FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: Protiokonazol 300 EC

Product name: HERA 300 EC

Chemical active substance:

Prothioconazole, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023; March 2024

MS Finalisation date: March 2024; July 2024 December 2024

Version history

When	What
March 2024	Applicant's justification for carried efficacy trials on cereals in one season
March 2024	ZRMs evaluated dRR submitted by Applicant
July 2024	The final Registration Report
December 2024	ZRMs corrected fRR in line to reviewed comments from MRiRW

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of ZRMs are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document were marked by grey colour). Changes made in line to reviewed comments from MRiRW are marked by turquoise.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

All uses claimed by Applicant in the GAP table were accepted by ZRMs (use on winter wheat against ERYSYGR was accepted conditionally). Within 24 months after authorisation product, Applicant should presented at least 1-2 eff. trials carried out on winter wheat against ERYSYGR in N-E EPPO zone or neighbouring country to Poland. For winter oilseed rape (autumn and spring application) – only dose 0.6 L/ha is recommended. ~~Against ALTEBA – ZRMs proposed application scheme~~. Recommended use against ALTEBA – once in autumn or twice in spring. Detailed assessment is presented in commenting boxes after each chapter.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Use -No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max				
Zonal uses (field or outdoor uses, certain types of protected crops)															
1	PL	Winter wheat	F	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR **Powdery mildew of cereals** (*Blumeria graminis)* ERYSGR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant	SEPTTR acceptable	ERYSGR accepted conditionally
2	PL	Spring wheat	F	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant	Acceptable	
3	PL	Winter triticale	F	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR **Powdery mildew of cereals** (*Blumeria graminis)* ERYSGR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant	Acceptable	
4	PL	Spring triticale	F	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR **Powdery mildew of cereals** (*Blumeria graminis)* ERYSGR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant	Acceptable	
5	PL	Spring barley	F	Controlled diseases (0.5 – 0.65 L/ha):	broadcast spraying	BBCH 29-65	1	14	0.5 – 0.65 L/ha	150-195 g	100-400	35	not relevant	Acceptable	

				Net blotch of barley (*Pyrenophora teres)* PYRNTE		Spring, post emergence	a) 1 b) 2		a) 0.65 L/ha b) 1.3 L/ha	a) 195 g b) 390 g				
6	PL	Winter barley	F	Controlled diseases (0.5 – 0.65 L/ha): **Net blotch of barley** (*Pyrenophora teres)* PYRNTE	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant	Acceptable
7	PL	Winter Rye	F	Controlled diseases (0.5 – 0.65 L/ha): **Powdery mildew of cereals** (*Blumeria graminis)* ERYSGR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant	Acceptable
8	PL	Winter oilseed rape	F	Controlled diseases (~~0.5 –~~ 0.6 L/ha): **Dark spot of crucifers** (*Alternaria brassicae)* *ALTEBA **Dry rot of crucifers** (*Plenodomus lingam)* LEPTMA **Downy mildew of rape** *(Hyaloperonospora brassicae)* HPERBR	broadcast spraying	BBCH 13-19 Autumn, post emergence	1 a) 1 b) 1	NA	~~0.5 –~~ 0.6 L/ha a) 0.6 L/ha b) 0.6 L/ha	~~150-~~180 g a) 180 g b) 180 g	100-400	56	~~not relevant~~ ~~* against ALTEBA the scheme application with spring treatment is recommended.~~ **ALTEBA, LEPTMA and HIPERBR – accepted one treatment in autumn.**	Acceptable Recommended dose should be 0.6 L/ha
9	PL	Winter oilseed rape	F	Controlled diseases (~~0.5 –~~ 0.6 L/ha): **Dark spot of crucifers** (*Alternaria brassicae)* *ALTEBA **Cottony rot** (*Sclerotinia sclerotiorum)* SCLESC	broadcast spraying	BBCH 61-72 Spring, post emergence	1 a) 1 b) 2	21	~~0.5 –~~ 0.6 L/ha a) 0.6 L/ha b) 1.2 L/ha	~~150-~~180 g a) 180 g b) 360 g	100-400	56	~~not relevant~~ ~~Use in the following application scheme against ALTEBA:~~ ~~" 1 appl. at BBCH 13-19 at autumn and 1 appl. at BBCH 61-72 at spring; Interval between treatments: at least 90 days;~~ ~~or~~ ~~" use twice a season in spring application at~~	Acceptable. Recommended dose should be 0.6 L/ha.

													BBCH 61-72. Interval between treatments: at least 21 days **Against SCLESC and ALTEBA two spring application are accepted.**	
Minor uses according to Article 51 (Zonal uses)														
10	PL	Spring oilseed rape	F	Controlled diseases (~~0.5 –~~ 0.6 L/ha): **Dry rot of crucifers** (*Plenodomus lingam)* LEPTMA **Cottony rot** (*Sclerotinia sclerotiorum)* SCLESC **Dark spot of crucifers** (*Alternaria brassicae)* ALTEBA	broadcast spraying	BBCH 16-69 Spring Post-emergence	a)1 b)2	14-21	~~0.5 –~~ 0.6 L/ha a) 0.6 L/ha b) 1.2 L/ha	~~150~~ 180 g a) 180 g b) 360 g	100-400	56	not relevant	Acceptable. Recommended dose should be 0.6 L/ha.

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This is the application for registration of a plant protection product under working name Protiokonazol 300 EC according to Article 33 of Regulation 1107/2009. Protiokonazol 300 EC is an emulsifiable concentrate (EC) formula, containing 300 g/L of active substance – Prothioconazole, to be used as a fungicide to control diseases in cereals and oilseed rape. This is a core dossier in order to allow the approval of Protiokonazol 300 EC in **Poland** (zRMS).

The trials of Protiokonazol 300 EC have been performed in winter oilseed rape in 2021 (autumn application) and 2022 (spring application) and 2023 (autumn application) seasons.

The trials of Protiokonazol 300 EC have been performed in cereals in 2022 season (winter barley, winter wheat, winter triticale, spring wheat, spring barley, spring triticale, winter rye) and in 2023 (winter rye).
According to EPPO Standard PP 1/223 (2) *Efficacy evaluation of plant protection products*: the minimum number of trials required to establish acceptable efficacy depends on many factors, including: extent of knowledge of the active substance, extent of variability in the proposed area of use (e.g. plant health conditions, climatic differences, range of agricultural practices, uniformity of crops, importance of crop and target pest).
Normally, trials on effectiveness and phytotoxicity (including, where relevant, measurement of yield) should be conducted over at least two growing seasons, unless results from a single season are considered to provide adequate confirmation of the validity of the proposed claims.
With this document applicant provided ~~28~~ 59 efficacy trials in winter wheat, spring wheat, winter triticale, spring triticale winter barley and spring barley and winter rye and winter oilseed rape performed in Poland and Czech Republic (winter barley – 1 trial, winter oilseed rape – 1 trial) territory in different regions with distinct environmental conditions. The results of those trials are comparable in efficacy and phytotoxicity so it has been assumed that they are adequate and sufficient for confirmation of the validity of the proposed claims.

Moreover, based on EPPO Standard PP 1/226 (3) *Number of efficacy trials*: *t*he full number of trials is needed, particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought, or for intended uses for which no extrapolation of any aspect of efficacy from other uses is possible.
Prothioconazole is well known and “old” as well as known active substance, which is common use for protection cereals against fungal diseases. There are many plant protection products registered in Poland recommended to use in the same cereals, the same dose and against the same fungal diseases, as proposed for Protiokonazol 300 EC, so extrapolation from knowledge provided by others applicants is possible.

Considering the above, it was assumed, that the safety and effectiveness of the plant protection product Protiokonazol 300 EC, against fungal diseases for uses in cereals, was confirmed on the basis of the studies submitted by the applicant, and knowledge about the active substance prothioconazole.

Description of active substances

Active substance in Protiokonazol 300 EC fungicide is: Prothioconazole (300 g/L) which is included into Annex I of Directive 91/414. Prothioconazole is on the list of approved active substances (*Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances*). The active substance of the product is well known and commonly used in Poland and other EU countries. The efficacy of the substances has been proved in many trials and in crop protection practice.

Mode of action

Prothioconazole is a selective, systemic and broad spectrum fungicide used to control key foliar diseases. Can be used with protective, curative and eradicative action. According to FRAC active substance prothioconazole belongs to group 3 (DMI-fungicides). Its fungicidal properties are mainly attributed to prothioconazole ability to inhibit Lanosterol 14α-demethylase (CYP51A1) enzyme, which in fungi cells is required to biosynthesize ergosterol. Ergosterol is a key component in fungi cell membranes.

Table 3.2-1: Details of the active substances

Active substance	Prothioconazole
Concentration	300 g/L
Chemical group	Triazoles
Mode of action	DMI-fungicide
Biological action	Preventively, intervening or to destroy pathogens

Description of the plant protection product

Prothioconazole 300 EC is an emulsifiable concentrate (EC) containing 300 g/L prothioconazole

Table 3.2-2: Simplified table of requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Winter wheat, Winter triticale, Spring triticale	**Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR **Powdery mildew of cereals** (*Blumeria graminis)* ERYSGR	PL	0.5 – 0.65 L/ha	-
Spring wheat	**Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR	PL	0.5 – 0.65 L/ha	-
Winter barley, Spring barley	**Net blotch of barley** (*Pyrenophora teres)* PYRNTE	PL	0.5 – 0.65 L/ha	-
Winter Rye	**Powdery mildew of cereals** (*Blumeria graminis)* ERYSGR	PL	0.5 – 0.65 L/ha	-

Uses		Mem-ber State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	**Target(s)**			
Winter oilseed rape	**Dry rot of crucifers** (*Plenodomus lingam)* LEPTMA **Dark spot of crucifers** (*Alternaria brassicae)* ALTEBA **Cottony rot** (*Sclerotinia sclerotiorum)* SCLESC **Downy mildew of rape** *(Hyaloperonospora brassicae)* HPERBR	PL	~~0.5~~ 0.6 L/ha	ZRMs recommended for use only dose 0.6 L/ha ~~and against ALTEBA were proposed 2 schemes of applications (detailes in GAP).~~

The applicant carried out efficacy trials on winter wheat, spring wheat, winter triticale, spring triticale, winter barley, spring barley, winter oilseed rape. Selectivity trials are not required for fungicides, however phytotoxicity effect, along with yield and its quality analysis was assessed in each of the performed trial.

Further details are in the table "All intended uses" in Part B - Section 0.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name*
ALTEBA	*Alternaria brassicae*	Dark spot of crucifers
LEPTMA	*Plenodomus lingam*	Dry rot of crucifers
ERYSGR	*Blumeria graminis*	Powdery mildew of cereals
PYRNTE	*Pyrenophora teres*	Net blotch of barley
SCLESC	*Sclerotinia sclerotiorum*	Cottony rot
SEPTTR	*Zymoseptoria tritici*	Septoria leaf blotch
HPERBR	*Hyaloperonospora brassicae*	Downy mildew of rape

* optional

Agricultural crop production has been the main branch of plant production in Poland for years. Season 2022 was analysed in this document since data for this period is available on the Statistics Poland website. Taking into consideration season 2022, following numbers were presented:

Total arable land area reached 8 700 000 ha

Crop:	Crop yield (t):	Sowing area (ha):
Wheat	13 400 000	2 500 000
Barley	2 800 000	600 000
Rye	2 300 000	700 000
Triticale	5 500 000	1 200 000
Oilseed rape	3 600 000	1 100 000

The above presented numbers show that sown area of wheat, barley, rye and triticale in total exceeded 5 mln ha in 2022, while area where oilseed rape was sown was slightly above 1.1 mln hectares.

Hence, an appropriate protection in terms of weeds, fungal diseases and to control insects in the aforementioned crops, is inevitable. Chemical control of fungus-bourne diseases is highly important in production of agricultural crops, especially in cereals and oilseed rape. Uncontrolled, diseases can not only lower the yield and its quality, but in favourable conditions for pathogens, the plantation can be destroyed completely. Below can be found a short overview of the diseases which were found in Protiokonazol 300 EC field trials.

Wheat, triticale, rye

Powdery mildew of cereals – disease caused by the fungus *Blumeria graminis*, attacks species from *Poaceae* family, but in some countries can also attack other plants. Symptoms on the host plant are characteristic – white, delicate, powdery coating which occurs on the leaves. On the winter cereal varieties, first symptoms of the disease can occur in autumn. In spring, after the start of vegetation, the disease intensifies. The powdery coating is getting bigger, reaching higher parts of the plant and within time they are getting darker and the form of coating turns into felt like layer where fruiting bodies of the fungus can be found. They are in the form of small, dark spots. *B.graminis* coating on the plant limits its photosynthesis capability, and also makes the evaporation water loss higher. This leads grain to become smaller but high pest severity can cause plants death. The disease causes biggest damages in wheat and barley crops, where yield loss can reach up to 20%.

Wheat, triticale

Septoria leaf blotch – disease caused by the species *Zymoseptoria tritici*. It can be found around the whole world. Attacks mainly wheat and triticale. First symptoms of the disease are chlorotic, yellow-ish spots on the lower leaves and later climbing up, which are usually forming between the leave nerves (hence their usual, long shape). Later in the growing season, spots are getting bigger and they are turning into necrotic leasions. Within those blotches pycnidiums are being formed by the fungus. Leasions can cover the whole leaf, which leads to its death, and less leaves = less grains. Disease is most dangerous, and causes highest loss of yield when flag leaf is attacked. Yield decrease can reach up to 30%, high pest pressure can cause death of the plant. Economic injury level for this disease is 5-10% of the infected leaves. Fungus can also attack the blades of the plant, and cobs.

Barley

Net blotch of barley – is a disease caused by the fungus *Pyrenophora teres.* The species is a necrotrophic fungal pathogen and has highest economic significance in barley. Symptoms of the diseases are brown, necrotic spots on leaves. As time passes the spots are becoming bigger, and they are becoming brown lesions surrounded by the chlorotic halo. The diseases spreads within the areas limited by the conductive beams in the leave, however the disease can also spread within the leaf width. Symptoms oftenly occur as net-like shapes on the leaves, hence the common name of the disease. High severity of the disease can lead to leaves death, and in most critical cases plant death. The fungus can survive the winter on the straw left on the field. Yield decrease, in favourable conditions, can reach up to 40%.

Oilseed rape

Dark spot of crucifers – caused by the *Alternaria brassicae* saprotrofic fungus. Fungus spores are infecting the crucifer plants through damages caused by the insects/tillage and/or through stomata, water presence is needed for the infection. When the temperature is optimal (8-30^{o}C) they are germinating. Symptoms of the infection are dark coloured (oftenly surrounded by yellow halo) spots, on which dark, silk like coating occurs in damp conditions (conidial spores). In the attacked places, plant tissue oftenly dies, cracks and holes are formed. Spores and mycelium of the pathogen can survive many years on (and inside of) infected seeds and plant debris left in the soil, where they become chlamydospores which have high resistance to water loss and low temperatures.

Dry rot of crucifers – caused by the *Plenodomus lingam.* Pathogen starts to attack plants in the autumn, and the autumn infections are the most dangerous, since oilseed rape seedlings can be attacked. Fungus survives the winter time in the oilseed rape debris (usually stalks, or part of the root system). Symptoms can be visible on cotyledons and first leaves, they are in the form of lightly brown (can also be gray or white),

usually circle shaped, blotches of 3-20mm diameter, surrounded by dark brown halo. In the blotches area, pycnidiums can be observed. They are in the form of tiny, black spots. Fully developed pycnidiums are releasing conidial spores, when weather is damp and/or rainy, which are infecting other plants. Another symptom can be observed in spring in the root area – root neck or roots themselves can be narrower. This leads the stems to be weakened and easy to break. Such plants are ripening faster which causes yield to decrease.

Cottony rot – caused by the soilbourne pathogen *Sclerotinia sclerotiorum.* Species is a polyphage and attacks many species of plants (more than 400). Fungus survives the winter in the form of sclerotia and mycelium in the soil. When the winter ends, fungus spreads itself by the division of the mycelium and sclerotia. First symptoms of the disease in oilseed rape are visible after blooming. On the stem, blotches of whiteish – greyish colour occur, which are expanding within time. Later these blotches are covered by the white cottony mycelium, hence the disease name. Economic injury level for this disease is 1% of the infected plants. On species other than oilseed rape, cottony rot can also occur during the storage of plants.

Downy mildew of rape – caused by the *Hyaloperonospora brassicae* is a disease of major importance on the horticultural Brassica species. It is most serious on the flowerhead types (cauliflower, broccoli), less serious on the leaf brassicas (cabbage, Brussels sprouts), and least serious on the root brassicas (turnips, swedes) and oil brassicas (rape). The pathogen persists as oospores in the soil. Attacks are most important in Brassica seedbeds, with infection appearing as yellow speckling of the upper surface of seedling leaves, and white mildew on the lower surface. Severely affected seedlings are stunted or killed. Similar symptoms appear on leaves in the field, causing premature senescence and favouring bacterial spoilage in the cold store after harvest. Affected Brussels sprouts show black spotting, which reduces their market quality. The heads of flowerhead brassicas can be severely affected, and become unmarketable.

Diseases present in field trials of Protiokonazol 300 EC are the known as serious cereals and winter oilseed rape competitors. The results are showing that these crops major diseases can be effectively controlled by the product (please see the table below for an abstract of trials summary).

Diseases presented in field trials	**Winter wheat, Winter triticale, Spring triticale** **Dose rate (l/ha)**	**Spring wheat,** **Dose rate (l/ha)**	**Winter barley, Spring barley** **Dose rate (l/ha)**	**Rye** **Dose rate (l/ha)**	**Winter oilseed rape** **Dose rate (l/ha)**
ALTEBA *Alternaria brassicae* Dark spot of crucifers	x	x	x	x	~~0.5$_{mc}$~~ 0.6
ERYSGR *Blumeria graminis* Powdery mildew of cereals	0.5-0.65	x	x	0.5-0.65	x
LEPTMA *Plenodomus lingam* Dry rot of crucifers	x	x	x	x	0.6
PYRNTE *Pyrenophora teres* Net blotch of barley	x	x	0.5-0.65	x	x
SCLESC *Sclerotinia sclerotiorum* Cottony rot	x	x	x	x	~~0.5~~ 0.6
SEPTTR *Zymoseptoria tritici* Septoria leaf blotch	0.5-0.65	0.5-0.65	x	x	x
HPERBR *Hyaloperonospora brassicae* Downy mildew of rape	x	x	x	x	~~0.5~~ 0.6

mc – moderate control
red –reduction
r - resistant
x – not present

According to Statistics Poland in 2020 (latest available data) 69 849.40 tonnes of pesticides were used in agricultural sector. According to Statistics Poland, sales of fungicides in Poland have reached 21 761.40

tonnes in 2020 (latest year available on Statistics Poland). From the fungicides group, almost 6 899.4 tonnes of fungicides based on imidazoles and triazoles (included pesticides based on prothioconazole) was used by farmers in Poland, which makes it 31.7% of total fungicide use for the year 2020 (Statistics Poland).

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Winter wheat,	X		Powdery mildew of cereals	X	
			Septoria leaf blotch	X	
Spring wheat,	X		Septoria leaf blotch	X	
Winter triticale	X		Powdery mildew of cereals	X	
			Septoria leaf blotch	X	
Spring triticale	X		Powdery mildew of cereals	X	
			Septoria leaf blotch	X	
Winter barley	X		Net blotch of barley	X	
Spring Barley	X		Net blotch of barley	X	
Winter Rye	X		Powdery mildew of cereals	X	
Winter oilseed rape	X		Dark spot of crucifers	X	
			Cottony rot	X	
			Dry rot of crucifers	X	
			Downy mildew of rape	X	

Compliance with the Uniform Principles

The assessment was performed according to the uniform principles and EPPO guidelines and with the principles of GEP.

