

Efficacy evaluation of plant protection products
Evaluation biologiques des produits phytosanitaires**Comparable climates on a global level****Specific scope**

This standard provides guidance to regulatory authorities and applicants in the EPPO region in determining comparability of climatic conditions between geographical areas on a global level, where efficacy evaluation trials on plant protection products are performed. The comparable global climatic areas are linked to the four comparable climatic zones in the EPPO region. Further information about how these zones were defined is provided by Bouma (2005).

Specific approval and amendment

First approved in 2010–09.

Introduction

As described in EPPO Standard PP 1/223 *Introduction to the efficacy evaluation of plant protection products*, in most EPPO countries, an evaluation of efficacy is required before a plant protection product can be marketed. The objective of this document is to give national registration authorities ('the Authority') information to better inform the process of evaluation of efficacy data that is submitted in support of registration of a plant protection product.

Applicants for registration ('the Applicant') should subject their own efficacy information to the same evaluation process when developing the proposed recommendations for use.

Further guidance on efficacy evaluation is available in several other documents, including:

- EPPO Standard PP 1/152 *Design and analysis of efficacy evaluation trials*
- EPPO Standard PP 1/213 *Resistance risk analysis*
- EPPO Standard PP 1/214 *Principles of acceptable efficacy*
- EPPO Standard PP 1/225 *Minimum effective dose*
- EPPO Standard PP 1/241 *Guidance on comparable climates*
- EPPO Standard PP 1/257 *Efficacy and crop safety extrapolations for minor uses*.

Regulation (EC) No 1107/2009, regarding the placing of plant protection products on the market, provides the new constitution of the framework for efficacy evaluation. This regulation

replaced Council Directive 91/414/EEC concerning the placing of plant protection products on the market as subsequently amended by Commission Directive 93/71/EEC, and in particular by Council Directive 97/57/EEC establishing Annex VI of Council Directive 91/414/EEC (*Uniform Principles for the evaluation of plant protection products*), constituting the framework for efficacy evaluation.

The EPPO Standards regarding Efficacy Evaluation of Plant Protection Products have also facilitated the use of data generated in one country to support registration in another country. Since the introduction of former Council Directive 91/414/EEC, which is now replaced by Regulation (EC) No 1107/2009, applicants in Europe are now beginning to generate data for the efficacy dossier for a Plant Protection Product on a Europe-wide basis. In addition, in the former Council Directive 91/414/EEC there was a specific provision for the mutual recognition of authorizations from other Member States. Regulation (EC) No 1107/2009 foresees a zonal authorization and 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 standardized procedures, but the Applicant and the Authority should also be able to establish the relevance of the data collected to local conditions in a particular country or region, i.e. whether the appropriate conditions (see below) are comparable in the countries concerned, particularly in relation to climate.

Table 1 Regions at a global level comparable to the Mediterranean zone

Continent	Country	Region
North America	USA	California, western half of Oregon and Washington
South America	Chile	31–39°S
	Argentina	37–50°S, 69–72°W
Australia	Australia	33–41°S, 114–143°E
Africa	South Africa	33–35°S, 17–20°E

Use of the document

The comparable climates on a global level were defined in comparison with the four climate zones within the EPPO-zone: the Mediterranean zone, the Maritime zone, the North-East zone, and the South-East zone.¹

This standard aims to assist both Authority and Applicant in determining the relevance of the climatic conditions in one area to another. It specifically addresses the issue of climate and presents agreed defined zones in and beyond the EPPO region within which conditions are considered climatically comparable. The text provides general guidance; however, localized points may have microclimates atypical of the broader local conditions.

Applicants can use this standard by referring to the defined zones rather than making a detailed case involving the submission of meteorological data. Resources are saved for all parties, because such cases will not have to be re-submitted (or evaluated) with each application.

The document may be used to justify, from a climatic perspective, the relevance of data generated outside the EPPO region to the different zones within the EPPO region or to a particular country. However, it is very important to remember that, even when climatic conditions are not comparable, use of the data may still be acceptable if it can be justified.

Minor uses of plant protection products

Minor uses are uses of plant protection products (PPPs) (defined in relation to crops and pests) in which either the crop covers a limited area of production at national level (minor crop), or the pest is of limited importance in a major crop (minor pest). It should be noted that a minor use in one country may be a major use in another country (each country is responsible for defining its minor uses).

It is necessary to collect efficacy data for minor uses, but the opportunity to use data from field trials beyond the EPPO region may be particularly beneficial in enabling minor use authorizations to be granted more efficiently.

Comparable climates

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 (e.g. 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.

