions but especially the extremes of conditions prevalent.

A list of the main conditions or factors that are relevant to the consideration of the performance of a plant protection product across an authorization zone of diverse conditions is provided in Appendix 1, with examples given of important considerations pertinent to each factor that might influence the results in an efficacy study. Such a list should be used as a guide and for any specific situation (i. e. plant protection product, pest and crop combination) other pertinent points may be applicable and should also be addressed (e.g. for fumigants intended for stored products, the gas-permeability of the structures to be treated is important).

It should be noted that some of these factors are only relevant to certain uses of plant protection products. In some cases they are interlinked: warmer temperatures tend to be associated with a higher number of generations of insect pests, and for some crops faster growth and different crop structures. Wet weather may be conducive to certain diseases; and soil type may influence cultivation and cropping practice and rotations, as well as more directly the activity

of soil applied plant protection products. As such, ensuring one range of conditions is met may result in another set of conditions for a different category also being met.

Climate

Including temperature and humidity, rainfall (frequency and intensity), light intensity. Climate has an overarching influence on cropping, on the crop growth and production system, and also on pest biology. Agroclimatic zones within the EPPO region are defined in EPPO Standard PP 1/241 *Guidance on comparable climates* which states that ‘when both the trial locations and proposed regions of use are within the same defined zone, then the applicant may simply refer to this guidance to establish climate comparability’.

Climate is relevant to the performance of the plant protection product both because the plant protection product itself may be affected by temperature, rainfall or light intensity, and because of the influence of climate on other aspects important in determining performance, such as the pest pressure (number of generations of insect pests, disease epidemiology, or weed and crop growth).

The applicant should consider how the climate and its interaction with these other factors might be important and ensure that the dataset addresses at least the extremes likely to be encountered in the authorization zone. This should include worst case situations where the active substance is most challenged and thus more likely to be adversely affected by the combination of climatic and other factors.

Pest related factors including resistance

Including pest pressure, number of generations, and sensitivity/susceptibility to the plant protection product. Pest pressure is likely to vary across an authorization zone. Most challenging situations are those where pest pressure is highest, number of generations are greatest and where, if there is a range of sensitivity of the target to the active substance, local populations are least susceptible. The applicant should explain how the pest challenge might vary across the authorization zone, and where relevant and available, maps can provide a useful means of illustration. Where information is available to indicate important differences in pest populations across the authorization zone which may affect pesticide performance (e.g. different resistance strains or populations) this should be provided in a clear manner, e.g. susceptibility of pollen beetle in Europe (Fig. 1).

A proportion of effectiveness trials should be sited in situations representative of the different challenges. For the different challenges, and especially for the most and least challenging situations, the use of different doses in the trials will enable a demonstration of the minimum effective dose and may also, if relevant, provide justification for different GAPs in different areas within an authorization zone. (See section on Minimum effective dose.) Information derived from baseline monitoring may also be used to pro-

vide evidence to substantiate the location of trials in areas where the target has different sensitivities to other plant protection products.

Regarding sensitivity information for resistance risk analysis, such information should generally be presented from a suitable distribution of locations across the authorization zone and where relevant, beyond the authorization zone. This should include locations of high plant protection product use and of low plant protection product use and from areas where resistance is known to be present to other plant protection products. Detailed information on sensitivity data is presented in PP 1/213 *Resistance risk analysis* (in section 6.5 Sensitivity data and Appendix 3).

Product and active substance related factors

Including mode of action/method of uptake (soil applied, foliar etc.), susceptibility to high or low temperature, persistence, degradation by light, pH.

The applicant should explain the mode of action and method of uptake of the active substance and product, including how it, and its performance, may be affected by specific conditions. This may be justified by the use of preliminary data. The properties of the active substance should be considered when designing a trials programme, and when considering the location of trial sites, to ensure that the sites chosen provide a range of challenges to the product so that its performance can be tested under different conditions.

Crop

Including crop structure and growth habit, varietal diversity and sensitivity to adverse effects, and dose expression.

Crop influence regarding effectiveness

Taken at the extreme, certain crops for which authorization is sought may not be grown in some parts of the authorization zone, clearly influencing trial site location. A map illustrating key crop growing regions may be helpful. Different cultural practices may lead to substantive differences in cropping and rotations, or in crop structure and these should be explained by the applicant.