Information on trials submitted (3.1 Efficacy data)

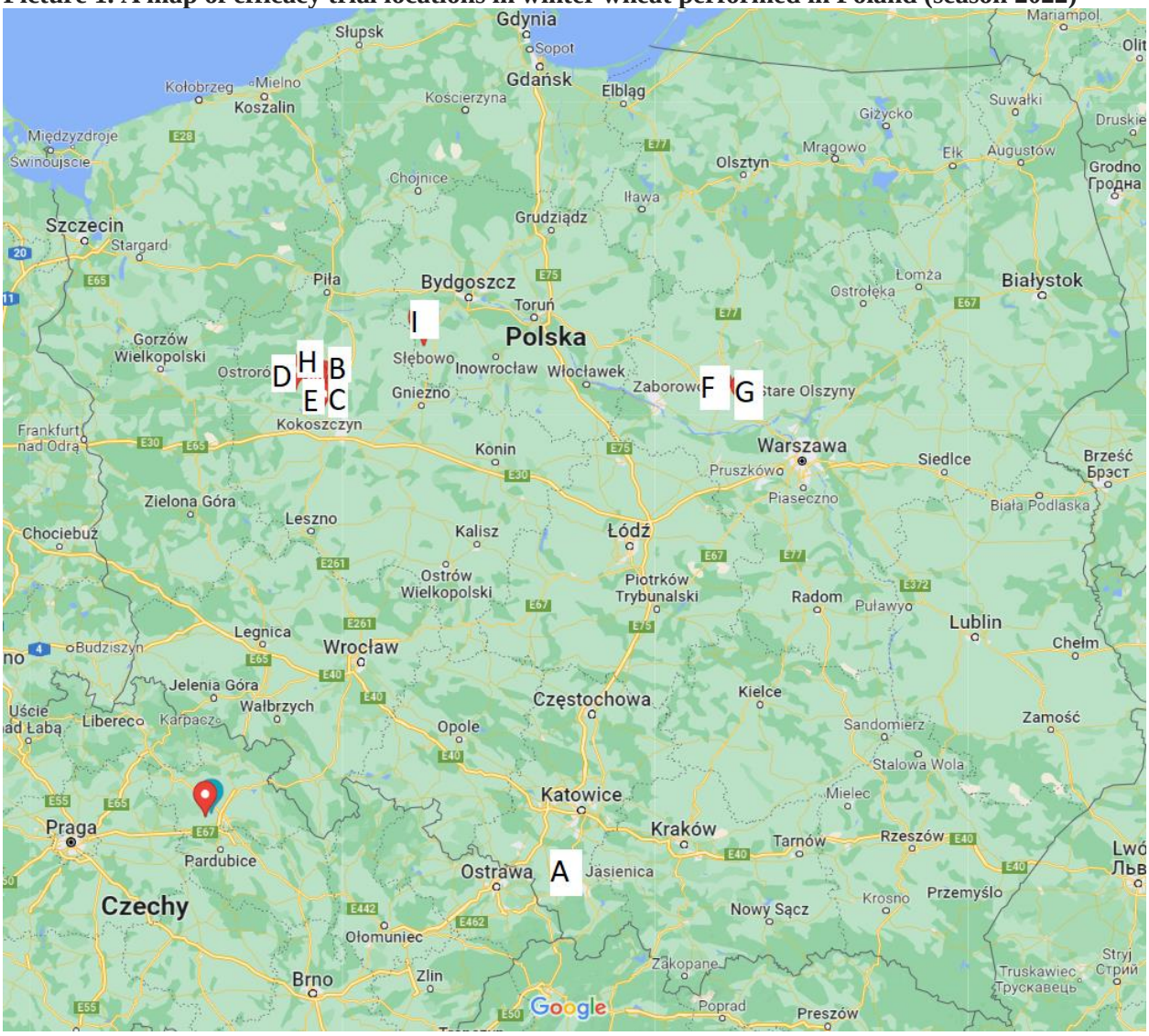
Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials...)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)	GEP, non-GEP, official***	Comments (any other relevant information)
					North-East zone		
Winter wheat	ERYSGR (5) SEPTTR (8) PUCCSI (3) PYRNTR (3)	Poland, Czech Republic	2022	MED + E	10 (10)	GEP	-
Spring wheat	SEPTTR (2) PUCCSI (1) PYNTR (1)	Poland	2022	MED + E	2 (2)	GEP	-
Winter triticale	ERYSGR (1) SEPTTR (1) PYRNTR (1)	Poland,	2022	MED + E	2 (2)	GEP	-
Spring triticale	ERYSGR (1) SEPTTR (1) PUCCSI (1) RHYNSE (1)	Poland	2022	MED + E	2 (2)	GEP	-
Winter barley	PYRNTE (3) ERYSYGR (1)	Poland, Czech Republic	2022	MED + E	3 (3)	GEP	-
Spring barley	PYRNTE (8) ERYSYGR (1) PUCCRE (2)	Poland,	2022	MED + E	9 (9)	GEP	-
Winter Rye	ERYSGR (1) SEPTTR (2) RHYNSE (2) PUCCSI (1) PYRNTR (1)	Poland	2022, 2023	MED + E	5 (5)	GEP	-
Winter oilseed rape (autumn use)	ALTEBA (5 in 2022 and 1 in 2023) LEPTMA (6 in 2022 and 1 in 2023) HPERBR (8)	Poland	2021,2023	MED + E	16 (16)	GEP	-
Winter oilseed rape (spring use)	ALTEBA (7) SCLESC (9)	Poland, Czech Republic	2022	MED + E	10 (10)	GEP	-
TOTAL				**MED + E**	**59 (59)**	**GEP**	**-**

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Efficacy trials of Protiokonazol 300 EC fungicide were carried out during two growing seasons – 2021, 2022 and 2023 in different regions of Poland and Czech Republic. Maps below presents locations of the trials in each crop.

Picture 1. A map of efficacy trial locations in winter wheat performed in Poland (season 2022)



From total of ten trials, nine Protiokonazol 300 EC trails in winter wheat during spring 2022 season were performed in Poland. Trials were set in four voivodeships: Masovian, Kuiavian-Pomeranian, Greater Poland and Silesia.

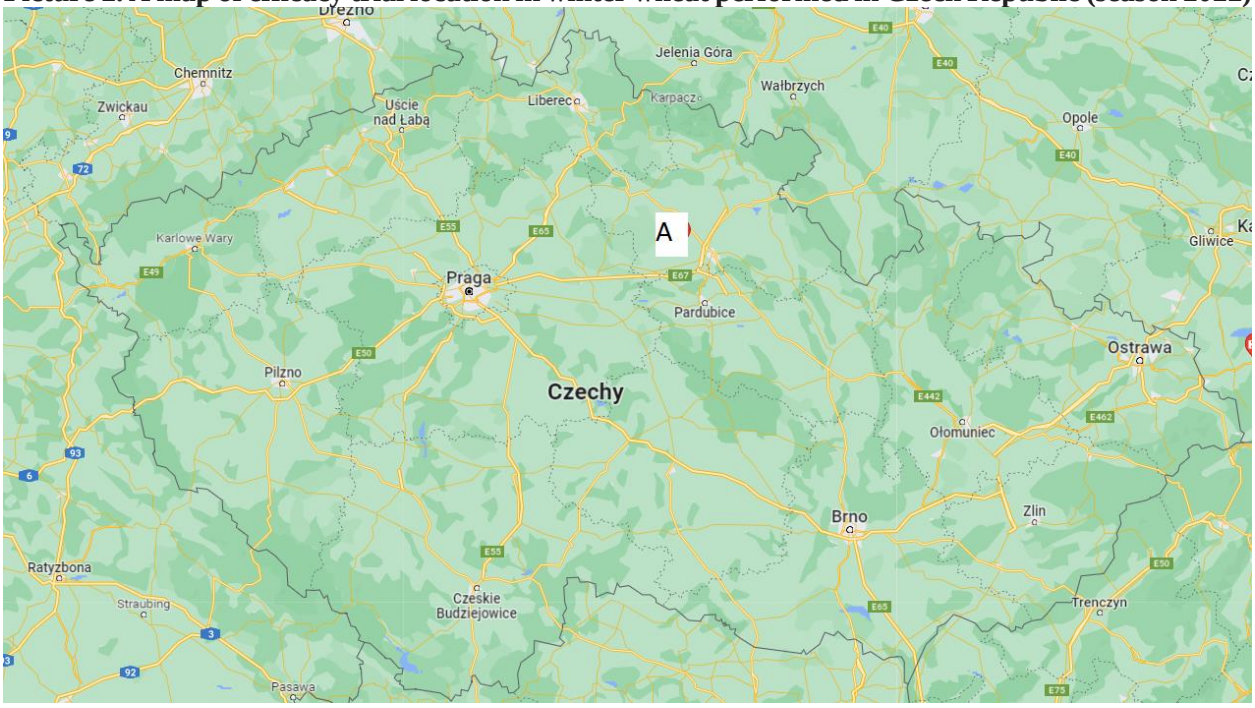
Trials were set in 2022 and conducted by Eurofins Agroscience Green & Property Consulting in the locations below:

	Year	Country	Trial ID	Location	Variety	Soil type	pH
A	2022	PL	S22-03727-01	Jasienica	Formacja	Loam	5.9
B	2022	PL	S22-03727-02	Górka	Linus	Sandy loam	5.4
C	2022	PL	S22-03727-03	Mrowino	Euforia	Sandy loam	6.5
D	2022	PL	S22-03727-04	Ostroróg	Arkadia	Loamy sand	6.7
E	2022	PL	S22-03727-05	Kokoszczyn	Arkadia	Sandy loam	7.7
F	2022	PL	013GPSE202201	Zaborowo	Astoria	Sandy loam	6.1
G	2022	PL	013GPSE202202	Stare Olszyny	Hondia	Sandy loam	7.2
H	2022	PL	013GPSE202203	Baborówko	Arkadia	Sandy loam	5.8
I	2022	PL	013GPSE202204	Słębowo	Astoria	Clayey sand	6.6

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day between crop BBCH 32 and

33. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after application B. Evaluations were done in accordance with EPPO PP 1/26 (4) “Foliar and ear diseases on cereals” guideline.

Picture 2. A map of efficacy trial location in winter wheat performed in Czech Republic (season 2022)



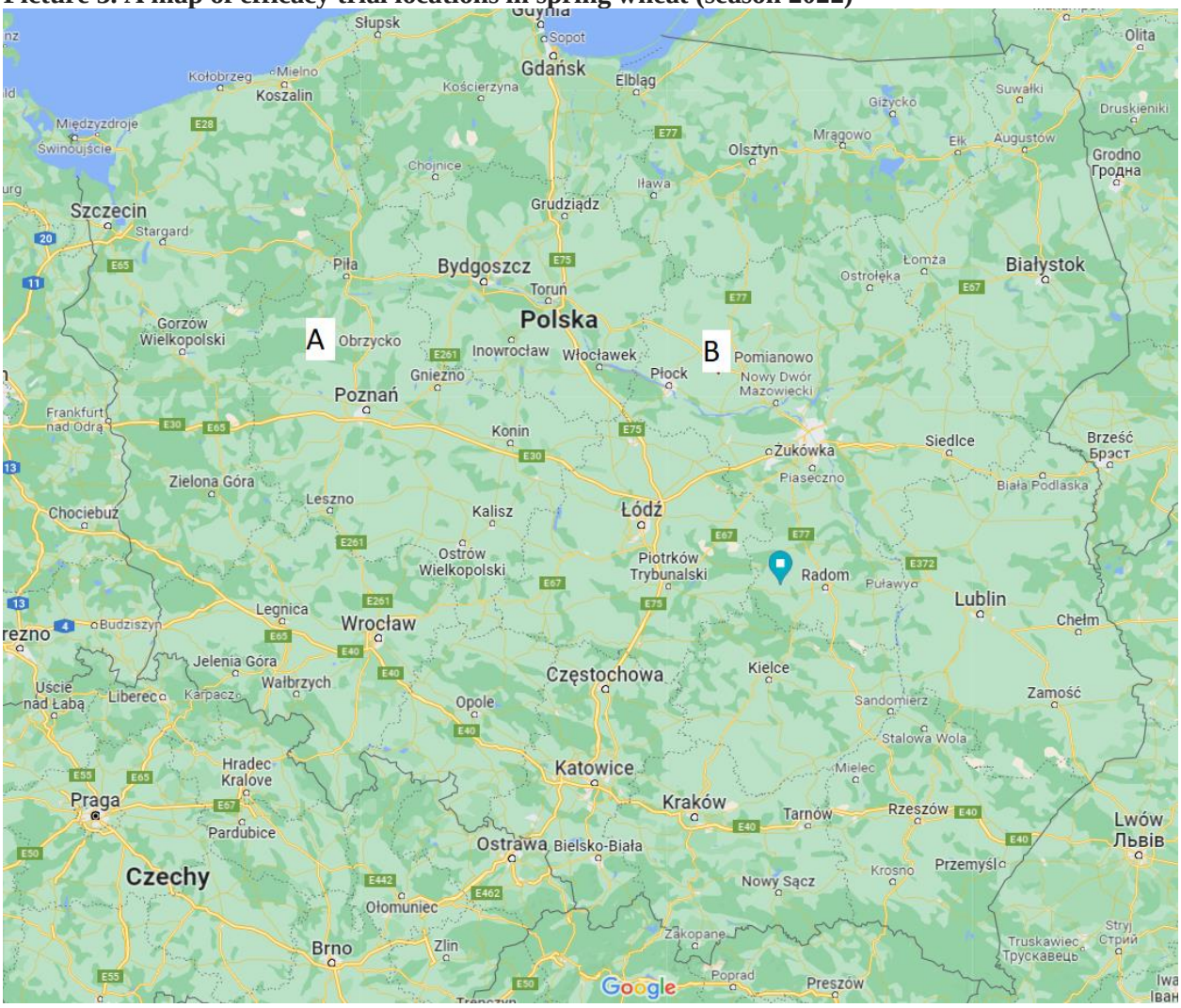
One Protiokonazol 300 EC trail in winter wheat during spring 2022 season was performed in Czechia. Trial was located in Hradec Králové Region.

Abovementioned trial was set in 2022 and conducted by Zkušební Stanice Nechanice:

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2022	CZ	CZOR-PSZ22-TRZAW-053NEC	Nechanice	Julie	sandy clay loam	6.1

The abovementioned trial was conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day at crop BBCH 39. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after application B. Evaluations were done in accordance with EPPO PP 1/26 (4) “Foliar and ear diseases on cereals” guideline.

Picture 3. A map of efficacy trial locations in spring wheat (season 2022)



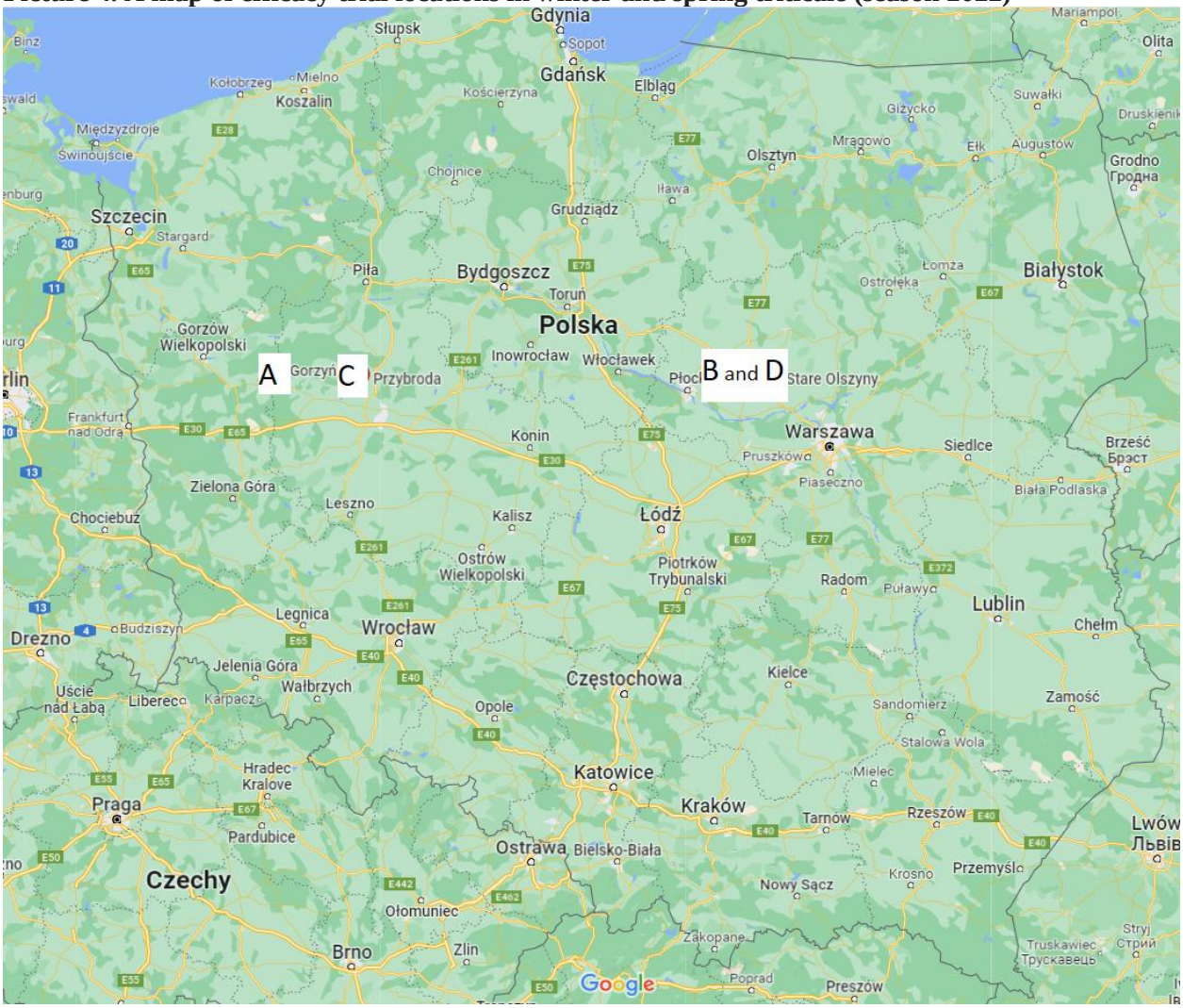
Two Protiokonazol 300 EC trails in spring wheat during spring 2022 season were performed in Poland. Trials were set in two voivodeships: Masovian and Greater Poland.

Trials were set in 2022 and conducted by Eurofins Agroscience Green & Property Consulting in the locations below:

	Year	Country	Trial ID	Location	Variety	Soil type	pH
A	2022	PL	S22-03727-06	Obrzycko	Harenda	Sandy loam	6
B	2022	PL	014GPSE202201	Pomianowo	Arabella	Loamy sand	6.4

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day between crop BBCH 31 and 37. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after application B. Evaluations were done in accordance with EPPO PP 1/26 (4) “Foliar and ear diseases on cereals” guideline.