Defined zones

The comparable zones have been defined by taking into account the agro-meteorological data (including temperature, dew-point temperature, relative humidity, precipitation, short-range radiation and frost-free period) of the ERA-40 data [ERA-40 = the ReAnalysis of the European Centre for Medium-Range Weather Forecast (ECMWF)]. The ERA-40 data for the four EPPO zones were compared to the ERA-40 data from other agricultural regions worldwide. Regions with comparable climates were

Table 2 Regions at a global level comparable to the Maritime zone

Continent	Country	Region
North America	USA	Appalachian Mountain area of Pennsylvania, West-Virginia and Tennessee and part of Idaho
	Canada	Coast line of British Columbia
South America	Chile, Argentina, Uruguay and Brazil	20–55°S, 42–77°W
Australia	Australia, New Zealand	East and South-East Australia (28–39°S, 140–157°E), Tasmania, North and South Islands of New Zealand (except mountains of South Island)
Africa	South Africa	29–35°S, 22–32°E
	Kenya	Regions east of Lake Victoria (3°N–3°S, 30–35°E)

Table 3 Regions at a global level comparable to the North-east zone

Continent	Country	Region
North America	USA, Canada	Broad line on both sides of the Canadian–American border, 40–55°N, 52–115°W, and parts of the Rocky Mountain area
Asia	Russia, Kazakhstan	47–59°N, 50–90°E

¹See EPPO Standard PP1/241.

found for the Mediterranean zone, the Maritime zone and the North-East zone (see Tables 1–3), but not for the South-East zone.

The defined regions in the tables may be used as guidance for defining comparable climates at a global level.

These regions are presented in Maps 1–4 (see Appendix 1), which also indicate that there is an area of gradual change in climate between the regions considered.

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

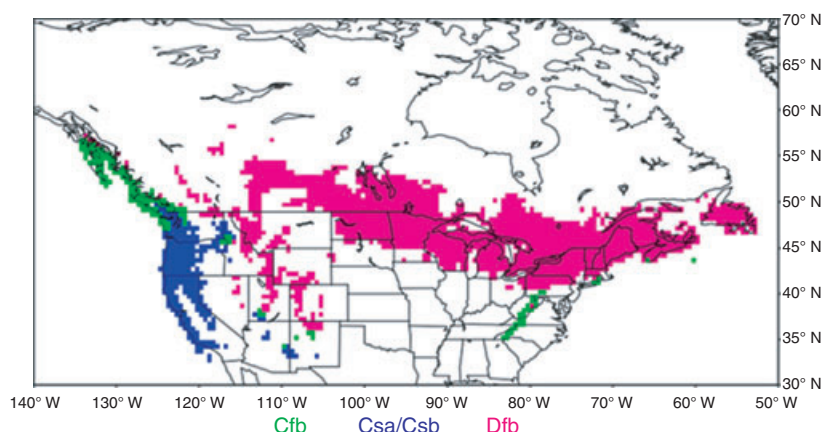
References

Bouma E (2005) Development of comparable agroclimatic zones. *Bulletin OEPP/EPPO Bulletin* **35**, 233–238.

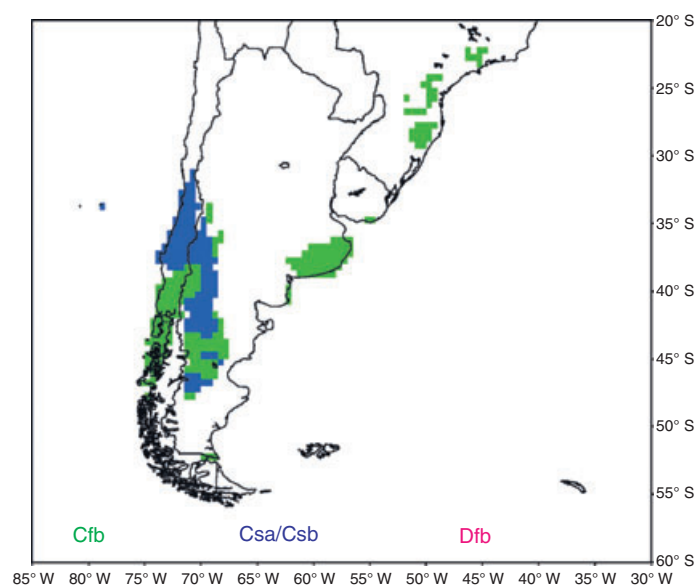
Köppen W & Geiger R (1936) Das Geographische System der Klimate. In: *Handbuch der Klimatologie* (Ed. Köppen W & Geiger R), pp. 44. Bd 1, Teil C, Berlin.

