

Examples of zonal efficacy evaluation

Clarification of efficacy data requirements for the authorization of an herbicide for the control of loose silky bent (*Apera spica-venti*, APESV) on winter wheat (*Triticum aestivum*, TRZAW) in the European Central authorization zone

This document is intended to assist applicants and evaluators to interpret EPPO Standard PP1/278 *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 authorisation process for plant protection products (as defined in EU Regulation 1107/2009).

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 the EPPO Standard PP 1/93 *Weeds in Cereals* (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 PP 1 (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 EU Member states (cMS) 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 herbicide (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, RAC classification).

Information on *Apera spica-venti*

Apera spica-venti (APESV) is also known as loose silky bent, wind-grass, and silky wind-grass. It germinates in autumn, sometimes also in early sown spring cereals and is widespread in winter cereals and winter oilseed rape, especially on sandy or light loam soils. It is found across the Central zone but is less common in the UK and Ireland. In the UK, for example, it is only present on sandy or light loam soils in the east and south of England. In these locations it can become a problem in continuous cereals. There are various estimates of the economic threshold for *Apera spica-venti*. This ranges from 10 plants/m² (Beer, 1993) to 20 plants/m²

(Wahmhoff, 1994)¹. The applicant should provide relevant details of the biology of the weed and the agronomic importance in all countries in the zone.

Information on winter wheat production in the Central Zone²

Wheat (common and durum wheat) is by far the crop with the highest production in European agriculture. In 2007, wheat accounted for 46 % of cereal production in the EU. It is also one of the most widely distributed crops in the EU. The main wheat producing countries are France, Germany, UK and Poland. Winter wheat is the predominant type produced in these countries. According to the statistics, only five regions in the EU do not produce wheat and these are not located in the Central zone. The applicant should provide full details of the importance of winter wheat in the countries in the zone and also an overview of production systems across the zone. Further information on wheat production is available from the [Eurostat](#) website.

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). In this example, winter wheat is chosen as the intended crop. If applications are proposed in the autumn and spring or pre- and post-emergence, this has to be specified in different uses, and BBCH growth stages included for both crops and weeds. 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) Commission Regulation 284/2013), (OECD KIIIA1 6.1.3)

The importance of *Apera spica-venti* is different not only in the countries of the central EU zone but also in the countries within the maritime EPPO zone (see Figure: Krähmer 2009). In certain Member States within the Central zone loose silky bent is a major weed species in winter wheat.

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. Clearly this requirement is less where loose silky bent is a minor weed.

To support an authorization in the Central Zone, which encompasses different EPPO climatic zones, more than the EPPO recommended number of trials results (6-15) for a single EPPO zone will 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 from these 3 EPPO climatic zones are therefore necessary to encompass the likely range of conditions encountered to support an authorization across the whole Zone. A total of at least 22 fully supportive effectiveness trials results are expected to be required to support an authorization for each intended use.

¹ Wahmhoff (1994) Mechanische Unkrautbekämpfung in Winterraps [Mechanical weed control in rape seed]. Journal of Plant Diseases and Protection Sonderheft (XIX, 303-313).

² Source : Eurostat.

Apera spica-venti is a major target across the zone except in the UK and Ireland. Effectiveness trials should be conducted in those countries where loose silky bent is a key target and also where winter wheat is a major crop. An effectiveness programme to represent the Central zone might, therefore, include trials conducted in the Czech Republic and Germany to represent the Maritime zone (at least 10 trials results), Poland to represent the North East zone (at least 6 trials results), with the remainder conducted in the South-East zone (at least 6 trials results).

Data from other countries that are climatically and agronomically comparable to those in the Central Zone and where loose silky bent is a major weed may also be used to provide evidence of effectiveness and could potentially replace some of the trials conducted in the Maritime countries of the Central zone.

Data should be presented separately for different EPPO climatic zones (or any other weed relevant geographic area) 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 performances, it may be possible to combine all relevant data together. But some initial analysis to demonstrate this is an acceptable approach may be required. 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.