Picture 4. A map of efficacy trial locations in winter and spring triticale (season 2022)



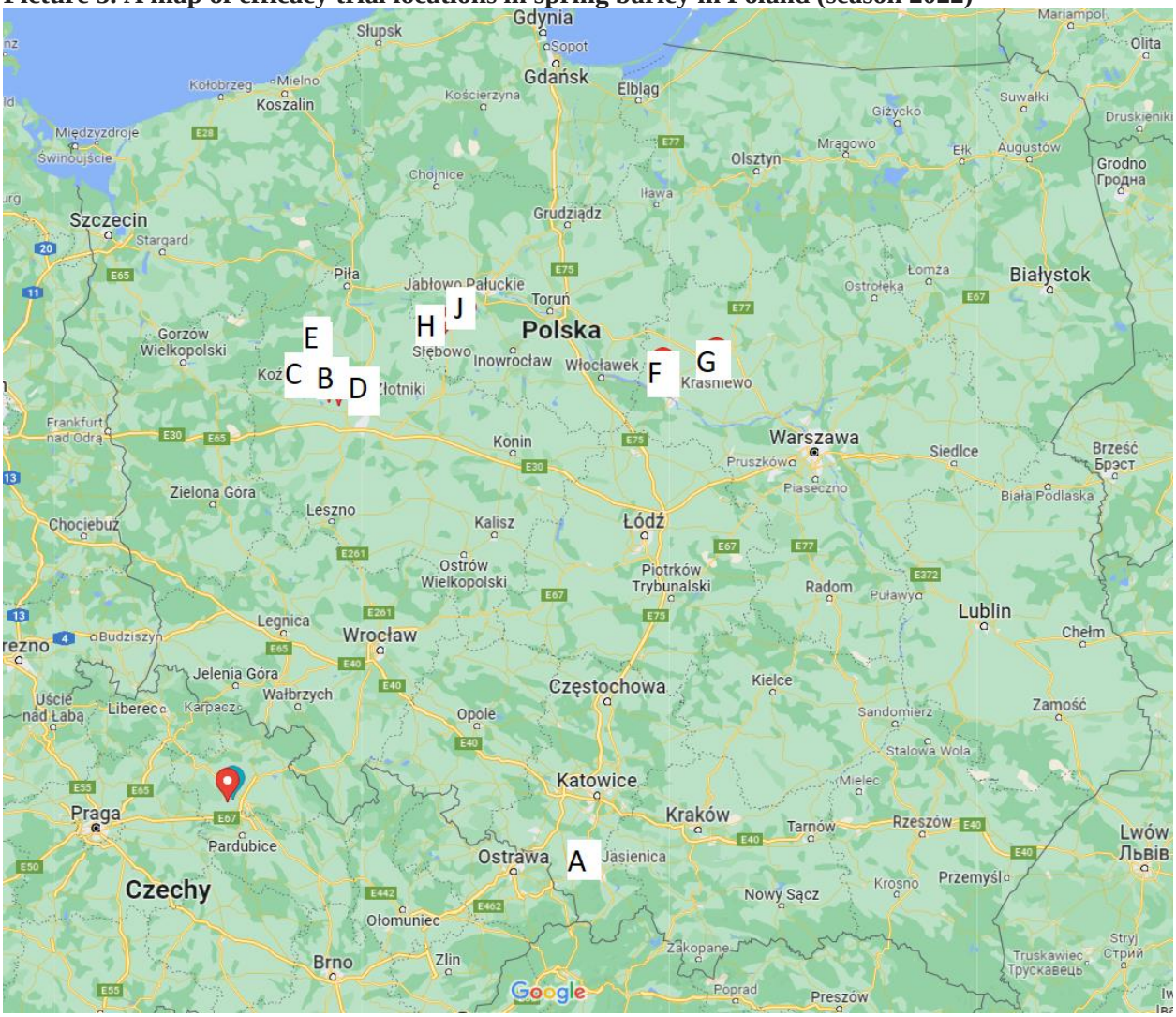
Four Protiokonazol 300 EC efficacy trails in triticale (winter and spring) during spring 2022 season were performed in Poland. Trials were set in two voivodeships: Masovian and Greater Poland.

Trials were set in 2022 and conducted by Eurofins Agroscience Green & Property Consulting in the locations below:

	Year	Country	Trial ID	Location	Variety	Soil type	pH
	Spring triticale						
A	2022	PL	S22-03727-08	Gorzyń	Milewo	Loamy sand	5.6
B	2022	PL	016GPSE202201	Stare Olszyny	Mamut	Sandy clay loam	6.3
	Winter triticale						
C	2022	PL	S22-03727-07	Przybroda	Grenado	Sandy loam	6.5
D	2022	PL	015GPSE202201	Stare Olszyny	Lombardo	Loamy sand	6.3

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day between crop BBCH 32 and 39. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after application B. Evaluations were done in accordance with EPPO PP 1/26 (4) “Foliar and ear diseases on cereals” guideline.

Picture 5. A map of efficacy trial locations in spring barley in Poland (season 2022)



Eight Protiokonazol 300 EC trails in spring barley during spring 2022 season were performed in Poland. Trials were set out in four Poland's voivodeships: Masovian, Kuiavian-Pomeranian, Greater Poland and Silesia.

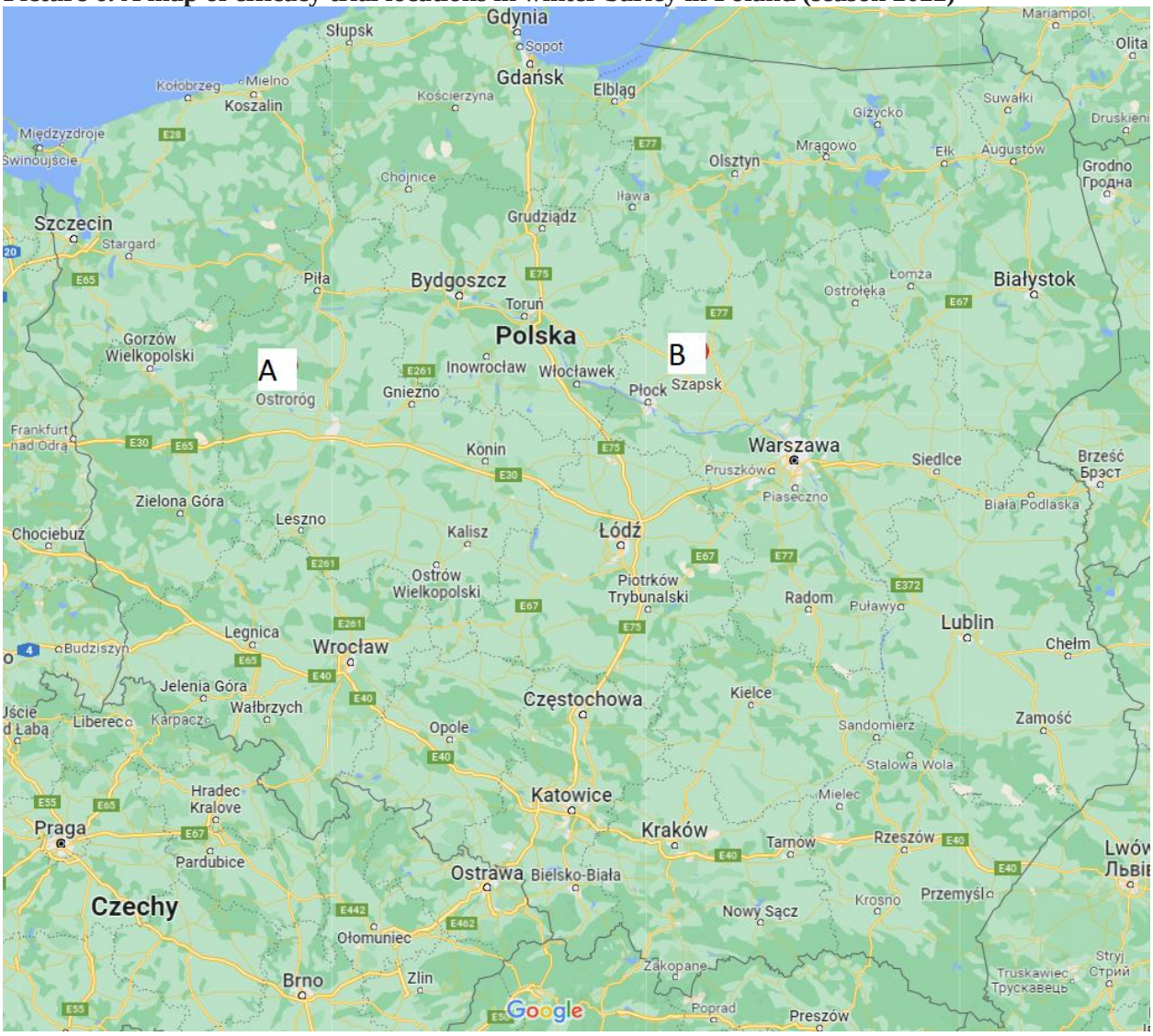
Abovementioned trials were set in 2022 and conducted by Eurofins Agroscience and Green & Property Consulting:

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2022	PL	S22-03727-10	Jasienica	Radek	Loam	5.9
B	2022	PL	S22-03727-11	Kaźmierz	Melius	Loamy sand	7.5
C	2022	PL	S22-03727-12	Koźle	Ela	Clay sandy loam	7.5
D	2022	PL	S22-03727-13	Złotniki	Etoile	Loamy sand	6.9
E	2022	PL	S22-03727-14	Kokoszczyn	Penguin	Sandy loam	6.8
F	2022	PL	019GPSE202201	Srebrna	Etoile	Loamy sand	5.8
G	2022	PL	019GPSE202202	Kraśniewo	Pilote	Loamy sand	6.2
H	2022	PL	019GPSE202203	Słębowo	Saldo	Sandy clay loam	6.2
J	2022	PL	019GPSE202204	Jabłowo Pałuckie	Ella	Sandy loam	7.2

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day between crop BBCH 29 and 49. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after

application B. Evaluations were done in accordance with EPPO PP 1/26 (4) “Foliar and ear diseases on cereals” guideline.

Picture 6. A map of efficacy trial locations in winter barley in Poland (season 2022)



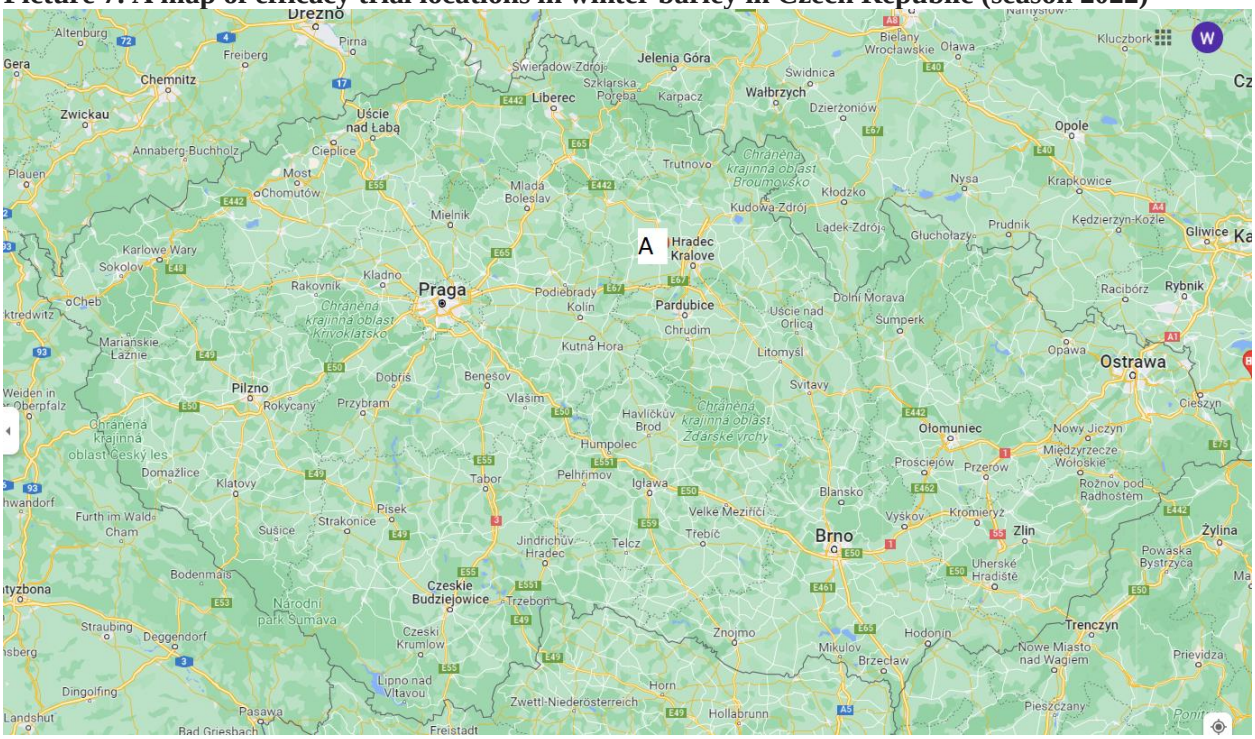
Two Protiokonazol 300 EC trails in winter barley during spring 2022 season were performed. All of the trials were set out in the area of Masovian Voivodeship and Greater Poland, Poland.

Those two trials were set in 2022 and conducted by Eurofins Agroscience and Green & Property Consulting:

	Year	Country	Trial ID	Location	Variety	Soil type	pH
A	2022	PL	S22-03727-15	Ostroróg	Zenek	Loamy sand	6.5
B	2022	PL	018GPSE202201	Szapsk	KWS Kosmos	Loamy sand	6.6

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day at crop BBCH 37. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after application B. Evaluations were done in accordance with EPPO PP 1/26 (4) “Foliar and ear diseases on cereals” guideline.

Picture 7. A map of efficacy trial locations in winter barley in Czech Republic (season 2022)



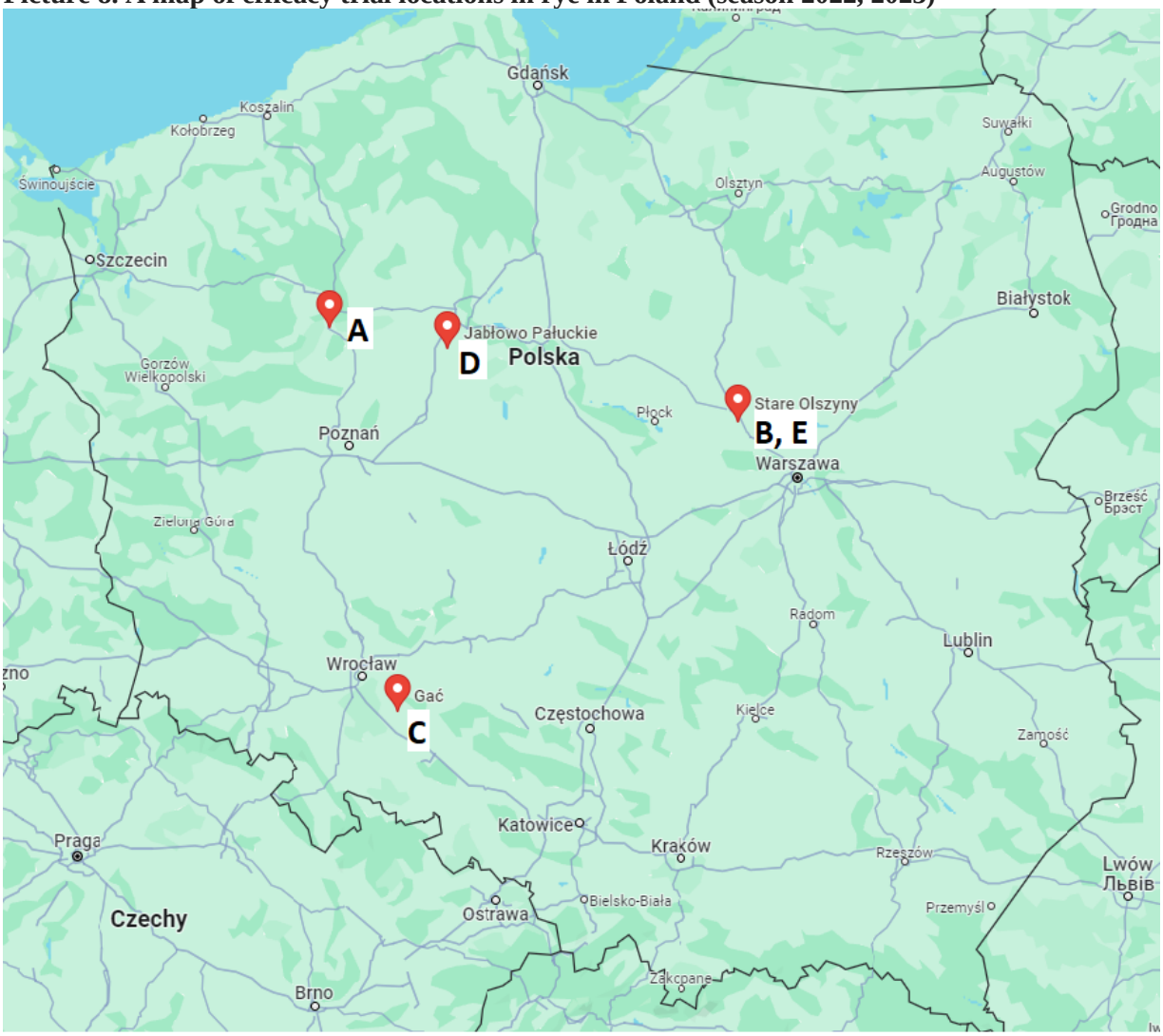
One Protiokonazol 300 EC trail in winter barley during spring 2022 season was performed in Czechia. Trial was located in Hradec Králové Region.

Abovementioned trial was set in 2022 and conducted by Zkušební Stanice Nechanice:

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2022	CZ	CZOR-PSZ22-HORVW-057NEC	Nechanice	Sonnegold	Sandy clay loam	6.1

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day at crop BBCH 45. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after application B. Evaluations were done in accordance with EPPO PP 1/26 (4) “Foliar and ear diseases on cereals” guideline.

Picture 8. A map of efficacy trial locations in rye in Poland (season 2022, 2023)



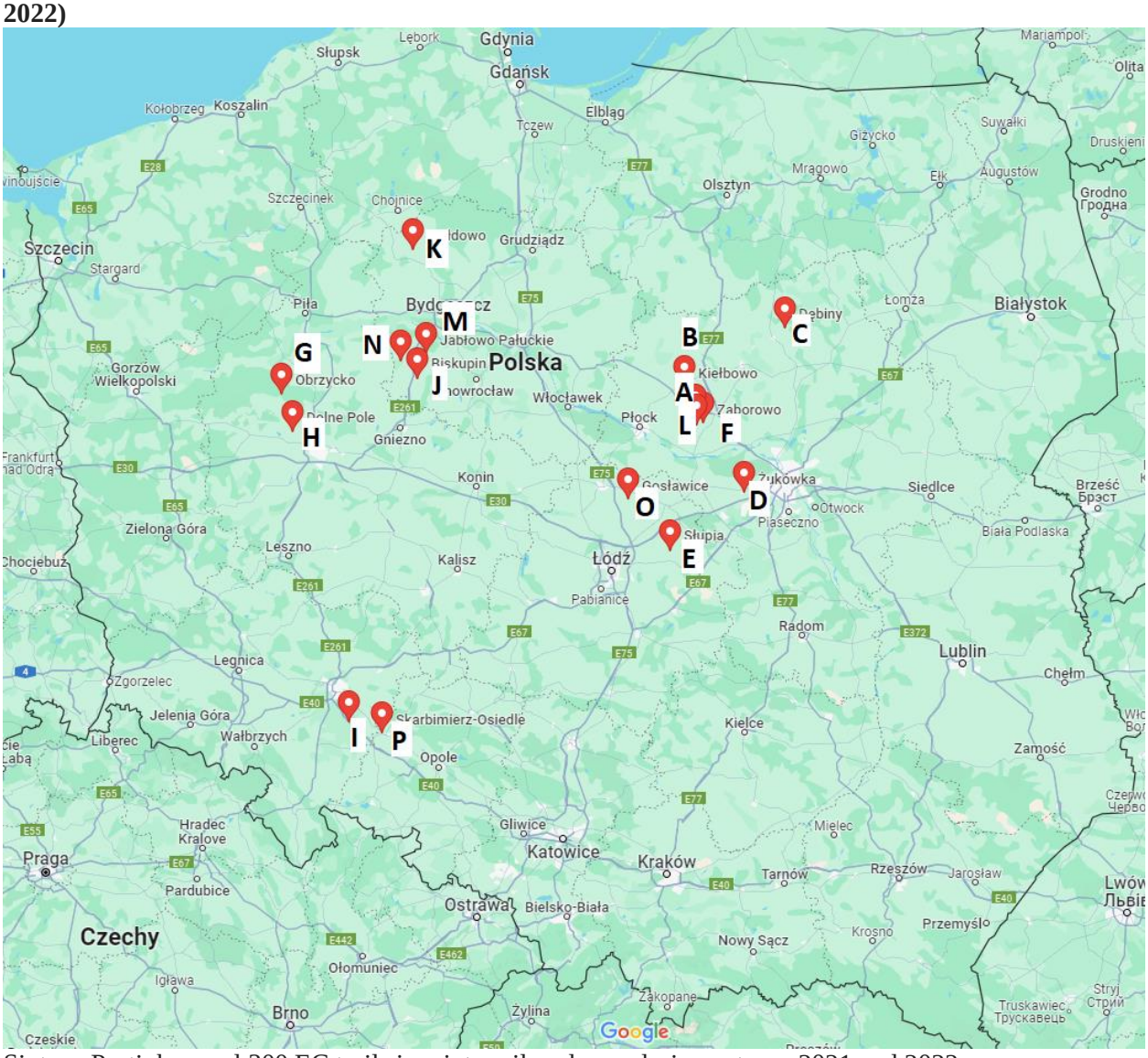
Five Protiokonazol 300 EC trails in winter oilseed rape during 2022 and 2023 season were performed. Trials were set out in four Poland's voivodeships: Masovian, Kuiavian-Pomeranian, Greater Poland and Lower Silesian.

