

Examples of zonal efficacy evaluation

Clarification of efficacy data requirements for the authorization of an insecticide against aphids, thrips and whiteflies in ornamental plants in greenhouses in the EU

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This document is intended to assist applicants and evaluators to interpret EPPO Standard PP 1/278 *Principles of zonal data production and evaluation*. Expert judgement should be applied in all cases.

The focus of this paper is in particular on the number and location of trials for the justification of effectiveness, phytotoxicity and resistance issues. There is a need to provide clarification of these areas as part of the zonal authorization process for plant protection products (as defined in EU Regulation 1107/2009 (EC, 2009)).

Regulation EC 1107/2009 specifies that the assessment of plant protection products should be conducted on a zonal basis. Article 33 of EC 1107/2009 considers that in the case of an application for use in greenhouses, only one Member State evaluates the application, taking account of all zones.

All trials should be carried out under Good Experimental Practice (GEP) and using all relevant general EPPO Standards. Efficacy trials should be performed according to relevant EPPO Standards PP 1/23 *Aphids on ornamental plants*, PP 1/160 *Thrips on glasshouse crops* and 1/36 *Whiteflies* (*Trialeurodes vaporariorum*, *Bemisia tabaci*) *on protected crops* (available at <http://pp1.eppo.int/>).

The most common and harmful sucking insects in ornamental plants are aphids, thrips and whiteflies and this example applies only to them.

All tests should be carried out with the formulation of the product intended for use. If other formulations were used such data may still be used to support the proposed formulation, however bridging data or a sound scientific justification should be supplied to demonstrate comparability of the formulations and allow bridging between formulations. See EPPO Standard PP 1 (in preparation) *Efficacy considerations and data generation when making changes to the chemical composition of plant protection products*.

Trials should be carried out across a range of conditions likely to be encountered, and over at least two years. Trials submitted to demonstrate effectiveness should contain challenging levels of pest. Pest-free or trials with low pest pressure may be used to support crop safety.

This example can be used for plant breeding crops and basic seed production for arable, vegetable and fruit crops, herbs and ornamental crops. This example is not to be applied for tuber and bulb production, because effectiveness data will normally be generated under field conditions and extrapolated to the protected conditions. If there is a full set of data on potted plants and cut flowers under protected conditions, this data can be used to support the use of the plant protection product on tuber and bulb flower production under protected conditions.

Definitions

Greenhouse

In Regulation EC 1107/2009 ‘greenhouse’ is defined as follows: ‘greenhouse’ means a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment. For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or endives) are also considered as greenhouses.

Ornamental plants

To make clear which crops are meant by ‘ornamental plants’ harmonization of crop grouping within the EU should be developed. For this paper the crop grouping used in the Netherlands is used as a starting point¹ (see Table 1).

Table 1 Overview of the group of ornamental plants²

Ornamental plants	Flower bulb and flower tuber crops flower bulbs and flower tubers (cultivation for reproduction) <ul style="list-style-type: none">- bulb flowers and tuber flowers (flower cultivation)
	Floriculture crops <ul style="list-style-type: none">- pot plants (including annual bedding plants)- cut flowers (including summer flowers, dried flowers, bulb and tuber flowers) forced shrubs- cut green
	Tree nursery crops
	Perennial crops
	Flower seed crops
	Marsh and Water plants

General information

The EU Zonal Rapporteur Member State (zRMS) and Concerned EU Member states (cMS) where a product authorization is sought should be named, together with the relevant EPPO climatic zones. Where the product/formulation is already authorized in countries, information should be provided about the insecticide (e.g. active substance, content, type of formulation), the current registration situation and the registration history in the zRMS and the cMS. Some information should be provided about the active substance(s) (e.g. approval status, mode of action, uptake and transport in the plant, behaviour in the soil, IRAC classification).

Information on the pest

Aphids, thrips and whiteflies are considered to be major pests.

Aphids

Aphids affect ornamental plants by sucking from the phloem of the vascular bundles often on young shoots and leaves. Plant parts affected by aphids will wilt, discolour or deform. Aphids also secrete sticky honeydew often resulting in sooty mould. Some aphids transmit viruses. Common species on ornamental plants include the polyphagous *Aphis gossypii*, *Aulacorthum circumflexum*, *A. solani*, *Myzus ornatus*, *M. persicae*, *Macrosiphum euphorbiae*, *M. rosae* and *Macrosiphoniella sanborni*.

