

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

PP 1/241 (2)

Efficacy evaluation of plant protection products Evaluation biologique des produits phytosanitaires

PP 1/241 (2) Guidance on comparable climates

Specific scope

This Standard provides guidance to regulatory authorities and applicants in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials on plant protection products are performed. It describes in particular four climatic zones in the EPPO region, within each of which climatic conditions may be considered comparable.

Specific approval and amendment

Proposed for approval in 2005–09.

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

Introduction

The main purpose of EPPO Standards on the efficacy evaluation of plant protection products is to harmonize the process of efficacy evaluation within the registration procedures of EPPO member countries by describing how field trials should be conducted. Recently, these standards have taken on formal importance within the registration process of the European Union, through their adoption under EC Regulation 1107/2009 (EC, 2009) and Commission Regulation (EU) 284/2013. This includes the requirement that organizations conducting, developing and carrying out efficacy and phytotoxicity trials in EU member states are official or officially recognized.

The published EPPO Standards have also facilitated an important secondary aim, which is to use data generated in one country to support registration in another country. Since the introduction of EC Regulation 1107/2009 (EC, 2009), applicants in the EU and EPPO generally are now beginning to generate data for the efficacy dossier on products on a Europe-wide basis. In addition, there is a specific provision under Article 40 of the Regulation for the mutual recognition of authorizations from other Member States. In establishing a Europe-wide dossier or in mutual recognition, not only should trials be conducted according to harmonized procedures, but the applicant and the registration authority should be able to establish the relevance of the data under local conditions, i.e.

whether the appropriate conditions (see below) are comparable in the countries concerned, particularly in relation to climate.

This Standard aims to assist both regulatory authorities and applicants in determining the comparability of conditions between given areas. It specifically addresses the issue of climate and presents agreed defined zones in the EPPO region within which conditions are considered climatically comparable. Applicants can use this Standard by referring to these defined zones rather than making a detailed case involving the submission of meteorological data. Resources are saved for all parties, as such cases will not have to be re-submitted with each application. Further information on how the zones were defined is provided by Bouma (2005).

Climate is only one factor that may affect the efficacy and crop safety of a product. The applicant still needs to address any other relevant factors (agronomic, edaphic, target-related) when establishing the relevance of data generated within different countries. The relative importance of each condition will depend on various factors including mode of action of the active substance, formulation type and intended use.

Finally, it is very important to remember that, even when climatic conditions are not comparable, use of the data may still be acceptable, as it may be possible to argue that the identified differences represent a more challenging situation, and the data can therefore be accepted for evaluation.

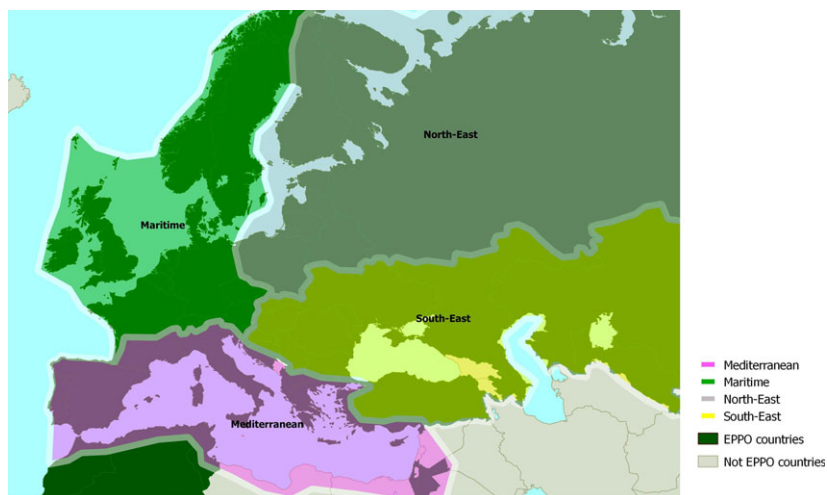


Fig. 1 Zones of comparable climate in the EPPO region for the purposes of efficacy evaluation trials on plant protection products. The borders are intentionally broad indicating that there is an area of gradual change in climate between the zones proposed.

Use of this Standard

General

Typically, the meteorological data reported in efficacy evaluation trials conducted following EPPO Standards provides a basis for acceptability of trial results. It is for the applicant to justify the relevance of this meteorological data, but generally the closer the locality of the trials to the proposed region (i.e. the country where a given plant protection product is intended to be used and where the applicant is seeking registration), the more likely the trial results are to be acceptable.

This Standard describes zones of comparable climates. 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.

Defined zones

The zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region (Bouma, 2005). The conclusion is that the following four zones are appropriate¹: the Mediterranean zone, the Maritime zone, the North-East zone and the South-east zone.

- the *Mediterranean zone* includes the countries or parts of countries around the Mediterranean sea, together with Jordan, Macedonia and Portugal
- The *Maritime zone* is the zone north of the line from the coastal zone of south-west France, through Lyon (France), to the south border of Switzerland and Austria, west of the border between Austria and Hungary, west of the border between the Czech Republic and Slovakia,

west of the river Oder (between Poland and Germany). This zone also includes Ireland, Sweden and the UK;

- The *North-east zone* is the zone in the north-eastern part of Europe: the countries and the regions east of the river Oder (between Poland and Germany), north of the border between the Czech Republic and Poland, west of the border between Poland and Ukraine, north of the border between Ukraine and Belarus, the Russian Federation north of 50° latitude;
- The *South-east zone* includes Bosnia-Herzegovina, Bulgaria, Croatia, Hungary, Moldova, Romania, the Russian Federation south of 50° latitude, Slovakia, Slovenia, Serbia and Montenegro, Turkey, Ukraine, except the Mediterranean coastal zones.

These zones are presented in Fig. 1, which also indicates that there is an area of gradual change in climate between the zones proposed.

Data from other zones may in any case be considered acceptable if the actual prevailing conditions are comparable.

Other factors relevant to the use of data generated in different areas

Climate is only one factor in establishing the relevance of data from one region to another. Below are some of the other conditions which may be considered. It is not possible to provide a prescriptive list as this will depend on the individual circumstances of use, mode of action, physical and chemical properties of the product. Instead, the case for comparability should focus on those factors relevant to the product that may affect performance or crop safety, and on the biology and pathogenicity of the target.

Edaphic conditions

For soil-applied products, it is important to consider soil types, organic matter content and pH. In addition it may

¹Mountain areas above 1000 m altitude are not taken into account in the agro-climatic zones.

also be important to consider soil moisture content/deficit during the growing season.

Agronomic conditions

Cultural conditions and agronomy (e.g. crop rotation, cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) may need to be considered if it is thought that these differ between the areas concerned.

Differences in biology and pressure of target pests

It will sometimes be necessary to consider specific details on the target pest, and whether the conditions encountered in other areas are likely to represent a harsher or less harsh test of the product (for both effectiveness and crop safety). Such detail would include differences in the epidemiology

of diseases, population dynamics of insects and other pests, and differences in races of organism to be controlled. The resistance status of the target pest in the relevant areas should be considered.

References

- Bouma E (2005) Development of comparable agro-climatic zones. *Bulletin OEPP/EPPO Bulletin* **35**, 233–238.
- 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.
- EC (2013) 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. *Official Journal of the European Union* L93, 85–152.