Those five trials were set in 2022 and 2023 and conducted by Green & Property Consulting and Eurofins:

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2022	PL	S22-03727-09	Nowa Wieś Ujska	KWS VI-NETTO F1	loamy sand	4.5
B	2022	PL	017GPSE202201	Stare Olszyny	KWS SE-RAFINO	silt loam	5.8
C	2023	PL	007GPSE202301	Gać	KWS Do-laro	loamy clay	6.8
D	2023	PL	007GPSE202302	Jabłowo Pałuckie	Stanko	sandy loam	6.5
E	2023	PL	007GPSE202303	Stare Olszyny	Antonińskie	loamy sand	6

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day between crop BBCH 32 and 39. First assessment after application was performed 14 - 21 days after application A and 14 - 21 days after application B. Evaluations were done in accordance with EPPO PP 1/26 (4) "Foliar and ear diseases on cereals" guideline. Only in this trial - 007GPSE202302 – ERYSYGR was studied.

Picture 9. A map of autumn efficacy trial locations in winter oilseed rape in Poland (season 2021, 2022)



Sixteen Protiokonazol 300 EC trails in winter oilseed rape during autumn 2021 and 2022 season were performed. Trials were set out in six Poland's voivodeships: Masovian, Kuiavian-Pomeranian, Greater Poland, Łódź, Opole and Lower Silesian.

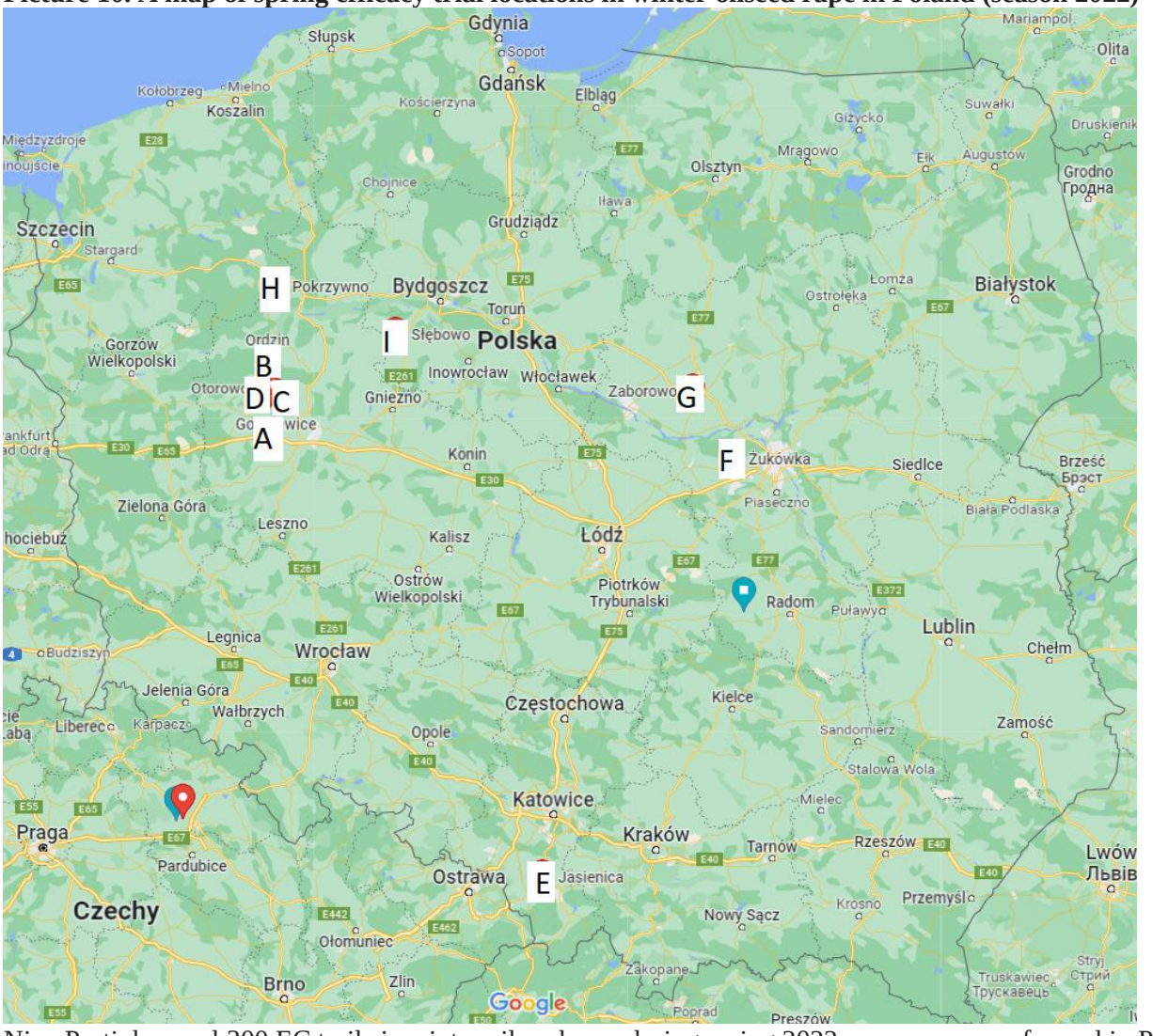
Those six trials were set in 2021 and 2022 and conducted by Green & Property Consulting and Eurofins:

	Year	Country	Trial ID	Location	Variety	Soil type	pH
A	2021	PL	004GP202101	Korytowo	Kuga F1	sandy clay loam	6.1
B	2021	PL	004GP202102	Kiełbowo	Derrick	sandy loam	6.9
C	2021	PL	004GP202103	Dębiny	Absolut	sandy clay	6.0
D	2021	PL	004GP202104	Żukówka	Duke F1	loamy sand	5.51
E	2021	PL	004GP202105	Słupia Gaj	ES Imperio	sandy loam	7.0
F	2021	PL	004GP202106	Zaborowo	KWS Marcopolos	sandy clay	6.9
G	2022	PL	S22-07447-01	Obrzycko	Annabella	loamy clay sand	6.9
H	2022	PL	S22-07447-02	Dolne Pole	Aganos	loamy sand	6

I	2022	PL	006GPAE2022-01	Piskorzó-wek	Sienna	silt loam	5.6
J	2022	PL	006GPAE2022-02	Biskupin	Hevelius	sandy loam	7.6
K	2022	PL	006GPAE2022-03	Wałdowo	Nelson	sandy loam	6.2
L	2022	PL	006GPAE2022-04	Nowy Nac-polsk	Factor KWS F1	loamy sand	6.2
M	2022	PL	006GPAE2022-05	Jabłowo Pa-łuckie	Uniwersum	loamy sand	6.6
N	2022	PL	006GPAE2022-06	Gorzyce	Kadore	clayey sand	6.7
O	2022	PL	006GPAE2022-07	Gosławice	Chopin	clayey sand	6.3
P	2022	PL	006GPAE2022-08	Skarbimierz Osiedle	SY Ilona	sandy loam	6.8

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day between crop BBCH 13 and 18. First assessment after application was performed around 2 weeks after application, second assessment was performed around 3-5 weeks after application. Evaluations were done in accordance with EPPO PP 1/78 (3) "Root, stem, foliar and pod diseases on oilseed rape" guideline.

Picture 10. A map of spring efficacy trial locations in winter oilseed rape in Poland (season 2022)



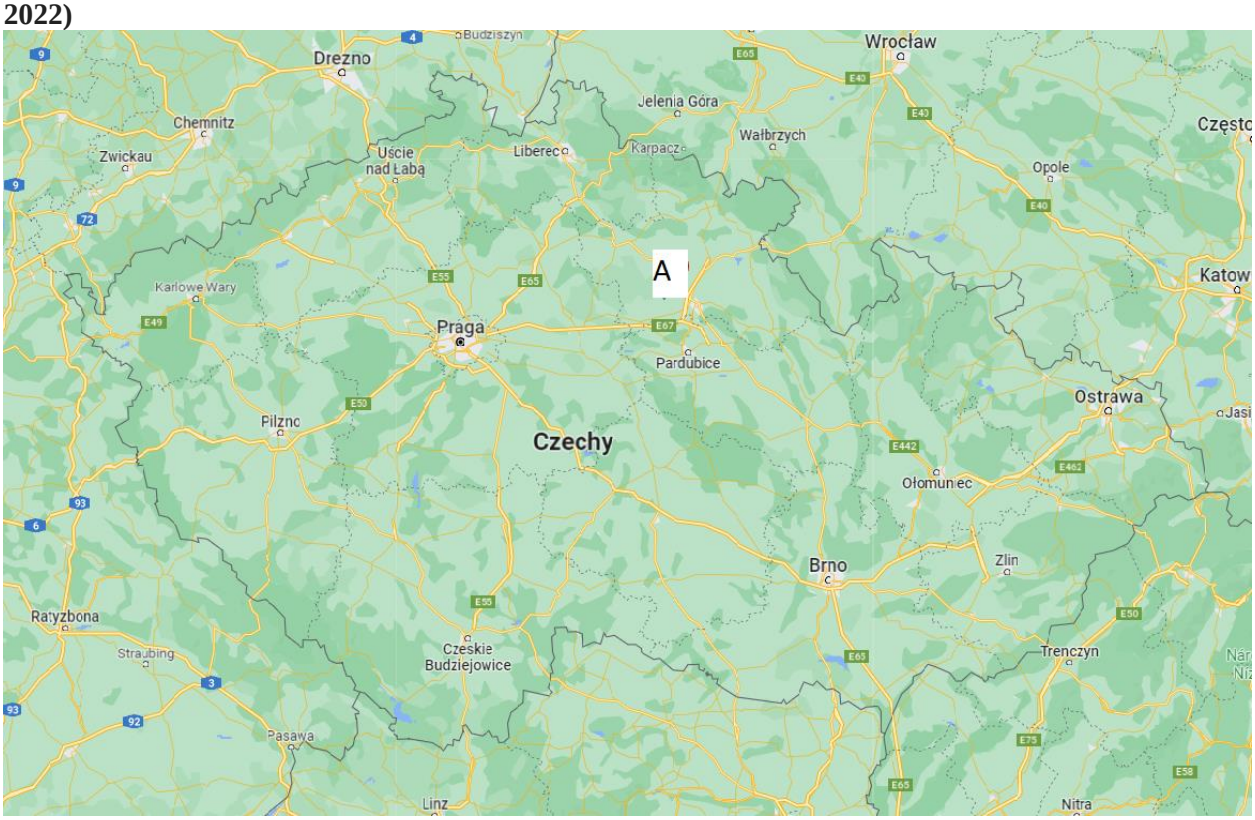
Nine Protiokonazol 300 EC trails in winter oilseed rape during spring 2022 season were performed in Poland. Trials were set out in four Poland's voivodeships: Masovian, Kuiavian-Pomeranian, Greater Poland and Silesia.

Those nine trials were set in 2022 and conducted by Eurofins Agroscience and Green & Property Consulting:

	Year	Country	Trial ID	Location	WOSR variety	Soil type	pH
A	2022	PL	S22-03740-01	Wierzchaczewo	LG Ambassador F1	Sandy loam	6.4
B	2022	PL	S22-03740-02	Ordzin	Derrick	Sandy loam	6.4
C	2022	PL	S22-03740-03	Gorszewice	Anabella	Loamy sand	5.3
D	2022	PL	S22-03740-04	Otorowo	Architekt	Loamy sand	5.5
E	2022	PL	S22-03740-05	Jasienica	KEPLER	Loam	5.9
F	2022	PL	020GP202201	Żukówka	Duke F1	Loamy sand	5.5
G	2022	PL	020GP202202	Zaborowo	KWS Marcopolo	Sandy clay	6.9
H	2022	PL	020GPSE202203	Pokrzywno	Ilona	Loamy sand	6.2
I	2022	PL	020GPSE202204	Słębowo	Kadore	Clayey sand	6.7

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day between crop BBCH 63 and 65. First assessment after application was performed 2-4 weeks after application, stem infection levels were also assessed at stages 50-85 of the crop and pod infection was assessed at stage 71-85 of the crop. Evaluations were done in accordance with EPPO PP 1/78 (3) “Root, stem, foliar and pod diseases on oilseed rape” guideline.

Picture 11. A map of spring efficacy trial locations in winter oilseed rape in Czech Republic (season 2022)



One Protiokonazol 300 EC trail in winter oilseed rape during spring 2022 season was performed in Czechia. Trial was located in Hradec Králové Region.

Abovementioned trial was set in 2022 and conducted by Zkušební Stanice Nechanice:

	Year	Country	Trial ID	Location	WOSR variety	Soil type	pH
A	2022	CZ	CZOR-PSZ22-BRSNN-045NEC	Nechanice	Allison	Sandy clay loam	6.4

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary disease infection levels assessments were done at the application day at crop BBCH 61. First assessment after application was performed 2-4 weeks after application, stem infection levels were also assessed at stages 50-85 of the crop and pod infection was assessed at stage 71-85 of the crop. Evaluations were done in accordance with EPPO PP 1/78 (3) "Root, stem, foliar and pod diseases on oilseed rape" guideline.

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials)

Crop(s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
Winter wheat; Spring wheat; Winter triticale; Spring triticale Spring barley; Winter barley; Rye	Poleposition 300 EC	PL	R-29/2020	Prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
Winter wheat; Rye	Protendo 300 EC	PL	R-224/2019	Prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
Winter wheat; Winter barley	ERA	CZ	5689-3	Prothioconazole	EC	300 g/L	0.6 L/ha	0.6 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
Winter oilseed rape (autumn)	Promino 300 EC	PL	R- 211/2019	Prothioconazole	EC	300 g/L	0.6 L/ha	0.6 L/ha	2. application per season; 200-400 L/ha of spray volume; foliar spray
Winter oilseed rape (autumn), Winter oilseed rape (spring)	Poleposition 300 EC	PL	R-29/2020	Prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.6 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
Winter oilseed rape (autumn)	Tauron 240 EC	PL	R-32/2018	Prothioconazole, tebuconazole	EC	80 g/L (prothioconazole), 160 g/L (tebuconazole)	0,75 L/ha	0,75 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray

Crop(s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active sub-stance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treat-ment)	Remark(4)
					Type(2)	Concentra-tion of a.s.			
Winter oilseed rape (spring)	ERA	CZ	5689-3	Prothio-conazole	EC	300 g/L	0.6 L/ha	0.6 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

Comments for ZRMS:

This document presented the information related to the efficacy of the plant protection product – Protiokonazol 300 EC. Applicant in this dRR did not submitted trade name of Protiokonazol 300 EC. However, project label of Protiokonazol 300 EC is prepared for HERA 300 EC. So, ZRMs has completed the missing trade name as HERA 300 EC in line to name of PPP from project label.

This dRR was prepared by Applicant for registration of HERA 300 EC (product code: Protiokonazol 300 EC) against SEPTTR and ERYSYGR on winter wheat, winter triticale and spring triticale and against SEPTTR on spring wheat, against PYRNTE on winter and spring barley and ERYSYGR on winter rye for spring post-emergence use and against ALTEBA, LEPTMA and HIPERBR on winter oilseed rape for autumn post-emergence use and against ALTEBA and SCLESC for spring post-emergence use. Also, in line to Article 51 Applicant would like to register spring post-emergence use against LEPTMA and ALTEBA on spring oilseed rape (as a minor use).

HERA 300 EC (product code: Protiokonazol 300 EC) is an emulsifable concentrate (EC) containing 300 g/L of prothioconazole.

Prothioconazole is a fungicide belonging to the group of SBI-Class I: Demethylation-Inhibitors (DMI) a subgroup of the Sterol Biosynthesis Inhibitors (SBI)-triazoles. Triazoles are the largest class of fungicides commonly used in medical and agriculture. They were first introduced for crop protection in 1973 by Bayer (triadimefon) [Morton and Staub 2008]. In the following years, the following substances were commercialized further substances from this group, including: tebuconazole [1986], epoxiconazole [1990] and prothioconazole [2002], which are currently the most widely used [Parker et al. 2014]. The active ingredient is classified after the target site and code FRAC to inhibition of biosynthesis in membrane G1 (group 3): C14-demethylase in sterol biosynthese. The active ingredient has systemic properties, is very rapidly absorbed into the plant and acropetally distributed in the transpiration stream. This results in both a protective and curative action. The result of the effect of prothioconazole is the abnormal formation of fungal infection structures and a strong inhibition of mycelial growth and spore germination. A penetration of the plant or the seed is thus prevented. The active ingredient is selective on a wide range of dicotyledonous and monocotyledonous crops species. Prothioconazole is used for foliar application and seed treatment.

For now, mentioned active substance (prothioconazole) is on the list of approved active substances. What is important, a large-scale efficacy trials are available to evaluate the effectiveness of products containing this active compound.

All necessary information's about tested PPP, active substance, studied fungal diseases, reference products, etc. are correctly presented in this dRR by Applicant.

In Poland 126 PPPs containing prothioconazole as an active substance are already registered (on the basis on Registry of Plant Protection Products, dated 14.03.2024).

Poland is a ZRMS. The PPP – HERA 300 EC (product code: Protiokonazol 300 EC) by Pestila Spółka z ograniczoną odpowiedzialnością has not been previously evaluated in any county according to Uniform Principles.

3.2.1 Preliminary tests (KCP 6.1)

No results of the preliminary range-finding tests are presented since no screening trials were carried out. However, the active substance used in Protiokonazol 300 EC, prothioconazole have been commonly used in agricultural practice for many years.

Comments for ZRMS:

The active substance of HERA 300 EC (product code: Protiokonazol 300 EC) – prothioconazole is registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. ZRMs agree with Applicant that preliminary tests are not described and not required in this case.

3.2.2 Minimum effective dose tests (KCP 6.2)

Minimum effective dose tests were not carried out. However, several doses of Protiokonazol 300 EC were tested during efficacy studies and the lowest effective dose was selected. The tests were conducted in accordance with EPPO standard PP 1/225 (2) '*Minimum effective dose',* which advises on the minimum requirements necessary to ensure consistency of decision making.

Cereals and winter oilseed rape diseases

59 field trials were set out to present the control of the diseases in cereals and winter oilseed rape. Protiokonazol 300 EC was tested in rates from 0.25 L/ha to 0.65 L/ha (75-195 g/ha of prothioconazole) in order to determine the minimum effective dose in cereals for the control of leaf diseases, and to determine MED in winter oilseed rape the doses used were: 0.2 L/ha to 0.6 L/ha (60 -180 g/ha of prothioconazole) for autumn application and 0.35 L/ha to 0.6 L/ha (105 -180 g/ha of prothioconazole). The rates reflect the proposed label rates, 60% and 80% of the lowest recommended rate in cereal trials and spring trials in winter oilseed rape, and 33%, 50%, 58% and 83% in case of autumn trials in winter oilseed rape. Which, in applicant opinion, covers the requirements from the EPPO standard PP 1/225 (2) '*Minimum effective dose'*.

Cereals:
For the BBCH 29-65, the 0.4 L/ha dose of Protiokonazol 300 EC provided inferior control when compared to 0.5-0.65 L/ha of Protiokonazol 300 EC in 33 trials out of 33 trials.