^{1,2} Definition list of areas of application for plant protection products [DTG] (in Dutch) <http://www.ctgb.nl/>

Thrips

Larvae and adult thrips feed on the epidermal cells of leaves, buds and flowers, giving leaves a silvery appearance or causing malformation and discoloration (on buds and flowers). The native species *Thrips tabaci* and *T. fuscipennis* as well as the introduced American species *Frankliniella occidentalis* are the most common and serious pests infesting ornamental plants in Europe. *F. occidentalis* can transmit viruses and has frequently developed resistance to insecticides.

Whitefly

Trialeurodes vaporariorum is very common worldwide in glasshouses, and *Bemisia tabaci* has become so in recent years. Whiteflies extract food from the plant which influences the plants physiological processes, and can cause growth reduction. Bigger larvae secrete honeydew whilst feeding, on which sooty mould develops. Larvae produce large amounts of wax on and around their dorsal surface. These substances soil the crop reducing the economic value. Viruses may also be transmitted.

Information on ornamental production in EU

The protected production of ornamental plants mainly occurs in the Central and Southern authorization zones of the EU. The main countries for the protected production of ornamental plants in the Central authorization zone are: the Netherlands, Germany, the Czech Republic, the United Kingdom and Belgium. The main production countries for the southern authorization zone are Italy, Spain and France³. Further information on wheat production is available from the Eurostat website and also the Belgium paper on EPPO zonal webpage⁴. However, the applicant should always make sure to use reliable and the most updated source of information.

Intended Use(s)

The applicant should clearly describe the details of the recommended use for each country where registration is sought. (See EPPO Standard PP1/240, *Harmonized basic information for databases on plant protection products* particularly points 15 - 34).

³ Source: Eurostat

⁴ http://www.eppo.int/PPP/PRODUCTS/zonal_efficacy/zonal_efficacy.htm

Number and distribution of trials required for an authorization

Effectiveness ((6.2) Commission Regulation 284/2013), (OECD KIIIA1 6.1.3)

To support an authorization for the whole group of ornamental plants in the EU, more than the EPPO recommended number of trials results (6-15) will be needed.

The EPPO Standard PP 1/278 *Principles of zonal data production and evaluation* states that for certain uses of plant protection products, the diversity of conditions encountered is more likely to be limited. For the use of plant protection products in protected conditions, where crops may be grown in controlled conditions perhaps using artificial growing media, diversity of conditions may be limited. 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 (growing) conditions likely to be encountered across all zones in which authorization is to be sought. Testing of the product should occur in extremes of the (growing) conditions encountered to ensure performance across the range of (growing) conditions.

Distribution and number of trials

The protected production of ornamental plants mainly occurs in the Maritime EPPO climatic zone and in the Mediterranean EPPO climatic zone. In crops grown under protected conditions, climate conditions like temperature and relative humidity can, to a certain extent, be controlled by heating or cooling. Still, differences in climate and growing conditions can occur between protected crops grown in different regions e.g. between crops grown in greenhouses and crops grown under plastic tunnels, differences in cropping systems, type of substrate and differences in light intensity. It is not necessary to spread the trials over the whole claimed region, but testing of the product should occur in extremes of the (growing) conditions encountered to ensure performance across the range of (growing) conditions. The applicant should clarify his choice for certain locations.

When planning the number and distribution of trials required for an authorization in the whole EU trials should preferably be carried out in the two regions where the protected production of ornamental plants mainly occur (central authorization zone: the Netherlands, Germany, the Czech Republic, the United Kingdom or Belgium and southern authorization zone: Italy, Spain or France). A minimum of 8 fully supportive trials per target crop-target pest combination, per region (a total of 16 trials per crop-pest combination) should be carried out (Figure 1). It is important in these trials that pest develop to challenging levels in the untreated plots. When trials are conducted in only one region, a reasoned case should be made by the applicant to justify why the data available are directly relevant to the (growing) conditions in the other region (e.g. warmer temperatures tend to be associated with a higher number of generations of insect pests, although e.g. aphids might stop development at high temperature). Also a good description (or photographs) of the greenhouses used in the trials, should be available in order to assess the comparability of trials carried out in the central authorization zone and the southern authorization zone.

Target crops and target pests

The group of ornamental crops consists of a wide range of different crops. To prove the effectiveness of the intended dose against aphids, thrips and whiteflies, trials needs to be conducted on target species and target crops. From results of trials conducted on target crops and target pests extrapolations to other pests and crops are possible. Relevant extrapolation

tables are not available at this moment. For this paper the extrapolation tables used in the Netherlands and the SANCO document (SANCO/D3/SI2.395857) are used as a starting point. An overview of relevant extrapolations (including target crops and target pest species) can be found in Appendix 1.



Figure 1. Visualization of the planning of trials for ornamental plants under protected production.