EPPO Standard PP 1/226 *Number of efficacy trials* states that ‘More challenging situations would include, for foliar treatments, dense crops where good spray cover is difficult, and for herbicides non-competitive crops’. The applicant should consider and explain the diversity in crop production and crop growth to ensure that key differences and worst case situations are addressed in efficacy trials, and if relevant different doses are proposed. Varietal variability may be important especially where systemic foliar applied treatments are being tested. While it is important to ensure that a broad range of representative varieties are tested, this issue is more significant for crop safety assessments. For certain 3-dimensional crops, different dose expressions may be used on national labels, and recommendations for dosing

2010 Susceptibility Monitoring

Charts indicate proportion of populations belonging to each pyrethroid susceptibility category within each country. The number assigned to each chart indicates the number of populations utilised in each country survey.

- Highly resistant
- Resistant
- Moderately resistant
- Susceptible
- Highly susceptible

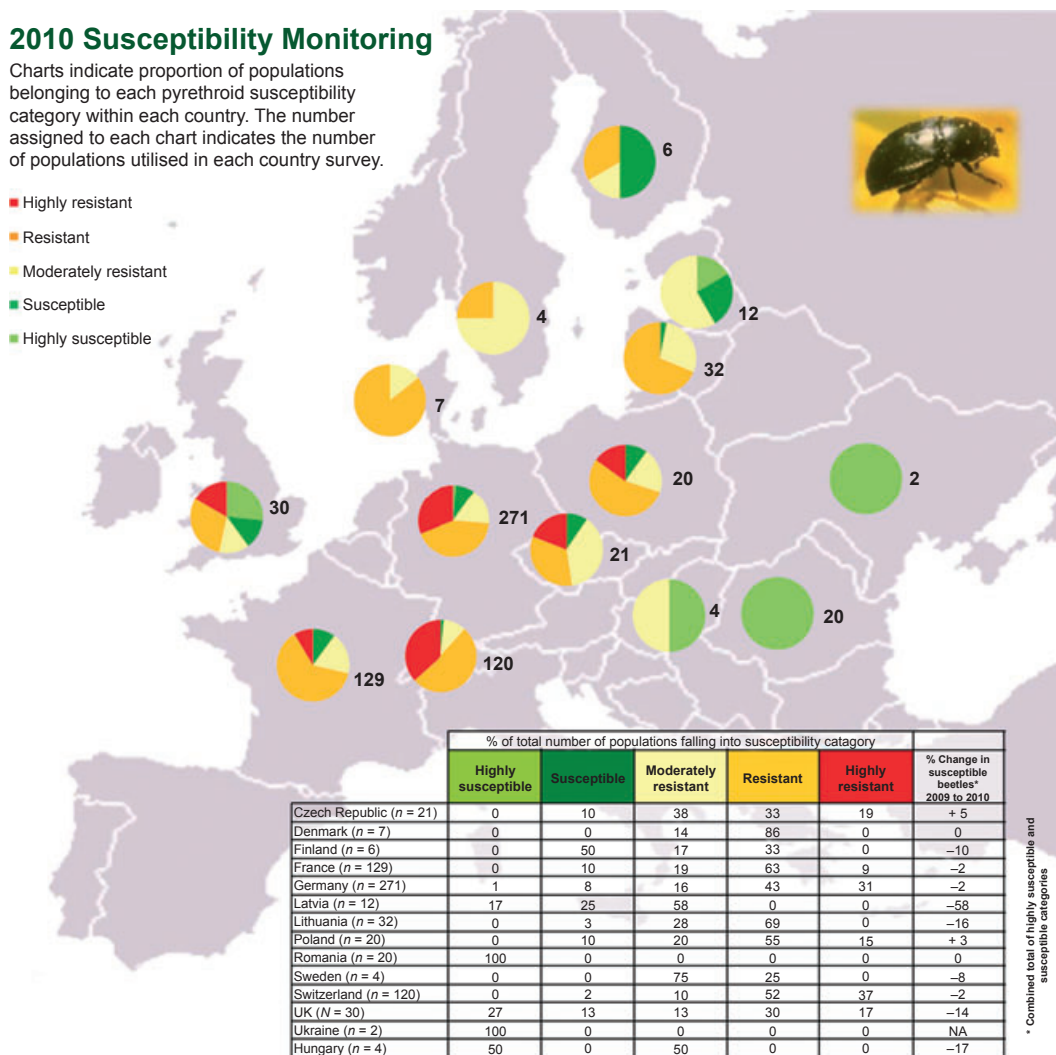


Fig. 1 Representation of the results of pyrethroids susceptibility monitoring of pollen beetle conducted by the Insecticide Resistance Action Committee (IRAC) – Oilseed Rape Pest Working Group.

should respect national requirements by the use of an appropriate conversion between doses. See EPPO PP 1/239 *Dose expression for plant protection products*. Different doses for the different cropping systems (or application systems) may be represented together on a master label, in order that appropriate doses and dose expressions can be authorized in respective countries.