Winter oilseed rape:
For the BBCH 13-19, the 0.2 L/ha, 025 L/ha and 0.3 L/ha, 03,5 L/ha doses of Protiokonazol 300 EC provided inferior control when compared to 0.6 L/ha of Protiokonazol 300 EC in 16 trials out of 16 trials.

For the BBCH 29-65, the 0.35 L/ha dose of Protiokonazol 300 EC provided inferior control when compared to ~~0.5 -~~0.6 L/ha of Protiokonazol 300 EC in 10 trials out of 10 trials.

Table 3.2-7: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 29-65 against diseases in winter wheat.

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.4 L/ha (60% of the lowest recommended rate)		0.5 L/ha (The lowest recommended rate)		0.65 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
ERYSGR	5	10.82%	7.1%-14.9%	69.78	64.9-77	82.76	75.3-98	87.06	81.1-100
SEPTTR	8	16.9%	5.1%-33.5%	67.6	51.8-90	82.21	69.2-94.2	88.89	78.2-98.2

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity

In case of ERYSGR A1 assesment was considered (14-21 days after the application A) in 3 out of 5 trials. In the remaining two trials, due to late disease development, A2 (14-21 days after the application B) assessment was taken into the consideration.

Table 3.2-8: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 29-65 against diseases in spring wheat.

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.4 L/ha (60% of the lowest recommended rate)		0.5 L/ha (The lowest recommended rate)		0.65 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
SEPTTR	2	23.6%	7.6%-39.6%	65.4	59.6-71.2	82.7	80.1-85.3	90.75	83.6-97.9

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity

Table 3.2-9: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 29-65 against diseases in winter triticale.

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.4 L/ha (60% of the lowest recommended rate)		0.5 L/ha (The lowest recommended rate)		0.65 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
ERYSGR	1	30.1%	30.1%-30.1%	91	91-91	97	97-97	100	100-100
SEPTTR	1	42.4%	42.4%-42.4%	58.6	58.6-58.6	74.1	74.1-74.1	80.8	80.8-80.8

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity

Table 3.2-10: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 29-65 against diseases in spring triticale.

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.4 L/ha (60% of the lowest recommended rate)		0.5 L/ha (The lowest recommended rate)		0.65 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
ERYSGR	1	12.7%	12.7%-12.7%	80.2	80.2-80.2	82.9	82.9-82.9	89.4	89.4-89.4
SEPTTR	1	35.3%	35.3%-35.3%	67.4	67.4-67.4	81.1	81.1-81.1	83.4	83.4-43.4

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity

Table 3.2-11: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 29-65 against diseases in winter barley.

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.4 L/ha (60% of the lowest recommended rate)		0.5 L/ha (The lowest recommended rate)		0.65 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
PYRNTE	3	6.46%	6%-7.3%	69.06	41.4-85	80.1	67.5-92	87.6	76-100

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity

Due to weather conditions in Czech Republic in 2022 season, and late development of the disease, for PYRNTE A3 assessment (at crop BBCH 75-83) was considered in the trial CZOR-PSZ22-HORVW-057NEC.

Table 3.2-12: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 29-65 against diseases in spring barley.

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.4 L/ha (60% of the lowest recommended rate)		0.5 L/ha (The lowest recommended rate)		0.65 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
PYRNTE	8	18.04%	5.8%-51%	67.76	47.2-79	82.59	71.3-90	90.41	81-97

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity

Table 3.2-13: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 50% and 66% of the lowest recommended dose rate at BBCH 29-65 against diseases in rye.

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.25 L/ha (50% of the lowest recommended rate)		0.33 L/ha (66% of the lowest recommended rate)		0.65 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
ERYSGR	1	6%	6%-6%	62.9	62.9-62.9	82.5	82.5-82.5	84.5	84.5-84.5

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity

Table 3.2-14: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 33%, 50%, 58% and 83% of the lowest recommended dose rate at BBCH 13-19 against diseases in winter oilseed rape (autumn application).

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.2 L/ha (33% of the lowest recommended rate)		0.3 L/ha (50% of the lowest recommended rate)		0.6 L/ha (Lowest recommended rate/Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
ALTEBA	5	9.66%	6.7%-15%	62.56	53.9-69	76.12	67.7-83.6	91.02	84.1-95.5
LEPTMA	6	14.72%	10%-18.3%	20.88	2.1-50.8	57.66	52.3-66.6	86.32	82.8-89.9
Grouping *	**Number of trials**	**Infestation of the untreated control (unit %)**		**% control with Protiokonazol 300 EC**					
				0.3 L/ha (50% of the lowest recommended rate)		**0.5 L/ha (83% of the lowest recommended rate)**		**0.6 L/ha (Lowest recommended rate/Full rate)**	
		Mean	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**
ALTEBA	1	6.8%	6.8%-6.8%	79	79-79	89	89-89	97	97-97
LEPTMA	1	6.9%	6.9%-6.9%	70	70-70	94	94-94	100	100-100
Grouping *	**Number of trials**	**Infestation of the untreated control (unit %)**		**% control with Protiokonazol 300 EC**					
				0.35 L/ha (58% of the lowest recommended rate)		**0.5 L/ha (83% of the lowest recommended rate)**		**0.6 L/ha (Lowest recommended rate/Full rate)**	
		Mean	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**
HPERBR	8	7.65%	5.2%-12,9%	66.6	56.1-76.2	79.67	68.8-93.4	87.39	77.3-97.1

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity. Results were presented as an total efficacy from average efficacy's from stem, pod and leaves

Results are clearly showing that for the control of the abovementioned diseases, rate of 0.6 L/ha has to be considered as the minimum effective dose.

Table 3.2-15: Minimum effective dose. Efficacy of Protiokonazol 300 EC at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 61-72 against diseases in winter oilseed rape (spring application).

Grouping *	Number of trials	Infestation of the untreated control (unit %)		% control with Protiokonazol 300 EC					
				0.35 L/ha (60% of the lowest recommended rate)		0.5 L/ha (The lowest recommended rate)		0.6 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
ALTEBA	7	6.35%	5%-25.5%	60.43	21.6-75.8	72.47	37.3-94	83.46	44.1-99
SCLESC	9	12.7%	5%-31%	61.1	29.9-91.4	80.54	54.2-100	90.32	76.7-100

* The level of plant infestation in the studied area was recorded directly before the first application of the product by % pest severity. Results were presented as an total efficacy's from average efficacy's from stem, pod and leaves

For two trials - 020GP202203 and 020GP202204 – PESSEV evaluated on pods was considered due to insufficient levels of disease severity on whole plants.

Results presented in the tables above are clearly showing the fact that rate 0.5 L/ha should be considered as minimum effective dose for the control of white mould. In the control of black spot of rape, 0.6 L/ha showed the effective control of this disease.

Summary and conclusions on the minimum effective dose

Winter wheat

3 doses of the Protiokonazol 300 EC were tested: 0.4 L/ha (60% of the target dose); 0.5 L/ha (80% of the target dose) and 0.65 L/ha (target dose).
Powdery mildew was controlled when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used. For **septoria leaf blotch** control of the disease was achieved when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used.

As a result, the proposed rate range of 0.5-0.65 L/ha used in the spring, should be considered as the minimum effective dose to deliver satisfying control of the winter wheat diseases.

Spring wheat

3 doses of the Protiokonazol 300 EC were tested: 0.4 L/ha (60% of the target dose); 0.5 L/ha (80% of the target dose) and 0.65 L/ha (target dose).
Septoria leaf blotch was controlled when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used.

As a result, the proposed rate range of 0.5-0.65 L/ha used in the spring, should be considered as the minimum effective dose to deliver satisfying control of the septoria leaf blotch in spring wheat.

Winter triticale

3 doses of the Protiokonazol 300 EC were tested: 0.4 L/ha (60% of the target dose); 0.5 L/ha (80% of the target dose) and 0.65 L/ha (target dose).
Powdery mildew was controlled when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used. For **septoria leaf blotch** control of the disease was achieved when 0.5-0.65 L/ha rates were used, reduction of the symptoms were observed when dose 0.4 L/ha was used.

As a result, the proposed rate range of 0.5-0.65 L/ha used in the spring, should be considered as the minimum effective dose to deliver satisfying control of the winter triticale diseases.

Spring triticale

3 doses of the Protiokonazol 300 EC were tested: 0.4 L/ha (60% of the target dose); 0.5 L/ha (80% of the target dose) and 0.65 L/ha (target dose).
Powdery mildew was controlled when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used. For **septoria leaf blotch** control of the disease was achieved when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used.

As a result, the proposed rate range of 0.5-0.65 L/ha used in the spring, should be considered as the minimum effective dose to deliver satisfying control of the spring triticale diseases.

Winter barley

3 doses of the Protiokonazol 300 EC were tested: 0.4 L/ha (60% of the target dose); 0.5 L/ha (80% of the target dose) and 0.65 L/ha (target dose).
Net blotch of barley was controlled when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used.

As a result, the proposed rate range of 0.5-0.65 L/ha used in the spring, should be considered as the minimum effective dose to deliver satisfying control of net blotch of barley in winter barley.

Spring barley

3 doses of the Protiokonazol 300 EC were tested: 0.4 L/ha (60% of the target dose); 0.5 L/ha (80% of the target dose) and 0.65 L/ha (target dose).
Net blotch of barley was controlled when 0.5-0.65 L/ha rates were used, moderate control was observed when dose 0.4 L/ha was used.

Winter Rye

5 doses of the Protiokonazol 300 EC were tested: 0.25 L/ha (38% of the target dose); 0.33 L/ha (51% of the target dose) 0,4 L/ha (62% of the target dose), 0,5 L/ha (77% of the target dose) and 0.65 L/ha (target dose).
Powdery mildew of cereals was controlled when 0.5-0.65 L/ha rates were used, control was observed when dose 0.4 L/ha was used

As a result, the proposed rate range of 0.5-0.65 L/ha used in the spring, should be considered as the minimum effective dose to deliver satisfying control of powdery mildew of cereals in rye.

Winter oilseed rape

- Autumn application – 5 doses of the Protiokonazol 300 EC were tested: 0.2 L/ha (33% of the target dose); 0.3 L/ha (50% of the target dose), 0,35 L/ha (58% of the target dose) 0,5 L/ha (83% of the target dose) and 0.6 L/ha (target dose). **Dry rot of crucifers** was only controlled when full dose (0.6 L/ha) was used, pathogen showed moderate resistance when dose 0.3 L/ha was used and no control effects were visible in the plots where 0.2 L/ha of product was applied. In case of **dark spot of crucifers**, lower doses (0.2 L/ha and 0.3 L/ha) of the product showed moderate control effect against this disease. In case of **downy mildew of rape**, lower doses (0.35 L/ha and 0.5 L/ha) of the product showed moderate control effect against this disease Highest dose of 0.6 L/ha reached highest, average efficacy from 16 performed trials.

As a result, the proposed rate of 0.6 L/ha should be considered as the minimum effective dose to deliver satisfying control of the dry rot of crucifiers and dark spot of crucifers and downy mildew of rape in winter oilseed rape treated in autumn.

- Spring application – 3 doses of the Protiokonazol 300 EC were tested: 0.35 L/ha (60% of the target

dose); 0.5 L/ha (80% of the target dose) and 0.6 L/ha (target dose). **Dark spot of crucifers** was only controlled when full dose (0.6 L/ha) was used, moderate control was observed when dose 0.5 L/ha was used and moderate control effects were visible in the plots where 0.35 L/ha of product was applied. In case of **cottony rot**, lowest rate (0.35 L/ha) showed moderate control of the disease, while rates ~~0.5~~ 0.6 L/ha showed control of this disease.

As a result, the proposed rate range of ~~0.5~~ 0.6 L/ha used in the spring, should be considered as the minimum effective dose to deliver satisfying control of the winter oilseed rape diseases

Comments for ZRMS:

To provide information to establish the minimum effective dose (MED), some of the trials conducted to demonstrate efficacy should include at least two lower dose (s) than recommended one. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line with EPPO 1/225 (2). Applicant submitted in total 59 trials carried out in 2023 (cereal: winter rye, autumn application in winter oilseed rape), 2022 (cereals: winter wheat, spring wheat, winter triticale, spring triticale, winter barley, spring barley, winter rye and winter oilseed rape – spring application) and 2021 (winter oilseed rape – autumn application).

Below, ZRMs presented MED assessment for those trials:

- on ***winter wheat*** against ERYSYGR (5 trials), SEPTTR (8 trials), PUCCSI (3) and PYRNTR (3) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) in 2022.
- on ***spring wheat*** against SEPTTR (2 trials), PUCCSI (1) and PYNTR (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) in 2022.
- on ***winter triticale*** against ERYSYGR (1), SEPTTR (1) and PYRNTR (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were carried out in PL (N-E EPPO zone) in 2022.
- on ***spring triticale*** against ERYSYGR (1), SEPTTR (1), PUCCSI (1) and RHYNSE (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) in 2022.
- on ***winter barley*** against PYRNTE (3 trials) and ERYSYGR (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) and CZ (Maritime EPPO zone – 1 trial) in 2022. In line to Polish rules, CZ and PL trials were assessed together.
- on ***spring barley*** against PYRNTE (8 trials), ERYSYGR (1) and PUCCRE (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (the full N rate). Those trials were carried out in PL (N-E EPPO zone) in 2022. Also, in 2 trials PUCCRE was studied – due to limited number of trials it was not claimed in GAP, also extrapolating results is not possible.
- on ***winter rye*** against ERYSYGR (1 trial), SEPTTR (2), PYRNTR (1), RHYNSE (2) and PUCCSI (1) – five different doses were studied: 0,25 L/ha (0.5N), 0.33 L/ha (0.66N), 0.4 L/ha (0.6N), 0.5 L/ha (the lowers N recommended) and 0.65 L/ha (N full rate recommended). Those trials were carried out in PL (N-E EPPO zone) in 2022 and 2023.
- ***spring application on winter oilseed rape*** against ALTEBA (7 trials) and SCLESC (9 trials) three different doses were studied: 0.35 L/ha (0.6N), 0.5 L/ha and 0.6 L/ha (full N rate recommended). Those trials were carried out in Poland (N-E EPPO zone) and Czech Republic from Maritime EPPO zone (1 trial) in 2022. In line to Polish rules, CZ and PL trials were assessed together.
- ***autumn application on winter oilseed rape*** against ALTEBA (6 trials) and LEPTMA (7 trials) three different doses were studied: 0.2 L/ha (0.33N), 0.3 L/ha (0.5N), 0.5 (L/ha) and 0.6 L/ha full N rate recommended). HIPERBR (8 trials) was studied in the following doses: 0.35 L/ha (0.58N), 0.5 L/ha

(0.83N) and 0.6 L/ha (N full recommended dose). Those trials were carried out in PL (N-E EPPO zone) in 2021 and 2023 (against HIPERBR).

Results for MED (Minimum Effective Dose):

– **against SEPTTR**

Cereal	No. trials	Infestation	Eff. at dose 0.4 L/ha	Eff. at dose 0.5 l/ha	Eff, at dose 0.65 L/ha
winter wheat	8	16.9%	67.6%	82.2%	88,89%
spring wheat	2	23.6%	65.4%	82.7%	90.75%
winter triticale	1	42.4%	58.6%	74.1%	80.8%
spring triticale	1	35.3%	67.4%	81.1%	83.4%

– **against ERYSYGR**

Cereal	No. trials	Infestation	Eff at dose 0.25 L/ha	Eff. at dose 0.33 L/ha	Eff. at dose 0.4 L/ha	Eff. at dose 0.5 l/ha	Eff, at dose 0.65 L/ha
winter wheat	5	10.82%	n.a.	n.a.	69.78%	82.76%	87.06%
spring wheat	n.a.	n.a.	n.a	n.a	n.a.	n.a.	n.a.
winter triticale	1	30.1%	n.a	n.a	91.0%	97.0%	100%
spring triticale	1	12.7%	n.a	n.a	80.2%	82.9%	89.4%
winter rye	1	6.0%	62.9%	82.5%	n.a.	n.a.	84.5%

– **against PYRNTE**

Cereal	No. trials	Infestation	Eff. at dose 0.4 L/ha	Eff. at dose 0.5 l/ha	Eff, at dose 0.65 L/ha
winter barley	3	6.46%	69.06%	80.1%	87.6%
spring barley	8	18.04%	67.76%	82.59%	90.41%

– **spring application on winter oilseed rape**

Cereal	No. trials	Infestation	Eff. at dose 0.35 L/ha	Eff. at dose 0.5 l/ha	Eff, at dose 0.6 L/ha
ALTEBA	7	6.35%	60.43%	72.47%	83.46%
SCLESC	9	12.7%	61.1%	80.54%	90.32%

– **autumn application on winter oilseed rape**

Cereal	No. trials	Infestation	Eff. at dose 0.2 L/ha	Eff. at dose 0.3 l/ha	Eff. at dose 0.35 L/ha	Eff. at dose 0.5 L/ha	Eff, at dose 0.6 L/ha
ALTEBA	5	9.66%	62.56%	76.12%	n.a.	n.a.	91.02%
	1	6.80%	n.a	79.0%	n.a	89.0%	
LEPTMA	6	14.72%	20.88%	57.66%	n.a.	n.a.	86.32%
	1	6.90%	n.a	70.0%	n.a	94.0%	
HIPERBR	8	7,65%	n.a.	n.a.	66.6%	79.67%	87.39%

<60% eff. | 60-80% eff | >80% eff.

Results reveal a positive dose response to increasing amounts of the test products. In many cases HERA 300 EC (product code: Protiokonazol 300 EC) was significantly more effective at full dose (0.65 L/ha for cereals and 0.6 L/ha for winter oilseed rate) than at the reduced rates (60% for cereals or 33% and 50% in winter oilseed rape). However dose 0.5 L/ha in cereal against fungal diseases was characterized also by good efficiency. So, both doses in cereals (0.5 and 0.65 L/ha) should be recommended for use. Dose 0.5 L/ha used in winter oilseed rape (at spring and autumn application) was characterized by lower

efficiency than dose 0.6 L/ha. In the opinion of ZRMs dose 0.5 L/ha should not been recommended for winter oilseed due to lower efficacy at autumn application against HIPERBR (ME-0.5 L/ha and E at 0.6 L/ha) and ALTEBA in spring application (0.5 L/ha-ME, 0.6 L/ha –E). Against ALTEBA and LEPTMA at autumn application – dose 0.5 L/ha was studied only in one trial so it is very difficult to make right conclusions. Only against SCLESC the efficacy between dose 0.5 L/ha and 0.6 L/ha was comparable.

It can be concluded that the dose rate of 0.5 -0.65 L/ha should be recommended for cereals against SEPTTR (winter and spring wheat, winter and spring triticale), ERYSYGR (winter wheat, winter and spring triticale) and PYRNTE (winter and spring barley). It can be concluded that dose 0.6 L/ha should be recommended for winter oilseed rape for spring application against ALTEBA and SCLESC and autumn application against ALTEBA, HIPERBR and LEPTMA.

3.2.3 Efficacy tests (KCP 6.2)

A total of 59 trials were carried out in years 2021, 2022 and 2023 to evaluate the efficacy of Protiokonazol 300 EC for the control of diseases in winter and spring cereals and winter oilseed rape in seven different regions of Poland and one region in Czech Republic, which differentiated by the type of soil and climatic conditions.

All trials were conducted in randomized complete block design in four replications. All treatments were performed using specialized plot application equipment, with 100-400 litres of working solution per hectare. All trials were conducted in compliance with GEP principles and following appropriate EPPO guidelines: EPPO PP 1/26 (4), EPPO PP 1/78 (3), EPPO PP 1/135 (4), EPPO PP 1/152 (4), EPPO PP 1/181 (4). Also EPPO PP 1/225 (2) guideline was considered when choosing Protiokonazol 300 EC doses for minimum effective dose.