Tables should be produced 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 the tables should include:

Crop growth stage (BBCH) at time of application; population levels at time of application and at each assessment; number of trials; mean % control/effect and the range of minimum and maximum levels, for both the test product and also for the reference products, at each assessment timing; weed species; weed growth stage (BBCH) at time of application and time of assessment; weed numbers at application (% ground cover or number/m²).

Results should only be included from trials conducted in accordance with EPPO Standards and where there are agronomically relevant weed populations present.

Minimum Effective Dose (6.2) (OECD KIIIA1 6.1.2)

Minimum effective dose trials should be conducted across the relevant different EPPO climatic zones (or any other weed relevant geographic areas) in the Central zone to demonstrate that the proposed dose is justified for representative uses. 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*. A justification for the number of applications applied may also be required if applications are proposed in the autumn and spring, or pre- and post-emergence.

Resistance 6.3 (OECD KIIIA1 6.2.8)

Reference should be made to EPPO Standard PP 1/213 *Resistance Risk Analysis*.

Loose silky bent is considered a high risk target very likely to develop resistance, based on its resistance history. The International Survey of Herbicide Resistant Weeds (<http://www.weedscience.org/in.asp>) cites cases of resistance in the Central zone in Germany, Poland and the Czech Republic to HRAC Groups A/1, B/2 and C2/7. Therefore sensitivity data should be generated, which allow a measure of sensitivity shift and resistance development in future. Populations need to be tested with standardized methods (e.g. any HRAC recommended methods for loose silky bent). Samples should be taken from different areas in the relevant Zone (similar to efficacy data distribution), with the majority being sampled in regions with high winter wheat production and high need for control of loose silky bent. But some samples should also be collected in areas with low need for control. If there are areas known in which resistance to other active substances has been noticed, such regions should also be sampled. Data from other Zones should also be presented if available. Samples from regions with known resistance to other actives should be tested for cross resistance as well as some samples from regions where no such resistance is expected.

A resistance management option has to be presented which may in the case of loose silky bent be different across regions depending on the availability of other herbicides and typical cultural practices. Detailed resistance management strategies will often need to be country specific. Reference may be made to Herbicide Resistance Action Committee (HRAC) recommendations, but should be tailored to individual Member States and reflect e.g. number of applications required, availability of other control options etc. In particular any advice from local 'Resistance Action Groups' should be followed, along with any individual National statutory restrictions.

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)

Observations on phytotoxicity should be made in effectiveness and specific crop safety trials (including 2N doses) in the absence of weeds. 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) (OECD KIIIA1 6.1.4.3)

Specific crop safety trials should be located across the zone in areas representative of winter wheat cultivation. EPPO Standard PP1/226 *Number of efficacy trials* indicates that for authorization 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 encompasses different EPPO climatic regions, more than the EPPO recommended number of trials (8) is 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 a major crop such as winter wheat at least 22 specific crop safety trials will be required. These should be located in areas where winter wheat is predominantly grown. It is essential that symptoms of phytotoxicity are clearly linked to any subsequent yield effects. Specific crop safety trials should include applications at N and 2N doses and trials should cover the range of proposed growth stages and treatment times for each use.

Effects on the quality of plants or plant product (6.4.3.) (OECD KIIIA1 6.1.4.1)

Appropriate quality assessments relevant to winter wheat should be made for herbicides. See EPPO PP 1/135 *Phytotoxicity assessment* for further details.

Effects on transformation processes (6.4.4) (OECD KIIIA1 6.1.4.2)

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) (OECD KIIIA1 6.2.5)

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) (OECD KIIIA1 6.2.6)

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 all crops which are likely to be present in rotation with winter wheat (either already emerged or yet to emerge) 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) (OECD KIIIA1 6.2.7)