Crop influence regarding crop safety

Crop safety trials should be sited on the crop in question, and in the major growing regions within the authorization zone where the pest occurs. Growing conditions influence crop growth and it is important to locate crop safety trials in situations that ensure a robust test of the product. These may be warmer situations where the crop is fast growing and thus foliage is more sensitive to crop damage, or slower growing situations where exposure of the treated

part of the crop may be more prolonged (e.g. for crop growth through soil treated with a pre-emergence herbicide). A data set covering the range of conditions should be provided. For varietal sensitivity a representative range of varieties should be tested and where there are substantive variations in variety across an authorization zone, special varietal trials may be an appropriate test methodology (see EPPO Standard PP 1/135 *Phytotoxicity assessment*).

For crop safety guidance, see specific EPPO Standards from the series PP1. In the absence of specific requirements or a specific EPPO Standard, see EPPO Standard PP 1/135 *Phytotoxicity assessment*.

Agronomy

Including cropping practice, crop structures, rotational crops, irrigation. In addition to the information presented

under 'crops' above, the potential for substantial variation in agronomic practices, including those associated with crop husbandry, across an authorization zone makes it important that the applicant and evaluator consider this diversity and ensure that when used as directed on the product label the plant protection product will perform both effectively and safely. The applicant should consider and explain the diversity across the region, and consider how this relates to the product in question. For example, irrigation used in some parts of an authorization zone may influence crop (and weed) growth, product uptake and availability, and of course epidemiology of diseases. Depending on the plant protection product and its use pattern it may be relevant to ensure some testing is conducted on irrigated crops. Differences in rotational cropping may require different specific rotational crop testing for certain areas within the authorization zone where testing indicate a risk of damage.

Similarly, potential adjacent crops across the authorization zone should be considered and evidence or justification of safety to at least the most sensitive crops should be provided. In such situations, and especially for fungicides and insecticides, preliminary evidence may form the basis of the justification.

Edaphic conditions

Including soil texture, soil moisture, soil porosity, organic matter content, and ability to achieve seedbed condition.

Soil conditions are relevant for a range of plant protection product types including soil acting herbicides, granular insecticides and other soil treatment products, and also to seed treatments and some vertebrate control agents. The applicant should provide information relating to the product mode of action, performance, and how it may be affected by soil type, and by using this information, ensure that trial sites are located where representative soil types are present that challenge the product performance.

For products where there are particular impacts on succeeding crops which warrant requirements to cultivate prior to subsequent cropping, the applicant should consider the relevance to the conditions occurring across the authorization zone and ensure any proposed wording is practical and achievable. There may be a need for specific testing based on typical crop rotations found within the authorization zone. EPPO Standard PP 1/207 *Effects on succeeding crops* provides further detail on the testing methods to determine the effects on succeeding crops.

Where soil types or conditions are such to impact on performance, specific label wording may be required to ensure adequate advice is presented to users of the product.

Use of extra-zonal data

Data from outside the authorization zone, or beyond the EPPO region, may still be relevant to supporting the use of

the plant protection product. EPPO Standard PP 1/269 *Comparable climates at a global level* may provide information on the climatic relevance of such data, and the applicant should provide a justification of the relevance of other conditions to areas within the authorization zone. Such data may be informative in adding to a data set, confirming efficacy in conditions relevant to some parts of the authorization zone, or even confirming efficacy in conditions which may be a more extreme test than those encountered within the authorization zone.

As a general principle, data from a wider area and more diverse conditions can give greater confidence in performance or any limitations on performance, than data from only those situations and conditions arising within the authorization zone.

Numbers of trials

In this text no attempt at being prescriptive in the number of trials required to support a zonal authorization is made. Such information is left to EPPO Standard PP 1/226 *Number of efficacy trials*.

With the information also presented in EPPO Standard PP 1/181 *Conduct and reporting of efficacy evaluation trials, including good experimental practice*, it is reasonable to consider that a series of generally 10 trials (range: 6–15) conducted over at least 2 years is sufficient to demonstrate efficacy against a major target species across an area with distinct conditions. This might be interpreted as a country or a justifiably homogenous area.