Table 3.2-14: Details on methodology of efficacy trials in winter wheat

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	19.5-30 m²
	Number of replications	4
Crop	Trials per crop	Winter wheat (10)
	Varieties per crop	Winter wheat: Arkadia, Astoria, Euforia, Formacja, Hondia, Julie, Linus
	Sowing period	Winter wheat: 06.10-04.11.2021
Application	Crop stage (BBCH)* at application	Winter wheat: BBCH 32-39
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 14-21 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	14-21 DA-A, 14-21 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Clayey sand, Loam, Loamy sand, Sandy clay loam, Sandy loam pH range 5.4-7.7
	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-15: Details on methodology of efficacy trials in spring wheat

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	30 m²
	Number of replications	4
Crop	Trials per crop	Spring wheat (2)
	Varieties per crop	Spring wheat: Arabella, Harenda
	Sowing period	Spring wheat: 24.03.2022 – 04.04.2022
Application	Crop stage (BBCH)*at application	Spring wheat: BBCH 31 - 37
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 14-17 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	14-21 DA-A, 14-21 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Loamy sand, Sandy loam pH range 6-6.4
	e.g. Natural / artificial inoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-16: Details on methodology of efficacy trials in winter triticale

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	30 m²
	Number of replications	4
Crop	Trials per crop	Winter triticale (2)
	Varieties per crop	Winter triticale: Grenado, Lombardo
	Sowing period	Winter triticale: 28.09.2021 – 10.10.2021
Application	Crop stage (BBCH)*at application	Winter triticale: BBCH 39
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 15-22 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	14-21 DA-A, 14-21 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Loamy sand, Sandy loam pH range 6.3-.5
	e.g. Natural / artificial inoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-17: Details on methodology of efficacy trials in spring triticale

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	24 - 30 m²
	Number of replications	4
Crop	Trials per crop	Spring triticale (2)
	Varieties per crop	Spring triticale: Mamut, Milewo
	Sowing period	Spring triticale: 23.03.2022 – 11.04.2022
Application	Crop stage (BBCH)*at application	Spring triticale: BBCH 32- 37
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 14-15 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	14-21 DA-A, 14-21 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Loamy sand, Sandy clay loam pH range 5.6-6.3
	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-18: Details on methodology of efficacy trials in winter barley

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	24.3 -27 m²
	Number of replications	4
Crop	Trials per crop	Winter barley (3)
	Varieties per crop	Winter barley: Zenek, KWS Kosmos, Sonnegold
	Sowing period	Winter barley: 20.09.2021 – 06.10.2021
Application	Crop stage (BBCH)*at application	Winter barley: BBCH 37 - 45
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 14-17 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	14-21 DA-A, 14-21 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Loamy sand, Sandy clay loam pH range 6.1 – 6.6
	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-19: Details on methodology of efficacy trials in spring barley

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	24 - 30 m²
	Number of replications	4
Crop	Trials per crop	Spring barley: (9)
	Varieties per crop	Spring barley: Ella, Etoile, Melius, Penguin, Radek, Saldo
	Sowing period	Spring barley: 10.03.2022 – 05.04.2022
Application	Crop stage (BBCH)*at application	Spring barley: BBCH 29-49
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 14-21 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	14-21 DA-A, 14-21 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Clay sandy loam, Loam, Loamy sand, Sandy clay loam, Sandy loam pH range 5.8 – 7.5
	e.g. Natural / artificial inoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-20: Details on methodology of efficacy trials in rye

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	24 - 30 m²
	Number of replications	4
Crop	Trials per crop	Rye: (5)
	Varieties per crop	Rye: KWS VINETTO F1, KWS SERAFINO, KWS Dolaro, Stanko, Antonińskie
	Sowing period	Rye: 14.09.2021 – 14.10.2021; 22.09.2022 – 07.10.2022
Application	Crop stage (BBCH)*at application	Rye: BBCH 32-39
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 14-18 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	14-33 DA-A, 14-49 DA-A; 44-91 DA-A
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Clay sandy loam, Loam, Loamy sand, Sandy clay loam, Sandy loam pH range 5.8 – 7.5
	e.g. Natural / artificial inoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-20: Details on methodology of efficacy trials in winter oilseed rape (autumn application)

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/78 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	19.5 – 30 m²
	Number of replications	4
Crop	Trials per crop	Winter oilseed rape: (16)
	Varieties per crop	Winter oilseed rape: Absolut, Derrick, Duke F1, ES Imperio, Kuga F1, KWS Marcopolo, Annabella, Aganos, Sienna, Hevelius, Nelson, Factor KWS F1, Uniwersum, Kadore, Chopin, SY Ilona
	Sowing period	Winter oilseed rape: 21.08.2021 – 11.09.2021; 19.08.2022 – 02.09.2022
Application	Crop stage (BBCH)* at application	Winter oilseed rape: 13-19
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	1 N/A
	Spray volumes	100-400 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	A1 c.a. 14 DA-A; A2 28 DA-A;
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Sandy clay loam, sandy loam, sandy clay, loamy sand, loamy clay sand, silit loam, clayey sand. pH range 5.51 – 7.6
	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-21: Details on methodology of efficacy trials in winter oilseed rape (spring applications)

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/78 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	19.5 - 30 m²
	Number of replications	4
Crop	Trials per crop	Winter oilseed rape: (10)
	Varieties per crop	Winter oilseed rape: Allison, Anabella, Architect, Duke, Ilona, Kadore, Kepler, KWS Marcopolo, LG Ambassador F1,
	Sowing period	Winter oilseed rape: 24.08.2022 – 06.09.2022
Application	Crop stage (BBCH)* at application	Winter oilseed rape: 61 - 65
	Timing Pest stage at application (1)	preventive / curative application
	Number of applications Intervals between applications	2 13-22 days
	Spray volumes	200-300 L/ha
Assessment	Assessment types	The frequency and the intensity of infection (%)
	Assessment dates	First assessment after application was performed 2-4 weeks after application, stem infection levels were also assessed at stages 50-85 of the crop and pod infection was assessed at stage 71-85 of the crop.
	e.g. Soil type, pH (in case of soil active substance …)	Clayey sand, Loam, Loamy sand, Sandy clay, Sandy clay loam, Sandy loam pH range 5.3 – 6.7

Other relevant information	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-22: Efficacy of active substance components in Protiokonazol 300 EC trials in winter wheat

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ %		Mean percentage (%) control based on disease severity on leaves compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 120 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 150 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 195 g/ha		**Poleposition 300 EC** 2x Prothioconazole 195 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
ERYSGR	5	10.82	7.1-14.9	69.78	64.9-77	82.76	75.3-98	87.06	81.1-100	85.56	72.8-100	2 trial > 2 trial < 1 trial =
SEPTTR	8	16.9	5.1-33.5	67.6	51.8-90	82.21	69.2-94.2	88.89	78.2-98.2	86.7	74-98.2	5 trial > 1 trial < 2 trial =

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

In case of ERYSGR A1 assesment was considered (14-21 days after the application A) in 3 out of 5 trials. In the remaining two trials, due to late disease development, A2 (14-21 days after the application B) assessment was taken into the consideration.

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of powdery mildew of cereals and septoria leaf blotch in winter wheat at the proposed rate of 0.65 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Poleposition/Protendo/Pecari 300 EC at maximum label rate of 0.65 L/ha.

Table 3.2-23: Efficacy of active substance components in Protiokonazol 300 EC trials in spring wheat

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ %		Mean percentage (%) control based on disease severity on leaves compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 120 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 150 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 195 g/ha		**Poleposition 300 EC** 2x Prothioconazole 195 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]

SEPTTR	2	23.6	7.6-39.6	65.4	59.6-71.2	82.7	80.1-85.3	90.75	83.6-97.9	89.85	71.5-98.2	1 trial > 1 trial <

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

For the efficacy against SEPTTR, A2 (14-21 days after the application B) assessment was taken into the consideration in the table above.

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of septoria leaf blotch in spring wheat at the proposed rate of 0.65 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Poleposition 300 EC at rate of 0.65 L/ha.
Only two trials for spring wheat were conducted due to the fact that differences between spring and winter cultivars are minor, or there are no such, in terms of their physiology during time of the application (they are the same species basically), and due to the fact that septoria leaf blotch is caused by the exactly same fungus, no matter if it is spring or winter wheat. It is also worth mentioning that Polish authority has issued an official extrapolation tables which are giving the applicant specific information on efficacy trial results extrapolations between crops, prepared for many pests. Among them, guideline states that efficacy results from winter wheat can be extrapolated onto spring wheat, when applicant will submit 1-2 efficacy trials performed on spring wheat.

Table 3.2-24: Efficacy of active substance components in Protiokonazol 300 EC trials in winter triticale

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ %		Mean percentage (%) control based on disease severity on leaves compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 120 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 150 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 195 g/ha		**Poleposition 300 EC** 2x Prothioconazole 195 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
ERYSGR	1	30.1	30.1-30.1	91	91-91	97	97-97	100	100-100	100	100-100	1 trial =
SEPTTR	1	42.4	42.4-42.4	58.6	58.6-58.6	74.1	74.1-74.1	80.8	80.8-80.8	77.8	77.8-77.8	1 trial >

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

For the efficacy against both ERYSGR and SEPTTR, A2 (14-21 days after the application B) assessment was taken into the consideration in the table above.

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of powdery mildew of cereals and septoria leaf blotch in winter triticale at the proposed rate of 0.65 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Poleposition 300 EC at maximum label rate of 0.65 L/ha.

Only two trials for winter triticale were conducted due to the fact that this hybrid crop shares many traits with winter wheat, and due to the fact that both septoria leaf blotch and powdery mildew are caused by the exactly same fungus species, no matter if it is wheat or triticale. It is also worth mentioning that Polish authority has issued an official extrapolation tables which are giving the applicant specific information on efficacy trial results extrapolations between crops, prepared for many pests. Among them, guideline states that efficacy results from winter wheat can be extrapolated onto winter triticale, when applicant will submit 1-2 efficacy trials performed on winter triticale.

Table 3.2-25: Efficacy of active substance components in Protiokonazol 300 EC trials in spring triticale

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity on leaves compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 120 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 150 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 195 g/ha		**Poleposition 300 EC** 2x Prothioconazole 195 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
ERYSGR	1	12.7	12.7-12.7	80.2	80.2-80.2	82.9	82.9-82.9	89.4	89.4-89.4	90.4	90.4-90.4	1 trial <
SEPTTR	1	35.3	35.3-35.3	67.4	67.4-67.4	81.1	81.1-81.1	83.4	83.4-83.4	83.1	83.1-83.1	1 trial >

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

For the efficacy against both ERYSGR and SEPTTR, A2 (14-21 days after the application B) assessment was taken into the consideration in the table above.

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of powdery mildew of cereals and septoria leaf blotch in spring triticale at the proposed rate of 0.65 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Poleposition 300 EC at maximum label rate of 0.65 L/ha.

Only two trials for spring triticale were conducted due to the fact that this hybrid crop shares many traits with winter wheat, and due to the fact that both septoria leaf blotch and powdery mildew are caused by the exactly same fungus species, no matter if it is wheat or triticale. It is also worth mentioning that Polish authority has issued an official extrapolation tables which are giving the applicant specific information on efficacy trial results extrapolations between crops, prepared for many pests. Among them, guideline states that efficacy results from winter wheat can be extrapolated onto spring triticale, when applicant will submit 1-2 efficacy

trials performed on spring triticale.

Table 3.2-26: Efficacy of active substance components in Protiokonazol 300 EC trials in winter barley

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity on leaves compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 120 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 150 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 195 g/ha		**Poleposition 300 EC** 2x Prothioconazole 195 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
PYRNTE	3	6.46	6-7.3	69.06	41.4-85	80.1	67.5-92	87.6	76-100	89.13	76.4-96	3 trial <

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

Due to weather conditions in Czech Republic in 2022 season, and late development of the disease, for PYRNTE A3 assessment (at crop BBCH 75-83) was considered in the trial CZOR-PSZ22-HORVW-057NEC.

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of net blotch of barley in winter barley at the proposed rate of 0.65 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Poleposition 300 EC at maximum label rate of 0.65 L/ha.

Only three trials for winter barley were conducted due to the fact that differences between spring and winter cultivars of barley are minor, or there are no such, in terms of their physiology during time of the application (they are the same species basically), and due to the fact that net blotch of barley is caused by the exactly same fungus, no matter if it is spring or winter barley. It is also worth mentioning that Polish authority has issued an official extrapolation tables which are giving the applicant specific information on efficacy trial results extrapolations between crops, prepared for many pests. Among them, guideline states that efficacy results from spring barley can be extrapolated onto winter barley (and backwards), when applicant will submit 1-2 efficacy trials performed on winter barley.

Table 3.2-27: Efficacy of active substance components in Protiokonazol 300 EC trials in spring barley

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity on leaves compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 120 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 150 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 195 g/ha		**Poleposition 300 EC** 2x Prothioconazole 195 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
PYRNTE	8	18.04	5.8-51	67.76	47.2-79	82.59	71.3-90	90.41	81-97	88.81	78.5-97	5 trial > 2 trial < 1 trial =

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of net blotch of barley in spring barley at the proposed rate of 0.65 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Poleposition 300 EC at maximum label rate of 0.65 L/ha.

Table 3.2-28: Efficacy of active substance components in Protiokonazol 300 EC trials in rye

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity on leaves compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 75 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 99 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 195 g/ha		**Protendo 300 EC** 2x Prothioconazole 195 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
ERYSGR	1	6	6-6	62.9	62.9-62.9	82.5	82.5-82.5	84.5	84.5-84.5	80.5	80.5-80.5	1 trial >

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of powdery mildew of cereals in rye at

the proposed rate of 0.65 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Protendo 300 EC at maximum label rate of 0.65 L/ha.

Table 3.2-29: Efficacy of active substance components in Protiokonazol 300 EC autumn trials in winter oilseed rape during 2nd assessment (ca. 4 weeks after the application)

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC Prothioconazole 60 g/ha		**Protiokonazol 300 EC** Prothioconazole 90 g/ha		**Protiokonazol 300 EC** Prothioconazole 180 g/ha		**Promino 300 EC** Prothioconazole 180 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
ALTEBA	5	9.66	6.7-15	62.56	53.9-69	76.12	67.7-83.6	91.02	84.1-95.5	87.88	79.1-93.5	5 trial >
LEPTMA	6	14.72	10-18.3	20.88	2.1-50.8	57.67	52.3-66.6	86.32	82.8-89.9	84.03	80.8-86.1	6 trial >
Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC Prothioconazole 90 g/ha		**Protiokonazol 300 EC** Prothioconazole 150 g/ha		**Protiokonazol 300 EC** Prothioconazole 180 g/ha		**Poleposition 300 EC** Prothioconazole 180 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
ALTEBA	1	6.8	6.8-6.8	79	79-79	89	89-89	97	97-97	99	99-99	1 trial <
LEPTMA	1	6.9	6.9-6.9	70	70-70	94	94-94	100	100-100	100	100-100	1 trial =
Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC Prothioconazole 105 g/ha		**Protiokonazol 300 EC** Prothioconazole 150 g/ha		**Protiokonazol 300 EC** Prothioconazole 180 g/ha		**Tauron 240 EC** Prothioconazole 60 g/ha, tebuconazole 120 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
HPERBR	8	7.65	5.2-12,9	66.6	56.1-76.2	79.67	68.8-93.4	87.39	77.3-97.1	85.5	73.4-97.9	3 trial > 1 trial = 4 trial <

Results were presents for total control of pest on the basis on avreage from results in which leaves, pods and stems were assessed.

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of dry rot of crucifers caused by *Plenodomus lingam* (LEPTMA) in winter oilseed rape at the proposed rate of 0.6 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of reference product Promino 300 EC/Poleposition 300 EC in the rate of 0.6 L/ha (registered label rate) in 7 out of 7 performed trials in which this disease occured. In terms of black spot of crucifers caused by *Alternaria brassicae* (ALTEBA) in winter oilseed rape, Protiokonazol 300 EC used in the rate of 0.6 L/ha controlled the disease at the same level (there was no statistically significant difference between the results) as the reference product Promino 300 EC/Poleposition 300 EC 0.6 L/ha (registered label rate) in 6 out of 6 performed trials in which this disease occurred. In terms of downy mildew of rape caused by *Hyaloperonospora brassicae* (HPERBR) in winter oilseed rape, Protiokonazol 300 EC used in the rate of 0.6 L/ha controlled the disease at the same level (there was no statistically significant difference between the results) as the reference product Tauron 240 EC 0.75 L/ha (registered label rate) in 8 out of 8 performed trials in which this disease occurred.

Table 3.2-30: Efficacy of active substance components in Protiokonazol 300 EC spring trials in winter oilseed rape

Grouping *	Number of trials	Infestation of the untreated control ~~(number of plants)~~ [% severity]		Mean percentage (%) control based on disease severity compared to untreated plots								No of trials where Protiokonazol 300 EC at full recommended dose is >, <, = compared to standard(s)**
				Protiokonazol 300 EC 2x Prothioconazole 105 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 150 g/ha		**Protiokonazol 300 EC** 2x Prothioconazole 180 g/ha		**Poleposition 300 EC** 2x Prothioconazole 180 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	%	%	%	%	%	%	%	%	%	%	[-]
ALTEBA	7	6.35	5-25.5	60.43	21.6-75.8	72.47	37.3-94	83.46	44.1-99	81.27	47.1	5 trials > 1 trial < 1 trials =
SCLESC	9	12.7	5-31	61.1	29.9-91.4	80.54	54.2-100	90.32	76.7-100	88.56	73.4-100	5 trials > 4 trials =

Results were presents for total control of pest on the basis on avreage from results in which leaves, pods and stems were assessed

* A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

** Optional

Due to weather conditions in Czech Republic in 2022 season, and late development of the disease, for ALTEBA A3 assessment was considered in the trial CZOR-PSZ22-BRSNN-045NEC.

According to statistical analysis, data assessed in trials demonstrated that the efficacy of Protiokonazol 300 EC in control of dark spot of crucifers and dry rot of crucifers in winter oilseed rape at the proposed rate of 0.6 L/ha was equivalent (there was no statistically significant difference between the results)

Minor use

Not relevant.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

9 trials in Poland and 1 trial in Czech Republic were carried out in 2022 on winter wheat, they revealed no negative impact of Protiokonazol 300 EC on quantity and quality of yield.

A summary of the yield data from efficacy trials is presented in Table 3.2-10.

A total of 10 trials were carried out in 2022 in Czech Republic and Poland. The objective was to confirm the yield response of Protiokonazol 300 EC in the presence of disease.

Table 3.2-31: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in winter wheat

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
				Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha			
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal diseases	10	a) 100% b) 6.626	NR 5.13-8.6	a) 102.6% b) 6.799	97%-110% 4.99-8.6	a) 105.3% b) 6.974	97%-112.7% 4.99-8.53	a) 106.2% b) 7.04	97-120.2% 5.21-8.53	a) 104.9% b) 6.95	100%-111% 4.7-8.20	5 trials > 4 trials < 1 trials =	5 trials > 3 trials < 2 trials =

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.65 L/ha had positive effect on the yield of winter wheat in the presence of disease. In fact, there was average 6.2% increase in yield over the untreated.

Table 3.2-32: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in winter wheat

Grain yield compo-nent	Number of trials	Untreated control		Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	10	6.626	5.13-8.6	6.799	4.99-8.6	6.974	4.99-8.53	7.04	5.21-8.53	6.95	4.7-8.20
Moisture (%)	10	13.025	11.8-14.5	13.013	11.8-14.38	13.073	11.9-14.28	13.098	11.9-14.28	13.043	11.9-14.58
Weight of 1000 grains (g)	10	42.614	37.38-48.25	43.019	39.01-48.35	43.049	39.76-48.19	43.099	39.23-48.35	43.241	39.58-48.913
Test weight (kg/ hl)	10	77.932	69.3-83.38	78.159	71.3-82.9	78.079	69.9-83.57	77.916	70.1-83.08	78.122	70.5-83.36

10 efficacy trials were carried out in 2022, there was no significant effect of dose 0.5-0.65 L/ha Protiokonazol 300 EC on grain yield component in winter wheat.

Protiokonazol 300 EC at the proposed label rate of 0.6-0.65 L/ha in both trials had no negative impact on the grain yield. It is worth mentioning that in one trial, used product had quite significant positive effect on the yield of winter wheat in the presence of disease (12.7% increase when compared to control in case of 0.5L/ha rate, and 20.2% increase in case of 0.65 L/ha rate. In comparison, reference product had just 11% of yield increase when compared to control).

