

Examples of zonal efficacy evaluation

Clarification of efficacy data requirements for the authorization of a plant growth regulator in winter oilseed rape in the European Central authorization zone

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This document is intended to assist applicants and evaluators to interpret EPPO Standard PP1/278 *Principles of zonal data production and evaluation*. Expert judgment 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 EC Regulation 1107/2009, (EC, 2009).

All trials should be carried out under Good Experimental Practice (GEP) and using all relevant general EPPO Standards. Effectiveness and selectivity trials should be performed according to the EPPO Standard PP1/153 *Control of lodging and growth regulation in brassica oil crops*. (Available at <http://pp1.eppo.int/>).

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 PP1/in preparation *Efficacy considerations and data generation when making changes to the chemical composition of plant protection products*.

General information

The EU Zonal Rapporteur Member State (zRMS) and Concerned Member states (cMS) where a product authorization is sought should be named, together with the relevant EPPO climatic zones and the status of the use (major or minor) in each country. Where the product/formulation is already authorized in countries in the Central zone, information should be provided about the plant growth regulator (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).

Information on the importance of plant growth regulation for oilseed rape in the Central EU zone

The target for plant growth regulators in oilseed rape may vary depending on the product. For example, plant growth regulators may be used for the manipulation of canopy structure, winter hardiness or the control of lodging. However, in all cases the applicant should describe the required effect and its agronomic importance across all Zonal Rapporteur Member State (zRMS) and Concerned Member States (cMS) where authorization is intended. For example

the applicant should include details on any variation in crop height, management and propensity to lodge.

The applicant should provide details of the biology of the pest and the agronomic importance in all countries in the Zone.

Information on oilseed rape production in the Central Authorization Zone

Oilseed rape (spring and winter) is widely grown across the Central zone. In 2013 it was grown on 6.7 million ha across the EU. The main oilseed rape growing Member States in the Central zone are Germany, Poland, UK, Romania and the Czech Republic. In some Member States the crop is predominantly winter oilseed rape e.g. UK whereas elsewhere spring sown oilseed rape is the major crop (EUMUDA¹). The applicant should provide full details of the importance of winter oilseed rape in the countries in the zone and also an overview of production systems across the zone. Further information on oilseed rape production is available from the [Eurostat](http://ec.europa.eu/eurostat)² website.

The applicant should always make sure that reliable and recently updated sources of information are used.

Intended Use(s)

The applicant should clearly describe the details of the recommended use/uses 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).

Both effectiveness and crop safety trials should be conducted at the growth stages proposed for the intended uses.

Number and distribution of trials required for an authorization

Effectiveness (6.2)

EPPO Standard PP1/226 *Number of efficacy trials* indicates that for authorization in a single country/climatic zone, 6 to 15 fully supportive results are required over 2 years for each intended use. **ADD sentence on zones**

To support an authorization in the Central Zone, which may encompass different EPPO climatic regions, more than the EPPO recommended number of trials results (6-15) for a single EPPO zone may be needed.

The Central zone encompasses 3 different EPPO zones of comparable climate: the Maritime zone (Ireland, UK, The Netherlands, Belgium, Luxembourg, Germany, Czech Republic and Austria); the North-east zone (Poland); and the South-east zone (Slovenia, Slovakia, Hungary and Romania). A sufficient number of trials distributed across the 3 zones are necessary to encompass the likely range of conditions encountered for an authorization across the whole Central zone. A minimum of at least 22 fully supportive effectiveness trials results are expected to be required to support an authorization for each intended use (e.g. 10 trials in the Maritime zone, 6 in the North-east and 6 in the South-east zone). For plant growth regulators which are proposed for use in both the autumn and the spring support should be provided at both application timings.

¹ European Minor Use Database <http://www.eumuda.eu/>

² http://epp.eurostat.ec.europa.eu/portal/page/portal/agriculture/data/main_tables

Data should be presented separately for different EPPO climatic zones (or any other relevant geographic areas) to enable a consideration of whether there is any impact of climatic conditions on performance. If data from all three zones are considered to show no detectable differences in performance, it may be possible to combine all relevant data together. But some initial analysis may be required to demonstrate this is an acceptable approach. When the data are supporting e.g. a new formulation/product, where it has been established that the whole zone can be considered comparable, then summarizing data for the whole zone may be more justified.

Results should be presented in accordance with EPPO Standards PP1/181 *Conduct and reporting of efficacy evaluation trials including good experimental practice* and PP1/152 *Design and analysis of efficacy evaluation trials*. The key information to provide in summary tables will depend on the proposed use and should include:

For plant growth regulators : crop growth stage (BBCH) at time of application; crop height at the time of application; plant numbers at application; reduction in lodging; number of trials; mean percentage effect and the range of minimum and maximum levels (height, plant numbers, lodging, yield), for both the test product and also for the reference products, at each assessment timing.

The effectiveness trials should seek to demonstrate a benefit to the use of the plant (e.g. reduced *crop height* and *lodging*) resulting in maintained/improved *grain yield*).