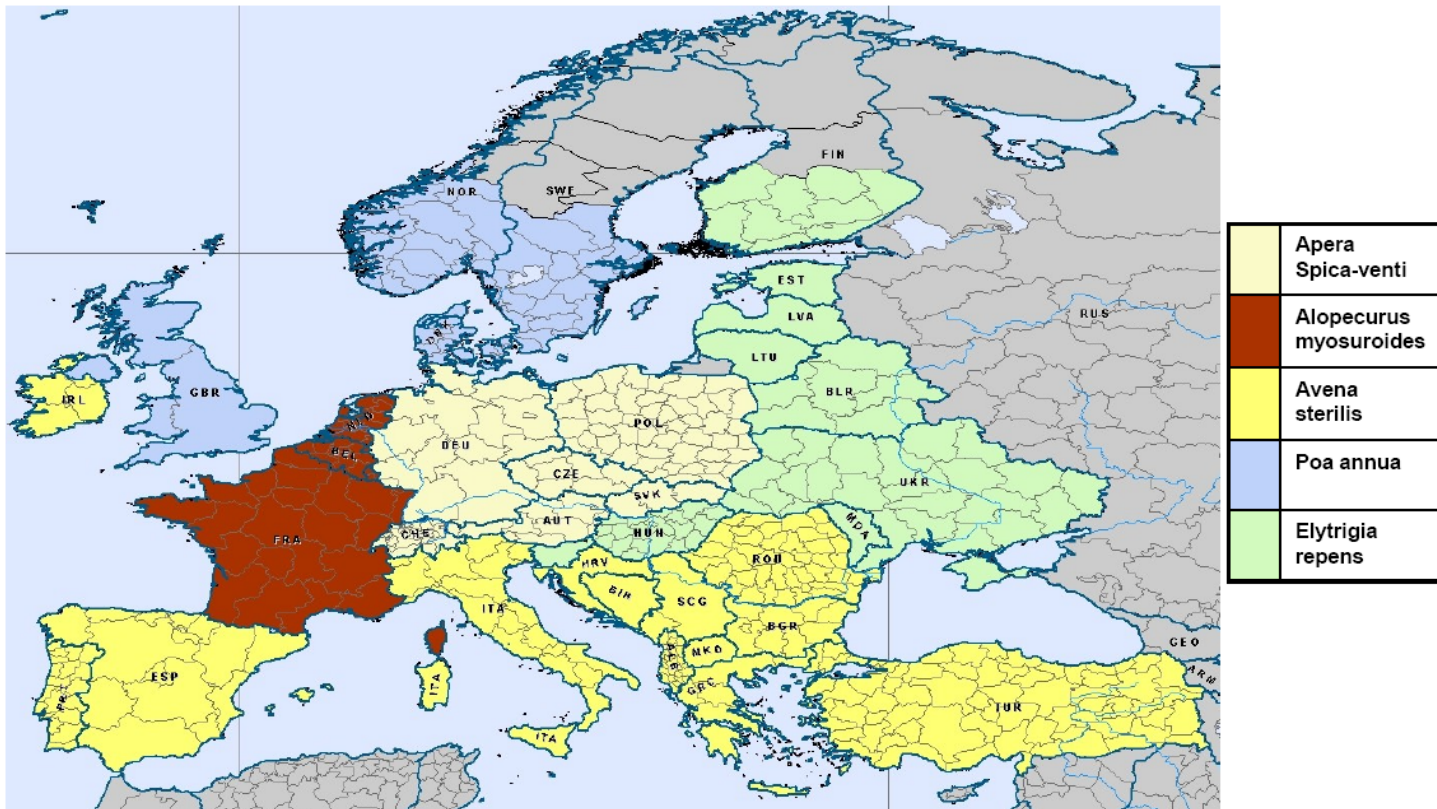
A step-wise approach should be taken following EPPO Standard PP1/256 *Effects on adjacent crops* and should be fully presented. It is important to consider all crops which are likely to be present as adjacent crops (either already emerged or yet to emerge) across the zone. Data from other parts of the 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) (OECD KIIIA1 6.2.4)

No special trials are required for herbicides if there are no claims for use as part of an Integrated Pest Management Strategy.

Europe: Cereals / most frequent grasses

(draft, medium certainty level)



Source: Krähler H., 1st EU Weed Mapping Meeting, May 14th, 2009 in Prague

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>