Table 3.2-33: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in spring wheat

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
				Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha			
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal dis-eases	2	a) 100% b) 4.885	NR 4.7-5.07	a) 108.3% b) 5.29	106.3-110.6% 5.2-5.38	a) 102.6% b) 5.01	100-105% 4.7-5.32	a) 103.9% b) 5.075	100-107.7% 4.7-5.45	a) 105.2% b) 5.14	104.2-106.4% 4.7-8.20	1 trials > 1 trials <	1 trials > 1 trials <

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.6-0.65 L/ha in both trials had no negative impact on the grain yield. It is worth mentioning that in one trial, used product had positive effect on the yield of spring wheat in the presence of disease (5% increase when compared to control in case of 0.5L/ha rate, and 7.7% increase in case of 0.65 L/ha rate).

Table 3.2-34: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in spring wheat

Grain yield compo-nent	Number of trials	Untreated control		Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	2	4.885	4.7-5.07	5.29	5.2-5.38	5.01	4.7-5.32	5.075	4.7-5.45	5.14	4.7-8.20
Moisture (%)	2	12.35	10.8-13.9	12.35	10.8-13.9	12.35	10.8-13.9	12.3	10.7-13.9	12.2	10.7-13.9
Weight of 1000 grains (g)	2	36.385	35.4-37.37	36.74	35.8-37.68	37.295	36.1-38.49	36.32	35.5-37.14	36.44	35.2-37.68
Test weight (kg/ hl)	2	73.335	67.2-79.47	73.51	67.6-79.42	73.67	67.4-79.94	73.675	68-79.35	73.67	67.6-79.74

2 efficacy trials were carried out in 2022, there was no significant effect of dose 0.5 – 0.65 L/ha Protiokonazol 300 EC on grain yield component in spring wheat.

Table 3.2-35: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in winter triticale

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
				Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha			
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal dis-eases	2	a) 100% b) 6.715	NR 6.5-6.93	a) 102.6% b) 6.89	101.5%-103.6% 6.6-7.18	a) 100.8% b) 6.77	96.9%-104.4% 6.3-7.24	a) 102.5% b) 6.885	96.9%-107.7% 4.99-8.53	a) 104.5% b) 7.015	98.5%-110% 6.4-7.63	2 trials < 2 trials <	2 trials < 2 trials <

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.6-0.65 L/ha in both trials had no negative impact on the grain yield. It is worth mentioning that in one trial, used product had positive effect on the yield of winter triticale in the presence of disease (4.4% increase when compared to control in case of 0.5L/ha rate, and 7.7% increase in case of 0.65 L/ha rate).

Table 3.2-36: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in winter triticale

Grain yield compo-nent	Number of trials	Untreated control		Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	2	6.715	6.5-6.93	6.89	6.6-7.18	6.77	6.3-7.24	6.885	6.3-7.47	7.015	6.4-7.63
Moisture (%)	2	11.55	10.7-12.4	11.65	11.1-12.2	11.55	10.9-12.2	11.6	11-12.2	11.55	10.9-12.2
Weight of 1000 grains (g)	2	39.205	39-39.41	39.26	38.5-40.02	37.87	37.04-38.7	39.305	38.5-40.11	39.23	38.4-40.06
Test weight (kg/ hl)	2	73.95	70.5-77.4	73.97	70.7-77.24	74.56	71.6-77.52	74.255	71.5-77.01	74.28	71.5-77.06

2 efficacy trials were carried out in 2022, there was no significant effect of dose 0.5-0.65 L/ha Protiokonazol 300 EC on grain yield component in winter triticale.

Table 3.2-37: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in spring triticale

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
				Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha			
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal dis-eases	2	a) 100% b) 4.42	NR 3.74-5.1	a) 99.8% b) 4.41	94.1%-107.6% 4.02-4.8	a) 100.3% b) 4.435	98%-103.5% 3.87-5	a) 95.1% b) 4.205	88.2%-104.4% 4.99-8.53	a) 99.3% b) 4.39	94.1%-106.3% 4.7-8.20	1 trials > 1 trials <	1 trials < 1 trials <

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.6-0.65 L/ha in both trials had no negative impact on the grain yield. It is worth mentioning that in one trial, used product had positive effect on the yield of spring triticale in the presence of disease (3.5% increase when compared to control in case of 0.5L/ha rate, and 4.4% increase in case of 0.65 L/ha rate).

Table 3.2-38: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in spring triticale

Grain yield compo-nent	Number of trials	Untreated control		Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	2	4.885	4.7-5.07	5.29	5.2-5.38	5.01	4.7-5.32	5.075	4.7-5.45	5.14	5-5.28
Moisture (%)	2	12.25	11.3-13.2	12.35	11.3-13.4	12.4	11.4-13.4	12.35	11.2-13.5	12.2	11.2-13.2
Weight of 1000 grains (g)	2	34.67	31.4-37.94	34.84	31.7-37.98	35.255	32.1-38.41	35.065	32.1-38.03	34.385	31.3-37.47
Test weight (kg/ hl)	2	58.68	49.46-67.9	58.69	49.08-68.3	58.55	48.7-68.4	58.77	49.14-68.4	58.74	49.08-68.4

2 efficacy trials were carried out in 2022, there was no significant effect of dose 0.5-0.65 L/ha Protiokonazol 300 EC on grain yield component in spring triticale.

Table 3.2-39: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in spring barley

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
				Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha			
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal dis-eases	9	a) 100% b) 4.58	NR 2.7-6.08	a) 106.8% b) 4.89	101.9%-116.2% 3.1-6.37	a) 109.3% b) 5	101.9%-120.8% 3.2-6.24	a) 114.3% b) 5.23	101.9%-129.5% 3.5-6.7	a) 110.6% b) 5.06	101.9%-119.8% 3.2-6.4	3 trials > 3 trials < 3 trials =	6 trials > 1 trials < 2 trials =

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.6-0.65 L/ha in both trials had no negative impact on the grain yield. It is worth mentioning that in 6 out of 6 of the trials, used product had higher positive effect on the yield of spring barley in the presence of disease than reference product.

Table 3.2-40: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in spring barley

Grain yield compo-nent	Number of trials	Untreated control		Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	9	4.58	2.7-6.08	4.89	3.1-6.37	5	3.2-6.24	5.23	3.5-6.7	5.06	3.2-6.4
Moisture (%)	9	12.31	9.2-14.1	12.32	9.1-14.6	12.34	9.2-14.4	12.38	9.1-14.7	12.3	8.9-14.6
Weight of 1000 grains (g)	9	45.27	40.4-48.4	45.26	39.9-48.7	45.26	40.2-48.5	45.7	41-49.19	45.49	40.7-48.8
Test weight (kg/ hl)	9	68.65	56.5-74.83	68.46	57.8-74.11	68.25	54.3-74.65	68.64	57.4-74.64	68.8	57.7-74.66

9 efficacy trials were carried out in 2022, there was no significant effect of dose 0.5-0.65 L/ha Protiokonazol 300 EC on grain yield component in spring barley.

Table 3.2-41: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in winter barley

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
				Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha			
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal dis-eases	3	a) 100% b) 7.73	NR 5.99-8.99	a) 105.6% b) 8.16	98.8%-117.7% 7.05-9.33	a) 105.2% b) 8.13	95.1%-117.2% 7.02-9.57	a) 107% b) 8.26	96.3%-119.9% 7.9-9.72	a) 106.9% b) 8.26	96.3%-119.8% 7.9-9.71	3 trials <	1 trials > 2 trials =

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.5-0.65 L/ha had positive effect on the yield of winter barley in the presence of disease.

Table 3.2-42: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in winter barley

Grain yield component	Number of trials	Untreated control		Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	3	7.73	5.99-8.99	8.16	7.05-9.33	8.13	7.02-9.57	8.26	7.9-9.72	8.26	7.9-9.71
Moisture (%)	3	12.67	12.2-12.6	12.2	11.7-12.6	12.1	11.6-12.5	12.2	11.7-12.6	12.2	11.7-12.5
Weight of 1000 grains (g)	3	46.63	42.6-48.8	47.4	43.64-49.95	47.7	43.33-50.98	47.69	43.1-51.08	47.92	43.73-51.33
Test weight (kg/ hl)	3	67.99	67.3-69.73	68.27	66.8-70.03	68.14	67.01-70.03	68.73	67.9-70.3	68.4	67.1-69.9

3 efficacy trials were carried out in 2022, there was no significant effect of dose 0.5-0.65 L/ha Protiokonazol 300 EC on grain yield component in winter barley.

Table 3.2-43: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in winter rye

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
				Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha			
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal diseases	2	a) 100% b) 6.52	NR 3.4-9.63	a) 110.4% b) 7.2	105.9%-112.2% 3.06-10.8	a) 107.4% b) 7	97.1%-111% 3.3-10.69	a) 111.2% b) 7.25	108.8%-112.1% 3.7-10.79	a) 108.3% b) 7.06	107.1%-111.8% 3.8-10.31	2 trials <	2 trials >
Grouping	**Number of trials**	**Untreated control a) Percent b) Absolute figures (t/ha)**		**a) % yield relative to the untreated b) absolute figures (t/ha)**								**No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)***	
				Protiokonazol 300 EC at 0.25 L/ha		**Protiokonazol 300 EC at 0.33 L/ha**		**Protiokonazol 300 EC at 0.65 L/ha**		**Protendo 300 EC at 0.65 L/ha**			
		Mean	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**0.65 L**	
Fungal diseases	3	a) 100% b) 5.88	NR 3.2-7.34	a) 103.2% b) 6.07	100%-105% 3.2-7.71	a) 104.8% b) 6.16	100%-107.5% 3.2-7.89	a) 105.7% b) 6.22	96.9%-109.7% 3.1-8.05	a) 106% b) 6.23	103.1%-107.6% 3.3-7.9	1 trial < 1 trial > 1 trial =	

* Optional.
Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.5-0.65 L/ha had positive effect on the yield of winter barley in the presence of disease.

Table 3.2-44: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in winter rye

Grain yield component	Number of trials	Untreated control		Protiokonazol 300 EC at 0.4 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	2	6.52	3.4-9.63	7.2	3.06-10.8	7	3.3-10.69	7.25	3.7-10.79	7.06	3.8-10.31
Moisture (%)	2	14.7	12.4-17	14.8	12.5-17.1	14.8	12.4-17.2	14.85	12.5-17.2	14.8	12.4-17.2
Weight of 1000 grains (g)	2	32.79	32.3-33.28	32.58	31.7-33.46	32.27	31.3-33.23	32.8	31.8-33.79	32.68	31.5-33.86
Test weight (kg/ hl)	2	74.25	69.1-79.39	74.5	68.8-80.19	74.03	68.2-79.86	75	69.2-80.79	74.74	69.3-80.18
Grain yield component	**Number of trials**	**Untreated control**		**Protiokonazol 300 EC at 0.25 L/ha**		**Protiokonazol 300 EC at 0.33 L/ha**		**Protiokonazol 300 EC at 0.65 L/ha**		**Poleposition 300 EC at 0.65 L/ha**	
		Mean	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**
Yield (t/ha)	3	5.88	3.2-7.34	6.07	3.2-7.71	6.16	3.2-7.89	6.22	3.1-8.05	6.23	3.3-7.9
Moisture (%)	3	13.01	12.13-13.9	13.1	12.56-13.9	13.11	12.13-14	13.22	12.54-14.1	13.03	12.29-13.8
Weight of 1000 grains (g)	3	31.29	28.93-32.9	31.59	29.38-33.4	31.42	29.03-33.2	31.53	28.85-33.7	31.27	28.65-33.1
Test weight (kg/ hl)	3	68.75	66.85-71.4	69.43	67.48-72.3	69.03	67.88-71	68.78	67.15-70.8	69.14	67.83-71.4

5 efficacy trials were carried out in 2022 and 2023, there was no significant effect of dose 0.5-0.65 L/ha Protiokonazol 300 EC on grain yield component in winter rye.

Table 3.2-45: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in winter oilseed rape (spring application)

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha) Protiokonazol 300 EC at 0.35 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.65 L/ha		Poleposition 300 EC at 0.65 L/ha		No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.5 L	0.65 L
Fungal diseases	10	a) 100% b) 3.15	NR 2.3-4.01	a) 107.3% b) 3.38	100%-117.5% 2.3-4.11	a) 110% b) 3.47	102.7%-118.6% 2.4-4.24	a) 113.3% b) 3.57	102.7%-124.8% 2.4-4.28	a) 110.6% b) 3.49	102.7%-121.3% 2.4-4.26	2 trials > 4 trials < 4 trials =	7 trials > 1 trials < 2 trials =

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.5-0.65 L/ha had positive effect on the yield of winter barley in the presence of disease.

Table 3.2-46: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in winter oilseed rape (spring application)

Grain yield component	Number of trials	Untreated control		Protiokonazol 300 EC at 0.35 L/ha		Protiokonazol 300 EC at 0.5 L/ha		Protiokonazol 300 EC at 0.6 L/ha		Poleposition 300 EC at 0.6 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	10	3.15	2.3-4.01	3.38	2.3-4.11	3.47	2.4-4.24	3.57	2.4-4.28	3.49	2.4-4.26
Moisture (%)	10	7.56	6-9.8	7.55	6-9.5	7.55	6-9.8	7.54	6-9.28	7.58	6-9.2
Weight of 1000 grains (g)	10	4.35	2.9-5.24	4.39	2.8-5.32	4.4	2.9-5.3	4.67	2.9-5.27	4.42	2.9-5.46
Oil content (%)	10	42.05	37.5-45.28	42.1	37.5-45.38	42.24	37.45-45.33	42.16	37.55-45.33	42.37	37.73-45.65

10 efficacy trials were carried out in 2022, there was no statistically significant effect of dose 0.6 L/ha Protiokonazol 300 EC on grain yield component in winter oilseed rape.

Table 3.2-47: Yield effect of Protiokonazol 300 EC in efficacy trials on fungal diseases in winter oilseed rape (autumn application)

Grouping	Number of trials	Untreated control a) Percent b) Absolute figures (t/ha)		a) % yield relative to the untreated b) absolute figures (t/ha)								No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)*
				Protiokonazol 300 EC at 0.2 L/ha		Protiokonazol 300 EC at 0.3 L/ha		Protiokonazol 300 EC at 0.6 L/ha		Promino 300 EC at 0.6 L/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	0.6 L
Fungal diseases	6	a) 100% b) 3.63	NR 3.1-4.3	a) 100.9% b) 3.66	97.4-108.8% 3-4.3	a) 100% b) 3.63	93.5-104.9% 2.9-4.3	a) 100% b) 3.63	94.7-108.8% 3.1-4.2	a) 100.5% b) 3.65	92.1-107.3% 2.9-4.4	3 trials > 3 trials <
Grouping	**Number of trials**	**Untreated control a) Percent b) Absolute figures (t/ha)**		**a) % yield relative to the untreated b) absolute figures (t/ha)**								**No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)***
				Protiokonazol 300 EC at ~~0.2~~ 0.3 L/ha		**Protiokonazol 300 EC at ~~0.3~~ 0.5 L/ha**		**Protiokonazol 300 EC at 0.6 L/ha**		**Poleposition 300 EC at 0.6 L/ha**		
		Mean	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**0.6 L**
Fungal diseases	2	a) 100% b) 3.54	NR 3.28-3.8	a) 99.4% b) 3.52	90.5-109.8% 3.44-3.6	a) 103.5% b) 3.67	90.5-118.6% 3.44-3.89	a) 107.9% b) 3.82	100-117.1% 3.8-3.84	a) 107.1% b) 3.79	97.6-118% 3.71-3.87	1 trial > 1 trial <
Grouping	**Number of trials**	**Untreated control a) Percent b) Absolute figures (t/ha)**		**a) % yield relative to the untreated b) absolute figures (t/ha)**								**No of trials where Protiokonazol 300 EC is >, <, = compared to standard(s)***
				Protiokonazol 300 EC at ~~0.2~~ 0.35 L/ha		**Protiokonazol 300 EC at ~~0.3~~ 0.5 L/ha**		**Protiokonazol 300 EC at 0.6 L/ha**		**Tauron 240 EC at 0.75 L/ha**		
		Mean	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**0.6 L**
Fungal diseases	8	a) 100% b) 3.77	NR 3.22-4.6	a) 104.4% b) 3.94	97.8-114.7% 3.34-4.5	a) 103% b) 3.88	97.8-106.5% 3.41-4.5	a) 105.2% b) 3.97	100-110.9% 3.55-4.6	a) 104.7% b) 3.95	97.8-109.9% 3.55-4.6	4 trials > 1 trials < 3 trials =

* Optional.

Mean value of yield quality in untreated control is treated as 100%.

Protiokonazol 300 EC at the proposed label rate of 0.6 L/ha statistically, had no negative nor positive effect on the yield of winter oilseed rape in the presence of the disease.

Table 3.2-48: Yield (quality) effect of Protiokonazol 300 EC and its impact on grain yield component in winter oilseed rape (autumn application)

Grain yield component	Number of trials	Untreated control		Protiokonazol 300 EC at 0.2 L/ha		Protiokonazol 300 EC at 0.3 L/ha		Protiokonazol 300 EC at 0.6 L/ha		Promino 300 EC at 0.6 L/ha	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	6	3.63	3.1-4.3	3.66	3-4.3	3.63	2.9-4.3	3.63	3.1-4.2	3.65	2.9-4.4
Moisture (%)	6	7.3	6.8-7.9	7.28	7-7.8	7.33	7.1-8	7.32	6.9-7.8	7.4	7.2-8
Oil content (%)	6	42,07	40.8-43.5	42.45	42-43.3	42.78	42-43.8	41.85	41-42.8	42.13	40.5-43.5
Grain yield component	**Number of trials**	**Untreated control**		**Protiokonazol 300 EC at 0.3 L/ha**		**Protiokonazol 300 EC at 0.5 L/ha**		**Protiokonazol 300 EC at 0.6 L/ha**		**Poleposition 300 EC at 0.6 L/ha**	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	2	3.54	3.28-3.8	3.52	3.44-3.6	3.67	3.44-3.89	3.82	3.8-3.84	3.79	3.71-3.87
Moisture (%)	2	6.1	5.8-6.4	6.25	6-6.5	6.15	5.9-6.4	6.15	6-6.3	6.2	6-6.4
Oil content (%)	2	43.38	42.05-44.7	44.01	43.28-44.73	44.88	44.78-44.98	45.09	44.95-45.23	44.73	44.58-44.88
Grain yield component	**Number of trials**	**Untreated control**		**Protiokonazol 300 EC at 0.35 L/ha**		**Protiokonazol 300 EC at 0.5 L/ha**		**Protiokonazol 300 EC at 0.6 L/ha**		**Tauron 240 EC at 0.75 L/ha**	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Yield (t/ha)	8	3.77	3.22-4.6	3.94	3.34-4.5	3.88	3.41-4.5	3.97	3.55-4.6	3.95	3.55-4.6
Moisture (%)	8	8.1	7.2-9.05	8.12	7.3-8.83	8.17	7.2-9.18	8.13	7.4-8.95	8.13	7.1-9.08
Oil content (%)	8	41.74	40.12-43.2	41.95	40.25-43.8	42.07	40.14-43.3	41.96	40.27-43.5	41.64	40.17-43.13

16 efficacy trials were carried out in 2021 with harvest in 2022, and 2022 with harvest in 2023 there was no statistically significant effect of target dose (0.6 L/ha) of Protiokonazol 300 EC on grain yield and its quality in winter oilseed rape.

Summary and conclusions on the efficacy tests

There were 59 efficacy trials conducted in Poland and in Czech Republic in growing season 2021 (autumn application on oilseed rape), 2022 and 2023 on winter wheat, spring wheat, winter triticale, spring triticale, winter barley, spring barley and winter oilseed rape as major crops and these trials were carried out to evaluate the efficacy of Protiokonazol 300 EC for the control of fungal diseases. All set up trials were conducted in compliance with GEP principles and were carried out appropriate EPPO guidelines. The efficacy of the Protiokonazol 300 EC at the proposed rates of 0.6-65 L/ha was equivalent to the efficacy of the reference products containing the same amount of the active substance – prothioconazole, at rates 0.6-0.65 L/ha against fungal diseases.

