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Clarification of efficacy data requirements for the authorization of a plant growth regulator in oilseed and turnip rape in the European Northern authorization zone

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[Based on the draft for a plant growth regulator in winter oilseed rape made by Ingrid den Hoed (GB)]

This document is intended to assist applicants and evaluators to interpret EPPO Standard PP 1/278 *Principles of zonal data production and evaluation* and the *Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone*. 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 and phytotoxicity. There is a need to provide clarification of these topics 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 PP 1/153 *Control of lodging and growth regulation in brassica oil crops*.

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 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 plant growth regulator (e.g. active substance, content, type of formulation, authorized dose), the current registration status 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, timing, uptake and transport in the plant, behaviour in the soil).

Information on the importance of plant growth regulation for oilseed rape in the Northern Authorization Zone

The target for plant growth regulators in oilseed rape (*Brassica napus* subsp. *oleifera*, BRSNN) may vary depending on the product and if the spring or winter varieties are grown. For example, plant growth regulators may be used for the manipulation of canopy structure, winter hardiness (winter oil seed rape) or the control of lodging. Currently, the use of plant growth regulators in spring oilseed rape is less important than the use in winter oilseed rape. There are few products authorized to regulate growth in oilseed rape in the Northern Authorization zone. The situation

is the same for spring and winter turnip rape (*Brassica rapa* subsp. *oleifera*, BRSRO). In all cases the applicant should describe the required effect and its agronomic importance across all Member States where authorization is intended. For example, the applicant should include details on any variation in crop height, management and propensity to lodge.

Information on oilseed rape production in the Northern Authorization Zone (from Belgian study and Eurostat)

Oilseed rape (spring and winter varieties) is widely grown in Europe. Turnip rape is grown less. In 2014 rape (oilseed rape and turnip rape) was grown on 6.7 million ha across the EU (Eurostat). The area of rape was only 0.7 million ha in the Northern zone. The main oilseed rape growing Member States in the Northern Authorization zone are Lithuania, Denmark, Sweden and Latvia. Winter oilseed rape is more widely grown in the Northern Authorization zone than spring oilseed rape, however, this varies greatly between the Member States: predominantly spring oilseed rape (Estonia, Norway, Finland), almost equal distribution of the winter and spring varieties (Latvia, Lithuania), more winter oilseed rape than spring oilseed rape (Sweden) and predominantly winter oilseed rape (Denmark) (Belgian study on crop distribution in Europe, Hucorne, 2012). The main Member States of the Northern Authorization zone growing spring oilseed rape are Estonia, Latvia, Lithuania, Sweden, and Finland, while the acreages are lower in Norway and Denmark (Table 1). Spring turnip rape is also grown, especially in Finland where it is the major oilseed crop, while in Sweden, Latvia and Norway it is a minor crop. Winter turnip rape can be grown in some countries in the Northern Authorization zone, but is less commonly grown than spring turnip rape.

Table 1. Example of a table showing distribution (area in 1000 ha) of winter and spring oilseed rape and spring turnip rape in the Northern Authorization zone.
N.D. means **No Data.** Source: Hucorne (2012) unless more updated sources are indicated.

	Maritime EPPO climatic zone			**North-East EPPO climatic zone**			
Crop	**Denmark**	**Sweden**	**Norway**	**Lithuania**	**Latvia**	**Estonia**	**Finland**
Winter oilseed rape	164.9[1]	80.4[1]	0-0.8[2]	123.1[2]	49.2[1]	35.3[1]	1.6[1]
Spring oilseed rape	1.0[2]	31.0	3.0[2]	40.4[2]	42.9	72.8	11.4
Spring turnip rape		4.0	1.0[2]	N.D.	1.6		89.0

[1] Data of 2014; Eurostat.
[2] Data of 2015; Denmark: Pedersen (2015) Norway: U. Abrahamsen pers. comm. (acreage based on sold seeds), Lithuania: http://osp.stat.gov.lt.

Further information on oilseed rape production is available from the Eurostat website. In this database oilseed rape and turnip rape are merged and given as 'Rape'.

Crop distributions changes over time and 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(s) for each country where registration is sought. (See EPPO Standard PP 1/240, *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. According to EPPO Standard PP 1/135 *Phytotoxicity assessment* no specific selectivity trials are needed and N and 2N dose may be included in effectiveness trials.

Number and distribution of trials required for an authorization

Effectiveness (6.2)

EPPO Standard PP 1/226 *Number of efficacy trials* indicates that for authorization in a single country/climatic zone, 10 (6 to 15) fully supportive results are required over 2 years for each intended major use. For minor uses 3 (2-6) fully supportive trials are required. For the Northern Authorization zone the zonal guidance is more important.