In the context of a zonal data set, and as indicated above, it may be expected that the variation in agricultural climatic and environmental conditions would be greater across an authorization zone (as defined in this Standard) than within a country. Moreover, it is to be expected that there will be greater variation in a range of other factors discussed in this document and as such a greater number of trials will be required. That number will be dependent on the following high level factors:

- The susceptibility or resilience of the active substance to diverse conditions.
- The variation in the conditions across the authorization zone.
- The consistency in performance across the conditions.
- Variation in pest susceptibility across the authorization zone.

The number of trials should be sufficient to cover the extremes of conditions encountered in the authorization zone as well as the main areas where the target is a significant pest problem on the crop in question. As a general guide, some 40–50% of the trials might be conducted in the major growing region of the crop and where use is intended. The remainder may be placed in the extremes of the conditions, with greater emphasis of trials in the more challenging conditions (perhaps 30–40%) and less emphasis (perhaps 20%) in the least challenging.

In line with the principles of EPPO Standard PP 1/226 *Number of efficacy trials*, minor uses and secondary targets can be addressed by reduced datasets, but again trials should be located to cover the diversity of conditions encountered, and especially the more challenging.

In published case studies (Sunley & Zlof, 2011), guidance on numbers of trials, and the justification for them is presented for a series of realistic scenarios.

Situations of more limited diversity

For certain uses of plant protection products, the diversity of conditions encountered is likely to be more limited. For example, use of plant protection products in stored grain or other storage situations, and in protected conditions where crops may be grown in controlled conditions perhaps using artificial growing media. Article 33 of EC Regulation 1107/2009 considers that in the case of an application for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, the whole of the EU area is considered as one authorization zone.

In situations where the diversity of conditions is likely to be more limited compared to conventional outdoor plant protection, the applicant should still consider and identify the different conditions likely to be encountered in the authorization zone. Testing of the product should occur in extremes of the conditions encountered to ensure performance across the range of conditions. As previously mentioned in some situations precautionary label warnings may be required (e.g. to advise users of possible reduced efficacy where fumigants are used for treatment of leaky rather than gas tight storage premises) or for example different doses against the main target species may be required if there are substantive differences in sensitivity. In the case of seed treatments, these are subject to the wide range of soil types and climatic conditions present across the authorization zone, as well as to variation in pest pressure and sensitivity. As such, it is considered that these treatments are more similar to conventional foliar plant protection products and a trials series should encompass the diverse conditions encountered in the authorization zone.

Some crops may be grown both indoors and outdoors in the same zone. In such situations and because of the difference in conditions that protection can bring, efficacy testing should be conducted in both situations although data from one condition may be relevant to the other (especially where those conditions result in a more severe challenge to performance).

Minimum effective dose

EPPO Standard PP 1/225 *Minimum effective dose* describes the criteria, as well as the experimental procedure for determining the minimum effective dose of a plant protection product.

Across an authorization zone where there may be substantial variation not only in climatic and environmental conditions, but also in agronomy and crop structures, and in pest pressure and its sensitivity to a plant protection product, there may be variation in the minimum dose required for effective control of a given target on a crop for those different conditions.

The applicant may already be aware of differences that might result in the requirement for different doses against a target (for example if a reference product is authorized at different doses in different countries for the same target), and these should be taken into account in the design of the trials series across the authorization zone. Alternatively the effectiveness trials may show differences in performance for certain conditions, and may warrant different doses.

EPPO Standard PP 1/225 *Minimum effective dose* requires that in order to establish the minimum effective dose, at least 1 lower dose than that which is to be recommended should be included in some trials. Where performance may be affected by the variation across the authorization zone, it is recommended that more than 1 additional dose than that proposed be included in some of the trials. In this way the applicant may be able to provide both sufficient data to demonstrate effectiveness of the appropriate dose for a given set of conditions as well as justify the dose proposed.

Therefore, where appropriate, and supported by data or reasoned argument, a different dose may be proposed on an individual National label for the same target. Further, the main target may differ on the same crop in different areas within the zone, so it is important to ensure that data supporting minimum effective dose are generated on an appropriate range of target pests or pest pressure within the crop. The applicant should explain/give an overview on what the proposed strategy is in terms of rates e.g. 1 dose for the same target across the zone, or proposals (and justification) for varying doses regionally within a zone.