***The EPPO climatic zones: please note that the borders are intentionally broad indicating that there is an area of gradual change in climate between the zones proposed (as defined in EPPO Standard PP 1/241 *Guidance on comparable climates*).**

Minimum Effective Dose (6.2) (OECD KIII A1 6.1.2)

The claimed dose rate(s) should be justified by including at least one dose below the recommended one (e.g. 0.5N) in a number of trials. The claimed dose rate(s) needs to be justified for all claimed uses. Trials may be conducted on target crops and target pest species. The majority of data should be generated where pest pressure is highest, but a proportion of trials should still include areas of more variable pest pressure. Trials should be conducted in accordance with EPPO Standard PP1/225 *Minimum effective dose*.

Resistance (6.3) (OECD KIII A1 6.2.8)

Most sucking insects are considered high risk targets, very likely to develop resistance. Therefore sensitivity data should be generated when high risk target species like the aphid species *Aphis gossypii*, the thrips species *F. occidentalis* or the whitefly *B. tabaci* are exposed. These data allow a measure of sensitivity shift and resistance development in future. Populations need to be tested with standardized methods (e.g. IRAC recommended methods). Samples from regions with known resistance to other actives should be tested for cross resistance as well as some samples from regions where such resistance is not expected.

A resistance management option has to be presented. Detailed resistance management strategies will often need to be country specific.

Phytotoxicity to target plants (including different cultivars), or to target plant products (6.4.1) (OECD KIIIA1 6.2.1, 6.2.5, KIIIA-6.1.4.1-3)

As a general principle, insecticides and fungicides would be expected to have low herbicidal activity with limited adverse effects on the target plant. However, because of the high cosmetic value of the crop, the great variety within the group of ornamental plants and the sensitivity of the group of ornamental plants for plant protection products, separate selectivity trials should be conducted. The selectivity trials are primarily designed to assess possible phytotoxicity to the crop in the absence of pests, and include the dose specified for the intended use and a higher dose (usually the double dose to allow for spray overlaps in practical conditions).

The crop should be examined for the presence of phytotoxic effects or visible remains of the product. Trials should preferably be conducted in a period with low natural light levels on a flowering crop. For plants under protected conditions this is a “worst case” circumstance, because plants in that period are most sensible for phytotoxicity symptoms and in general flowers are most sensitive and effects on the flowers have a great impact on the cosmetic value of the crop. Information of phytotoxicity of at least three different sensitive cut flower species and three different sensitive potted plant species, with two acceptable trials per crop are required (a total of 12 trials). Trials should be conducted on different varieties. A sensitive variety has to be chosen when there is a difference between varieties in sensibility for phytotoxicity. Appendix 2 gives an overview of sensitive ornamental species. Several of the test crops can be grown as a cut flower or as a potted plant (e.g. rose and chrysanthemum). However, those crops should not be tested as a cut flower and as a potted plant. Data on one or the other should be sufficient as extrapolation between the two types of the same crop is acceptable.

When phytotoxicity is found in the trials, it may be necessary to perform additional trials. In some situations precautionary label warnings may be required. Observation for phytotoxic effects should also be made in all effectiveness trials.

Impact on treated plants or plant products to be used for propagation (6.4.5) (OECD KIIIA1 6.2.5)

EPPO Standard PP 1/135 *Phytotoxicity assessment* provides an indication of the circumstances under which data on plant parts for propagation are required.

Impact on other plants, including adjacent crops (6.5.2) (OECD KIIIA1 6.2.7)

The decision frameworks in EPPO Standards PP 1/207 *Effects on succeeding crops* and PP 1/256 *Effects on adjacent crops* should be followed when addressing these points.

Effects on beneficial and other non-target organisms (6.5.3) (OECD KIIIA1 6.2.4)

When there are claims for use as part of an Integrated Pest Management Strategy, special trials may be required on a national basis for insecticides in ornamental plants. Relevant data produced for the Ecotoxicology section 9.5 or existing IOBC classifications for the active substance may be used.

Extrapolation to other crops

Harmonized extrapolation tables need to be developed within EPPO. For this paper the extrapolation tables used in the Netherlands⁵ and the SANCO document produced by the PSD (SANCO/D3/SI2.395857) are used as a starting point. An overview of relevant extrapolations can be found in Appendix 1.

The extent of extrapolation within or between crops is largely dependent on the use of the product, known sensitivity of the target crop and/or growth stage, and the depth of existing knowledge. If the results of tests on at least three species of cut flowers and three species of potted plants are satisfactory, extrapolation to all other floriculture crops, nursery crops and perennials is acceptable.