Appendix 1 – Maps of comparable climates at a global level

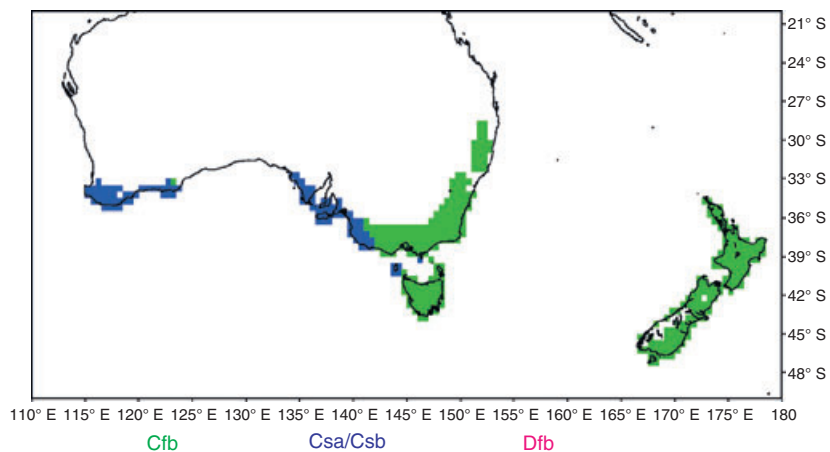
The Mediterranean zone is comparable with the blue area (comparable with the Köppen–Geiger (Köppen–Geiger, 1936) Csa/Csb-classification), the Maritime zone is comparable with the green area (comparable with the Köppen–Geiger Cfb-classification), and the North-East zone is the red area (comparable with the Köppen–Geiger Dfb-classification).



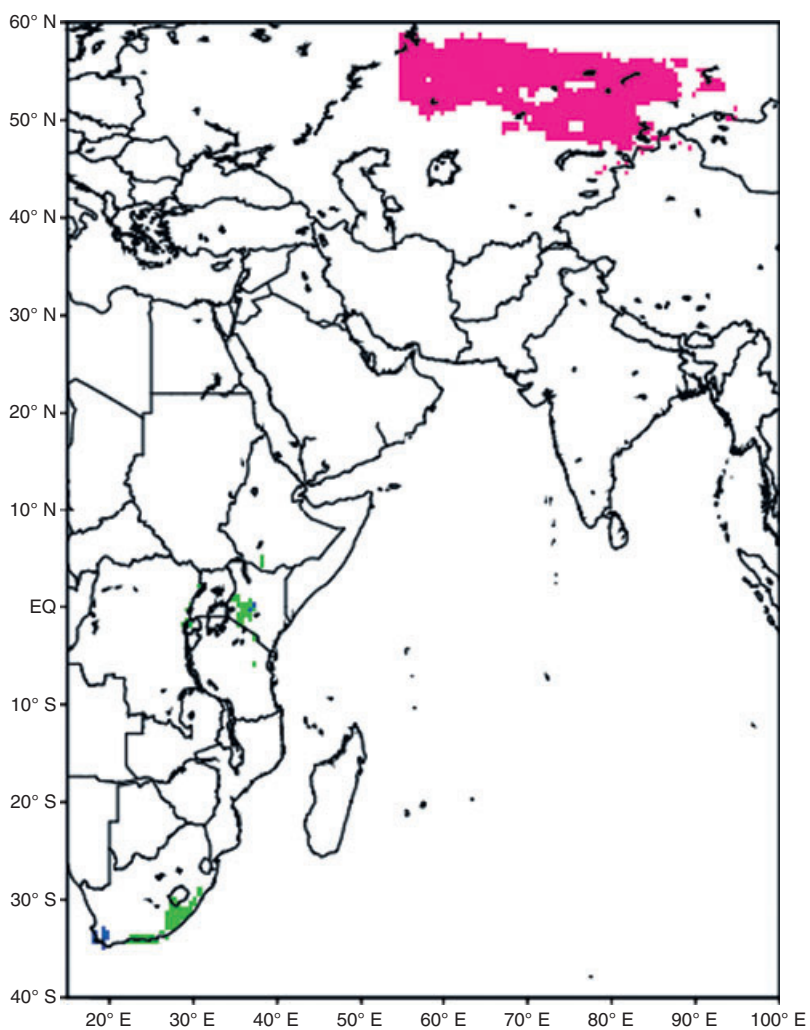
Map 1 Map with comparable climates of North America.



Map 2 Map with comparable climates of South America.



Map 3 Map with comparable climates of Australia.



Map 4 Map with comparable climates of Africa and Asia.