The Northern Authorization zone encompasses two different EPPO zones of comparable climate: the Maritime zone (Denmark, Sweden and Norway) and the North-East zone (Finland, Estonia, Latvia and Lithuania). A sufficient number of trials distributed across the two zones are necessary to encompass the probable range of conditions encountered for an authorization across the whole Northern Authorization zone. The distribution between the EPPO Maritime and the North–East zone is probably more important than the distribution from south to north in the Northern zone, e.g. half of the trials should come from locations at high latitudes (Finland, mid-Sweden and Norway) and the rest from more southern locations (the Baltic countries, Southern Sweden and Denmark). The distribution of trials should reflect where winter and spring oilseed rape is grown. According to the *Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone* at least 3-5 of trials in winter oilseed rape and, if relevant, 2-4 in spring oilseed rape should be conducted in the Northern Authorization zone for each intended use. Trials from spring/winter turnip rape can be included to fulfill the data requirement for spring/winter oilseed rape. If spring/winter turnip rape is a target crop, some of the trials should be conducted in this crop. For example, 2 trials could be conducted in spring/winter turnip rape and 3 trials in spring/winter oilseed rape.

Data on reduced height growth and lodging in winter oilseed rape cannot replace data requirements in spring oilseed rape, but can be used as supplementary data. Data from the Maritime and North-East EPPO climatic zones of the Central EU zone may be used as supplementary data. These data can only to some extent replace some of the data from the Northern Authorization zone to support an authorization for each intended use. If the intended use is to reduce height, it is possible to extrapolate to lodging. However, if the intended use is to reduce lodging, at least half of the trials should show the effects on lodging. For new formulations of registered active substances bridging trials can be used. If these trials show a similar performance as the previously registered product, the requirement for trials can be reduced.

Depending on the target use, the allocation of the trials should consider challenging conditions e.g. on reducing height and lodging in areas with more light (long days), intensive growth in early summer which gives longer stems and possibly heavy rain during summer which cause more lodging. Data from the North-East zone can be applicable to the Maritime zone and vice versa. A map illustrating the distribution of acreage of oilseed crops and target uses in the various countries and where the trials are conducted is preferable.

Data should be presented separately for different EPPO climatic zones and EU zones (or any other relevant geographic areas e.g. northern and southern latitudes) to enable a consideration of whether there is any impact of climatic conditions on performance. If data from the different zones or areas are considered to show no detectable differences in performance, it may be possible to combine all relevant data, however, evidence on comparability needs to be demonstrated.

Results should be presented in accordance with EPPO Standards PP 1/181 *Conduct and reporting of efficacy evaluation trials including good experimental practice* and PP 1/152

Design and analysis of efficacy evaluation trials. The key information to provide in summary tables should include:

For plant growth regulators : crop growth stage (BBCH) at time of application; crop height at the time of application; reduction in lodging; number of trials; mean percentage effect and the range of minimum and maximum levels (height, lodging, yield (see below)), 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 seed *yield*.

Minimum Effective Dose (6.2)

Minimum effective dose trials should be conducted across the relevant different EPPO climatic zones in the Northern Authorization 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 PP 1/225 *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)

Reference should be made to EPPO Standard PP 1/213 *Resistance risk analysis*. For plant growth regulators this 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 (for plant growth regulators efficacy and selectivity trial can be integrated including ½ N, 1 N and 2 N in the trials). Phytotoxicity can depend on BBCH growth stage at application, climatic conditions and the cultivars grown. Therefore it is necessary to have phytotoxicity data from all the different climatic zones/areas 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.)

Crop safety trials can be integrated with effectiveness trials (see above) and should be located across the Northern Authorization zone in areas representative of oilseed rape (or turnip rape) production. EPPO Standard PP 1/226 *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. The Northern Authorization zone encompasses two different EPPO climatic zones, which may increase the requirement for trials. On the other hand the acreage of oilseed crops in the Northern Authorization zone is small compared to e.g. the Central Authorization zone, and lower number of trials is therefore needed. According to the *Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone* at least 3-5 of trials in winter/spring oilseed rape should be conducted in the zone for each intended use. Trials from spring/winter turnip rape can be included to fulfill the data requirement for spring/winter oilseed rape. In cases where authorization is for spring

and winter oilseed rape, and for winter and spring turnip rape, crop safety trials must be conducted in each of these crops. Trials should be located, in areas where oilseed rape and turnip rape are predominantly grown, in the two different EPPO climatic zones and also at more extreme conditions with long days. It is essential that symptoms of phytotoxicity are clearly linked to any negative yield effects. 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.

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 (%)

(d) 1000-seed weight.

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 PP 1/243 *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 PP 1/242 *Taint tests.*

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

Reference may be made to EPPO Standard PP 1/135 *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 PP 1/207 *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 (or turnip 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 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)
No special trials are required for plant growth regulators if there are no claims for use as part of an Integrated Pest Management Strategy. Reference to individual Member States for any specific national requirements may be required.

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.

Hucorne P (2012) The actual distribution of crops in Europe. Available at: http://www.eppo.int/PPPRODUCTS/zonal_efficacy/zonal_efficacy.htm

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EUMUDA, European Minor Use Database. Available at: www.eumuda.eu

Pedersen JB (2015) Oversigt over Landsforsøgene 2015.

Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone. Available at: http://agro.au.dk/en/public-sector-consultancy/guidance-on-requirements-for-efficacy-data/