Clearly the target effect will determine the assessments conducted. In terms of products for the control of lodging it is important to achieve a sufficient number of trials which clearly show an association between the application of the product, crop height, the degree of lodging and crop yield.

Equally products where the target is an improvement in winter hardiness should seek to demonstrate that the application of the product reduces winter kill and that this leads to yield improvements.

In both cases this can be difficult to achieve but nonetheless this is an important requirement for justifying the agronomic need for the product.

Minimum Effective Dose (6.2)

Minimum effective dose trials should be conducted across the relevant different EPPO climatic zones in the Zone to demonstrate that the proposed dose is justified for representative uses. For control of lodging, data should be generated in situations where there is a high risk of lodging since it is important that trials are conducted where there can be an association between dose, plant height reduction, reduction in lodging and yield benefit. Trials should be conducted in accordance with EPPO Standard PP1/225 *Minimum effective dose*. A justification for the number of applications applied may also be required if applications are proposed in different seasons (e.g. autumn, spring).

Resistance (6.3)

For plant growth regulators resistance risk analysis is unlikely to be required.

Phytotoxicity to target plants (including different cultivars), or to target plant products (6.4.1)

Observations on phytotoxicity should be made in both effectiveness and specific crop safety trials. Phytotoxicity can depend on BBCH growth stage at application, climatic conditions and the varieties grown. Therefore it is necessary to have phytotoxicity data from all the different climatic zones concerned. Trials should also include a range of commercially grown varieties. Varietal sensitivity testing may also be conducted (see EPPO Standard PP1/135 *Phytotoxicity assessment*).

Effects on the yield of treated plants or plant products (6.4.2.)

Specific crop safety trials should be located across the Zone in areas representative of oilseed rape production. EPPO Standard PP1/226 *Number of efficacy trials* indicates that for authorisation in a single country/climatic zone, typically, at least 8 trials per major crop are required in an area of similar conditions, to cover the range of conditions of use, including soil types, weather conditions that are likely to be encountered. To support an authorization in the Central Zone which may encompass different EPPO climatic zones, more than the EPPO recommended number of trials (8) may be needed. The Central Zone encompasses 3 different EPPO zones of comparable climate and in order to encompass the range of conditions it is expected that for major crops such as winter oilseed rape at least 20 specific crop safety trials will be required. There is the potential for effectiveness trials in the absence of lodging to be yielded to address this requirement.

Trials should be located in areas where oilseed rape is predominantly grown. It is essential that symptoms of phytotoxicity are clearly linked to any negative yield effects. Specific crop safety trials must include applications at N and 2N doses and trials should cover the range of proposed growth stages and treatment times for each use.

Only the net plot should be harvested for quantitative and qualitative recording of yield. The following should be recorded (for effectiveness and crop safety trials):

- (a) Seed yield in kg ha⁻¹, adjusted to a fixed moisture level (national standard)
- (b) Oil content, %
- (c) Moisture content (%).

If the crop is grown for seed propagation, see EPPO Standard PP 1/135 *Phytotoxicity assessment*.

Effects on the quality of plants or plant product (6.4.3.)

Appropriate quality assessments relevant to that crop should be made. In some instances additional observations in the effectiveness trials may be sufficient to address the relevant point. See EPPO PP 1/135 *Phytotoxicity assessment* for further details.

Effects on transformation processes (6.4.4)

If relevant, reference may be made to EPPO Standard PP1/243 *Effects of plant protection products on transformation processes* which provides an indication of the circumstances under which data on transformation processes are required.

Taint

Reference may be made to EPPO Standard PP1/242 *Taint tests*.

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

Reference may be made to EPPO Standard PP1/135 *Phytotoxicity assessment* which provides an indication of the circumstances under which data on plant parts for propagation are required.

Impact on succeeding crops (6.5.1)

A step-wise approach should be taken following EPPO Standard PP1/207 *Effects on succeeding crops*, starting with the herbicidal activity of the active substance, through glasshouse screening, laboratory bio-assays of treated field soils, field screening, monitoring of effectiveness/crop safety field trials and if necessary, specific following crop 'replanting' trials using risk mitigation measures such as different cultivation techniques. It is important to consider crops which are likely to be present in rotation with oilseed rape across the zone. For testing the biological activity of the test product, the product should be incorporated into the soil and the activity given as an EC (effective concentration).

Impact on other plants, including adjacent crops (6.5.2)

A step-wise approach should be taken following EPPO Standard PP1/256 *Effects on adjacent crops* and should be fully presented. It is important to consider crops which are likely to be present as adjacent crops (either already emerged or yet to emerge) across the zone. Data from other parts of the submission (e.g. ecotoxicology, non-target plant pre- and post-emergence data) can be included in this section. In addition to drift, other routes of exposure should be considered for the formulated product as this may affect adjacent crops.

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

When there are claims on the label for use as part of an Integrated Management Strategy, special trials may be required on a national basis.

Relevant data produced for the Ecotoxicology section or existing IOBC classifications for the active substance may be used.

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.