Use of reference products in a zonal data set

To facilitate comparison of data produced in different conditions across a zone, it is preferable that the same reference product should be used in the trials. However, it is acknowledged that in a large zone spanning several countries, this may not be possible if the reference product is not authorized for the same uses and rates in all those countries. In such situations an alternative reference product may need to be used. It may be beneficial to include both reference products in some trials for comparative purposes if this is permitted by available authorizations. It is important to note that one of the purposes of a reference product is to indicate the validity of the trial.

In designing a trial series and considering conditions across an authorization zone, the applicant may observe that

a proposed reference product is authorized at different doses for the same target crop combination. Such variation in dose should be considered by the applicant when designing the trials series and considering the dose of the proposed plant protection product.

With regard to the use of reference products for trials to support formulation changes, see EPPO Standard PP 1/New (in preparation) *Efficacy considerations when making changes to the chemical composition of plant protection products*.

Other situations where a zonal approach may be appropriate

This standard, as well as other existing EPPO Standards, focuses predominantly on the efficacy considerations that might be relevant for the development of new active substances for use as a plant protection product. However, in addition to such activity, companies continue to extend uses or develop new formulations of existing plant protection products and to provide alternative methods of application to facilitate effectiveness and practical application in crop protection (e.g. granular rather than sprayable formulations).

While it is necessary to demonstrate effectiveness of new products and formulations of already authorized active substances, there will be a substantial knowledge base available from the trials supporting the existing plant protection products. This may be used to inform and influence the efficacy testing required for any new product or formulation. PP 1/226 *Number of efficacy trials* indicates that in such situations, bridging⁴ between existing and proposed plant protection products may enable a reduction in the number of trials required.

The same principles identified in this standard and in EPPO Standard PP 1/226 *Number of efficacy trials* should be adopted when comparing formulations across a broad range of conditions within an authorization zone. As such bridging trials comparing the 2 products/formulations may be appropriate with trials located in the extremes of the conditions. In such trials, good evidence enabling the comparison of performance can be achieved by the inclusion of a dose of the product that is substantively lower than the currently authorized and proposed doses. The use of bridging trials may facilitate a more limited dataset although further testing may be required where comparability between 2 formulations is not demonstrated in certain conditions. More detailed information on the number of trials required for the demonstration of comparability between formulations including new formulations of currently approved

⁴Bridging is the use of efficacy tests in which the performance of the existing and new plant protection product is compared across representative uses to enable a judgment on the relevance of the dataset available for the existing plant protection product to be used for the new plant protection product.

active substances is contained in EPPO Standard PP 1/226 *Number of efficacy trials*.

Elements needed for a decision

In order to reach a decision on whether the plant protection product proposed should be registered, the registration authority should satisfy itself that the information on efficacy presented by the applicant is adequate to ensure that:

- The conditions across the authorization zone relevant to the performance of the product have been identified.
- Trials have been conducted across the range of conditions to demonstrate efficacy, including the most challenging conditions.
- Results of trials have been summarized such that the performance across the different conditions can be determined.
- A label to reflect the proposed use where efficacy is demonstrated has been drafted.
- Impairments on efficacy (either effectiveness or crop safety, or other adverse effects) arising from the conditions across the authorization zone are made clear, or limitations on use are made clear on the label.
- The dose proposed for any target, which may include different doses for different conditions, has been adequately justified.

References

- 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.
- Sunley R & Zlof V (2011) Report of the EPPO workshop on zonal efficacy assessments (Berlin, DE, 2011-04-05/06). *Bulletin OEPP/EPPO Bulletin 41*, 157–169.

Appendix 1

Checklist of key factors to be considered

Climate

- Temperature and humidity.
- Rainfall (frequency and intensity).
- Light intensity.

Pest related

- Geographical distribution.
- Pest pressure.
- Number of generations.
- Sensitivity/susceptibility to the plant protection product.

Product and active substance related

- Mode of action/method of uptake (soil applied, foliar etc.).

Susceptibility to high or low temperature.

Persistence.

Degraded by light, pH.

Crop

Crop structure and growth habit.

Varietal diversity and sensitivity to adverse effects.

Dose expression.

Agronomy

Cropping practice.

Crop structures.

Rotational crops.

Irrigation.

Application technique.

Building structure (e.g. construction, building materials, controlled atmosphere, leak tightness)

Edaphic conditions

Soil texture.

Soil moisture.

Soil porosity.

Organic matter content.

Ability to achieve seedbed condition.

Appendix 2

Examples of data requirements to support specific pest-crop-zone combinations

Examples of data requirements to support specific pest-crop-zone combinations are available on the EPPO website at http://www.eppo.int/PPPRODUCTS/zonal_efficacy/zonal_efficacy.htm.