Extrapolation to nursery crops and perennials is possible because in general these crops are less sensitive for phytotoxicity compared to protected floriculture crops. In addition, extrapolation to protected breeding plants and seed production plants of arable and vegetable crops is acceptable.

However, in the case of such seed crops, safety to germination of the harvested seed should be specifically investigated in separate trials, unless there is considerable practical experience that no adverse effect is likely.

⁵ Possibilities for the Extrapolation of Efficacy and Crop Safety Data of Plant Protection Products, Version 1.0, January 2013.

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) 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

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:093:0085:0152:EN:PDF>

OECD Guidance Documents for Pesticide Registration

<http://www.oecd.org/env/ehs/pesticides-biocides/oecdguidancedocumentsforpesticideregistration.htm>

SANCO/D3/SI2.395857 Proposal for extending and harmonizing efficacy and crop safety extrapolations to reduce the need for efficacy trials on minor crops, Final Report, October 2005, European Commission (DG SANCO)

http://ec.europa.eu/food/plant/protection/resources/minorcrops_safety_en.pdf

Definition list of areas of application for plant protection products [DTG] (in Dutch)

<http://www.ctgb.nl/>

Possibilities for the Extrapolation of Efficacy and Crop Safety Data of Plant Protection Products, Board for the Authorisation of Plant Protection Products and Biocides, Wageningen, The Netherlands, January 2013. Version 1.0, January 2013

http://ctgb.suneco.nl/docs/default-source/Evaluation-Manual-PPP-part-NL/appendix_e_extrapolation_document_translation_versie_3_2012.pdf?sfvrsn=2

Appendix 1

Target pests and target crops for floriculture crops (SANCO/D3/SI2.395857, Dutch document on extrapolation possibilities and expert judgement)

Aphids

Target Pest		Target Crop	
From	To	From	To
<i>Aphis gossypii</i> APHIGO <i>Myzus persicae</i> MYZUPE <i>Myzus ascalonicus</i> MYZUAS <i>Macrosiphum rosae</i> MACSRO <i>Macrosiphum euphorbia</i> MACSEU <i>Brachycaudus helichrysi</i> ANURHE <i>Aphis fabae</i> APHIFA	Same species in other floriculture crops	<i>Dendranthema x grandiflorum</i> CHYHO (cut flower or potted plant) or Hibiscus 1HIBG or Rose (cut flower or potted plant)	Other floriculture, nursery crops, perennials, breeding/seed crops of arable and vegetables under protected conditions
<i>Aphis gossypii</i> APHIGO + two of above species (<i>A. gossypii</i> is most difficult to control of above species)	all aphids species on floriculture crops		

Whitefly

Target Pest		Target Crop	
From	To	From	To
<i>Bemisia argentifolii</i> BEMJAR	<i>Trialeurodes vaporariorum</i> TRIAVA Confirmatory data required on <i>T. vaporariorum</i> in those MS where <i>B. argentifolii</i> is not indigenous	Poinsettia (e.g. EPHPU) or Gerbera 1GEBG (cut flower or potted plant)	Other floriculture, nursery crops, perennials, breeding/seed crops of arable and vegetables under protected conditions

Thrips

Target Pest		Target Crop	
From	To	From	To
<i>Frankliniella occidentalis</i> FRANOC	<i>Thrips tabaci</i> THRITB and other native thrips species	<i>Dendranthema x grandiflorum</i> CHYHO or <i>Saintpaulia</i> 1SNPG	Other floriculture, nursery crops, perennials, breeding/seed
<i>Echinothrips americanus</i> ECHTAM	Requires separate testing because less susceptible than other thrips species	<i>Spathiphyllum</i> 1SQFG or <i>Dieffenbachia</i> 1DIFG	arable and vegetable crops under protected conditions

Appendix 2

Reference sensitive ornamental species (SANCO/D3/SI2.395857 and Dutch document on extrapolation possibilities)

Reference sensitive ornamental species

Cut flowers	EPPO code	Potted plants	EPPO code
<i>Lisianthus (Eustoma)</i>	1LJSG (1EVMG)	<i>Begonia</i>	1BEGG
<i>Rosa</i>	1ROSG	<i>Fuchsia</i>	1FUCG
<i>Dendranthema x grandiflorum</i>	CHYHO	<i>Ficus benjamina</i>	FIUBE
<i>Gerbera</i>	1GEBG	<i>Saintpaulia</i>	1SNPG
<i>Dianthus</i>	1DING	<i>Exacum</i>	1EXUG
<i>Gypsophila</i>	1GYPG	<i>Cyclamen</i>	1CYZG