Summary and conclusion

59 trials total were conducted to confirm efficacy of Protiokonazol 300 EC in control of diseases in cereals (winter and spring wheat, winter and spring triticale, winter and spring barley, rye) and in winter oilseed rape. Protiokonazol 300 EC showed its effectiveness in control of diseases listed below, at the proposed label rates:

0.6 L/ha –
Controlled diseases:
Winter oilseed rape (autumn application)
Dark spot of crucifers (*Alternaria brassicae)* ALTEBA
Dry rot of crucifers (*Plenodomus lingam)* LEPTMA
Downy mildew of rape *(Hyaloperonospora brassicae)* HPERBR

~~**0.5 –**~~**0.6 L/ha –**
Controlled diseases:
Winter oilseed rape (spring application)
Dark spot of crucifers (*Alternaria brassicae)* ALTEBA (moderate control at rate 0.5 L/ha)
Cottony rot (*Sclerotinia sclerotiorum*) SCLESC

0.5-0.65 L/ha –
Controlled diseases:
Winter wheat
Powdery mildew of cereals (*Blumeria graminis)* ERYSGR
Septoria leaf blotch (*Zymoseptoria tritici)* SEPTTR

Spring wheat
Septoria leaf blotch (*Zymoseptoria tritici)* SEPTTR

Winter triticale
Powdery mildew of cereals (*Blumeria graminis)* ERYSGR
Septoria leaf blotch (*Zymoseptoria tritici)* SEPTTR

Spring triticale
Powdery mildew of cereals (*Blumeria graminis)* ERYSGR
Septoria leaf blotch (*Zymoseptoria tritici)* SEPTTR

Winter barley
Net blotch of barley (*Pyrenophora teres)* PYRNTE

Spring barley
Net blotch of barley (*Pyrenophora teres)* PYRNTE

Rye
Powdery mildew of cereals (*Blumeria graminis)* ERYSGR

Comments for ZRMS:

Justification for the use of biological efficacy data included in this dossier is made in line to EPPO 1/241(2) "Guidance on comparable climates". All trials carried out in the respective EPPO zones can be extrapolated to each country belonging to this agro-climatic EPPO zone. Moreover, trials conducted at the border of one country are relevant for the neighbouring country. All presented trials can be therefore relevant for a submission in the Central Regulatory Zone. However, in the opinion of ZRMs for extrapolating results always should be presented weather and agro-technical conditions. For example, Poland can use results from neighbouring countries (ex. CZ) but results from other countries and other EPPO zones are not acceptable. Each country can have its own rules, so in the opinion of ZRMs decision about use results or extrapolating results should be made on cMS level.

Trials were conducted according to EPPO guidelines, for example with: 1/135 (4), 1/152 (4), 1/26 (4) and 1/78 (3). The GEP certificates of the official testing organizations were provided. EPPO standard PP 1/226 *Number of efficacy trials* provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization zone (PP 1/278 *Principles of zonal data production and evaluation*), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

Details of experiment are presented above by Applicant. All used methodology is in line with GEP rules, except for EPPO 1/181 (4). Spring cereals: wheat, barley, triticale (2022) and winter cereals: wheat, barley, triticale (2022) and spring application on winter oilseed rape (2022) were studied only in one growing season. Winter rye was characterized by studies conducting in two growing seasons (2022 and 2023) and autumn application on winter oilseed rape (2021 and 2023). In the opinion of ZRMs, this extension (for spring cereals and winter wheat, winter barley, winter triticale and spring application on winter oilseed rape) can be acceptable. Especially when prothioconazole is known as a fungicide for many years and commonly used. Applicant presented explanation as (accepted by ZRMS) for conducting field trials only in one growing season.

Cereals: The level of plant infestation in the studied area was recorded directly before the first application of the product by % severity or %incidence. As in most trials % of severity was assessed this parameter was used in the tables presented by Applicant above. The design of the trial was a randomized complete block (with 4 replicates) with included untreated plots. Disease control % - estimate the mean % area of specified leaves (separately for individual leaves, e.g. L-1 flag leaf, L-2 – flag leaf minus 1; L-3 – flag leaf minus 3; etc.) affected by individual diseases, on a minimum of 20 tillers per plot selected at random and recorded separately to allow for calculation of disease incidence/severity. So, mean percentage (%) control based on diseases incidence/severity on leaves compared to untreated plots. Two full efficacy assessments were done: at application B and 14-21 days after application B. Green leaf index % was also assessed - Estimate the mean % green leaf area on 20 randomly selected plants per plot on leaf L-1 (flagleaf). In the opinion of ZRMs, this methodology is in line to EPPO 1/26. Efficacy after first application was not noted.

Winter oilseed rape: Disease control %- leaf infection: Estimate the mean % area of plant, from the leaf layer with average infection, affected by individual diseases, derived from a minimum of 25 plants per plot, on an overall plot basis. Disease control % - stem infection Estimate the mean % area of stem, affected by individual diseases, derived from a minimum of 25 plants per plot, on an overall plot basis. Disease control % - pod infection Estimate the mean % area of pod, affected by individual diseases, derived from a minimum of 25 plants per plot, on an overall plot basis. For autumn application against ALTEBA (6 trials), HIPERB (8 trials) and LEPTMA (7 trials) only one application was studied. For spring application two application were studied against ALTEBA (7 trials), LEPTMA (2 trials) and SCLESC (9 trials). Efficacy after one spring application was assessed only in 2 trials against ALTEBA (020GPSE202201and 020GPSE202202), 2 trials against LEPTMA (020GP202201 and 020GP202202) and one trial against SCELSC (020GP202202). Assessed after two spring application was made in all

trials.

Applicant submitted in total 59 efficacy trials showing the results in research into product efficacy: 10 trials were carried out on winter wheat, 2 trials – spring wheat, 2 trials – winter triticale, 2 trials – spring triticale, 9 trials – spring barley, 3 trials – winter barley, 5 trials – rye and 16 trials – winter oilseed rape. Major crops should be represented by sufficient number of trials. Only for winter wheat (10), spring barley (9) and winter oilseed rape (16) – Applicant presented enough number of trials. Rest of crops claimed in the GAP table can be accepted on the basis on extrapolating results from winter wheat to spring wheat (2), winter triticale (2) and spring triticale (2). Also, winter barley (2 trails) can be accepted in line to extrapolate results from spring barley and winter rye (5 trials) on the basis on extrapolated results from winter wheat.

Following varieties were studied during trials: ***winter wheat*** – Formacja (1), Linus (1), Euforia (1), Arkadia (4), Astoria (2), Hondia (1); ***spring wheat***: Harenda (1), Arabella (1); ***spring triticale*** – Milewo (1), Mamut (1); ***winter triticale***: Grenado (1), Lombardo (1); ***spring barley*** – Radek (1), Melius (1), Ela (1), Etoile (2), Penguin (1), Pilote (1), Saldo (1), Ella (1); ***winter barley***: Zenek (1), KWS Kosmos (1), Sonnegold (1); ***winter rye***: KWS VI Netto F1 (1), KWS Serafino (1), KWS Delaro (1), Stanko (1), Antonińskie (1) and ***winter oilseed rape*** (**autumn application**) – ES Imperio (1), Derrick (1), Kuga F1(1), KWS Marcopolo (1), Duke F1 (1), Absolut (1), Anabella (1), Arganos (1), Sienna (1), Hevelius (1), Nelson (1), Factor KWS F1 (1), Uniwersum (1), Kadore (1), Chopin (1), SY Ilona (1) and ***winter oilseed rape*** **(spring application)** – LG Ambassador F1 (1), Derrick (1), Anabella (1), Architekt (1), Kepler (1), Duke F1 (1), KWS Marcopolo (1), Ilona (1) and Kadore (1).

Following BBCH window were studied during trials: ***autumn application on winter oilseed rape*** – BBCH 13-17; ***spring application on winter oilseed rape*** – BBCH 61-72; ***winter wheat*** – BBCH 16-65; ***spring wheat***: BBCH 31-47; ***winter triticale*** – BBCH 39-49; ***spring triticale*** – BBCH 32-61*;* ***winter barley*** – BBCH 37-61*;* ***spring barley*** – BBCH 29-65, ***winter rye*** – BBCH 33-61. **In the opinion of ZRMS proposed by Applicant application window for cereals: BBCH 29-65, spring application in winter oilseed rape (BBCH 61-72) and autumn application in winter oilseed rape (BBCH 13-19) can be accepted on the basis on submitted documentation.**

Following water volume were studied during trials: ***autumn application on winter oilseed rape*** –100-400 L/ha; ***spring application on winter oilseed rape*** – 200-300 L/ha; ***winter wheat*** – 200-300 L/ha; ***spring wheat***: 200-300 L/ha; ***winter triticale*** – 200-300 L/ha; ***spring triticale*** – 200-300 L/ha*;* ***winter barley*** –200-300 L/ha; ***spring barley*** – 200-300 L/ha; ***winter rye*** – 300 L/ha. **In the opinion of ZRMs, proposed by Application window can be accepted on the basis on submitted documentation and plant protection programs.**

Following plot size were studied during trials: ***autumn application on winter oilseed rape*** – 19,5 – 30 m^2; ***spring application on winter oilseed rape*** – 19,5-30m^2*;* ***winter wheat*** – 19,5-30m^2*;* ***spring wheat*** – 30 m^2*;* ***winter triticale*** –30 m^2*;* ***spring triticale*** – 24m^2*;* ***winter barley*** –*24.3*-27m^2*;* ***spring barley*** – 24-30m^2*;* ***winter rye*** – 19.5-30m^2. **Plot size used during trials was accepted as in line to appropriate EPPO standards (1/78 and 1/26).**

We are dealing with the active substance commonly used for many years in many countries. We must emphasize that each pest should been represented by sufficient number of field efficacy trials (at least 6 for major pest and at least 3 for minor pest). All fungal diseases claimed in GAP table are major for cereals and winter oilseed rape.

Against SEPTTR (8 trials) on winter wheat Applicant submitted enough number of trials. Also use against SEPTTR can be accepted on winter triticale (1 trial), spring triticale (1 trial) and spring wheat (2 trials) by extrapolating results from winter wheat (8). SEPTTR was also studied in 2 trials carried out on winter rye. However, in line to Polish extrapolating tables it is not allowed to extrapolate results from winter wheat to rye. So, this use was correctly not included in the GAP by Applicant.

Applicant submitted only 5 trials against ERYSYGR on winter wheat. In the opinion of ZRMs, limited number of trials against ERYSYGR can be accepted conditionally. Prothioconazole is a quite old active substance used commonly in PPPs used on cereals. So, its efficacy is already known against ERYSYGR. In order to reduce the number of trials, it is necessary to conduct research over two growing seasons.

Unfortunately, the Applicant has only submitted results for one season and therefore only a conditional registration is possible against ERYSYGR on winter wheat. Within 24 months of receiving the registration, the Applicant should submit the missing study, which should be conducted either in the North-Eastern Zone or in a neighbouring country. Use against ERYSYGR should be accepted also on winter triticale (1 trial), spring triticale (1 trial) by extrapolating results from winter wheat (5). ERYSYGR was also studied in 1 trial carried out on spring barley and 1 trial on winter barley. However, in line to Polish extrapolating tables it is not allowed to extrapolated results from winter wheat to winter barley and spring barley. So, this use was correctly not included in the GAP by Applicant.

PUCCSI (winter wheat: 3 trials, spring wheat: 1 trial, spring triticale: 1 trial, winter rye: 1 trial), PYRNTR (winter wheat: 3 trials, spring wheat: 1 trial, winter triticale: 1 trial, winter rye: 1 trial), PUCCRE (spring barley: 1 trial) and RHYNSE (spring triticale: 1 trial, winter rye: 2 trials) were not represented by enough number of trials. So, those uses were correctly not included in the GAP table by Applicant.

Applicant submitted enough number of trials for spring application on winter oilseed rape against ~~LEPTMA~~ ALTEBA (7 trials) and SCLESC (9 trials). LEPTMA should be excluded due to not enough number of trials (only 2 were presented, whilst at least 6 should be assessed).

Applicant submitted sufficient number of trials against PYRNTE on spring barley (8 trials). Use against PYRNTE can be also accepted on spring barley (3 trials) by extrapolating results between those crops.

Applicant submitted accepted number of trials against LEPTMA (7 trials), ALTEBA (6 trials) and HIPERBR (8 trials) for autumn application.

Lack of trials against LEPTMA, SCLESC and ALTEBA on spring oilseed rape for spring application. However, spring oilseed rape is a minor use, so it can be accepted in line to Article 51 as already Applicant claimed.

The following efficacy scale was used:

- L – limiting (0-60% efficacy) <60% eff.
- ME – moderately efficiency (60-80%) 60-80% eff
- E – effectively (80%) >80% eff.

All trials were characterized by sufficient level of infestation (at least 5%).

Below, ZRMs presented results for studied fungal diseases in cereals and winter oilseed rape:

- **against SEPTTR**

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	8	16.9%	67.6%	82.2%	88,89%	86.70%
spring wheat	2	23.6%	65.4%	82.7%	90.75%	89.85%
winter triticale	1	42.4%	58.6%	74.1%	80.8%	77.80%
spring triticale	1	35.3%	67.4%	81.1%	83.4%	83.10%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against SEPTTR can be accepted on winter wheat (enough number of trials), spring wheat (by extrapolating results from ww), winter triticale (by extrapolating results from ww) and spring triticale (by extrapolating results from ww). HERA 300 EC effectively control SEPTTR on winter cereals (wheat, triticale) and spring cereals (wheat, triticale) at dose 0.5 L/ha and 0.65 L/ha. Higher dose should be used only in case of high fungal disease pressure. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC) or even higher (in winter triticale).

- **against ERYSYGR**

Cereal	No. trials	Infestation	Hera 300 EC at dose 0.25 L/ha	HERA 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	Hera 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha	Protendo 300 EC at dose 0.65 L/ha
winter wheat	5	10.82%	n.a.	n.a.	69.78%	82.76%	87.06%	85.56%	n.a.

spring wheat	n.a.	n.a.	n.a	n.a	n.a.	n.a.	n.a.	n.a.	n.a
winter triticale	1	30.1%	n.a	n.a	91.0%	97.0%	100%	100%	n.a
spring triticale	1	12.7%	n.a	n.a	80.2%	82.9%	89.4%	90.40%	n.a
winter rye	1		62.9%	82.5%				84.5%	80.5%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against ERYSYGR can be accepted conditionally on winter wheat (accepted limited number of trials if Applicant present missing one trial (optimally two trials) within 24 months after authorisation the product), winter triticale (by extrapolating results from ww), spring triticale (by extrapolating results from ww) and winter rye (by extrapolating results from ww). HERA 300 EC effectively control ERYSYGR on winter cereals (wheat, triticale, rye) and spring cereals (triticale) at dose 0.5 L/ha and 0.65 L/ha. Higher dose should be used only in case of high fungal disease pressure. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC). Use on spring wheat against ERYSYG is not accepted due to lack of trials.

– **against PYRNTE**

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter barley	3	6.46%	69.06%	80.1%	87.6%	89.13%
spring barley	8	18.04%	67.76%	82.59%	90.41%	88.81%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against PYRNTE can be accepted on spring barley (enough number of trials) and winter barley (by extrapolating results from spring barley). HERA 300 EC effectively control PYRNTE on winter barley and spring barley at dose 0.5 L/ha and 0.65 L/ha. Higher dose should be used only in case of high fungal disease pressure. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC).

– **spring application on winter oilseed rape**

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Poleposition 300 EC at dose 0.6 L/ha
ALTEBA	7	6.35%	60.43%	72.47%	83.46%	81.27%
SCLESC	9	12.7%	61.1%	80.54%	90.32%	88.56%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against ALTEBA and SCLESC can be accepted for spring application on winter oilseed rape. HERA 300 EC effectively control ALTEBA and SCLESC on winter oilseed rape at dose 0.6 L/ha. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC at dose 0.6 L/ha).

– **autumn application on winter oilseed rape**

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.2 L/ha	HERA 300 EC at dose 0.3 l/ha	Hera 300 EC at dose 0.35 L/ha	Hera 300 EC at dose 0.5 L/ha	HERA 300 EC at dose 0.6 L/ha	Promino 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
ALTEBA	5	9.66%	62.56%	76.12%	n.a	n.a	91.02%	87.88%	n.a
	1	6.80%	n.a,	79.0%	n.a	89.0%	97.0%	99.0%	n.a
LEPTMA	6	14.72%	20.88%	57.66%	n.a	n.a	86.32%	84.03%	n.a
	1	6.90%	n.a	70.0%	n.a	94.0%	100%	100%	n.a
HIPERBR	8	7.65%	n.a.	n.a.	66.6%	79.67%	87.39%	n.a.	85.5%

All trials were characterized by sufficient level of infestation. For HIPERBR, ALTEBA and LEPTMA – Applicant submitted enough number of trials. HERA 300 EC effectively control ALTEBA, LEPTMA and HIPERBR on winter oilseed rape at dose 0.6 L/ha. Results of tested HERA 300 EC were comparable to st. ref. product (Promino 300 EC at dose 0.6 L/ha against LEPTMA and ALTEBA and Tauron 240 EC at dose 0.75 L/ha against HIBERBR). Dose 0.5 L/ha should not been recommended – HIBERBR at 0.5 L/ha was ME and efficacy against ALTEBA and LEPTMA is difficult to concluded only on the basis on 1 trial with studied dose 0.5 L/ha.

Summary: It can be concluded that the dose rate of 0.5 -0.65 L/ha should be recommended for cereals

against SEPTTR (winter and spring wheat, winter and spring triticale), ERYSYGR (winter wheat, winter and spring triticale, winter rye) and PYRNTE (winter and spring barley). It can be concluded that dose 0.6 L/ha should be recommended for winter oilseed rape for spring application against ALTEBA and SCLESC and autumn application against ALTEBA, HIPERBR and LEPTMA. Use on spring oilseed rape against LEPTMA, SCELSC and ALTEBA can be accepted in line to Article 51 without any submitted trials. HERA 300 EC applied twice a season effectively controlled studied fungal diseases on cereals and winter oilseed rape in spring against ALTEBA and SCLESC. Hera 300 SC applied once a season in autumn effectively control ALTEBA, HIPERBR and LEPTMA on winter oilseed rape. What is important, use against ALTEBA can be done only in autumn (once) or in spring (twice application).

HERA 300 EC contain only one active substance (prothioconazole) so risk of developing resistance is high in the case of multiple application (even only two per season). Applicant would like to register HERA 300 EC (product code: Protiokonazol 300 EC) for applied max 2 times per season for cereals and spring application on winter oilseed rape and for use once a season in case of autumn application on winter oilseed rape.

The products registered in Poland for the protection of winter oilseed rape based exclusively on prothioconazole, which are intended for use in autumn and spring, are recommended for two treatments only: one treatment in autumn and one treatment in spring or two treatments in spring [early spring and full spring], and, taking this into account the currently evaluated study package (not enough number of trials with evaluated efficacy from one spring application), it would be appropriate to consider recommending the use of the product in question either only in autumn (one treatment) or only in spring (two treatments).

We should remember that repeated application for cereals of DMI or amine fungicides alone should not be used on the same crop in one season against risky pathogens (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen. Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen in winter oilseed crops. **So, in line to resistance strategy Applicant proposed to included following entry in the label at point PRECAUTIONS AND SPECIFIC CONDITIONS OF USE:**

[1] With recommendations of resistance strategy in mind, it would be reasonable to limit the use of the product to one treatment on cereals per season against powdery mildew and barley net blotch[or the second treatment should already be carried out with a product containing a fungicide from another FRAC group – with a different mechanism of action.

[2] If only one treatment is planned in the adopted protection programme HERA 300 EC, in order to achieve satisfactory efficacy this treatment should be carried out as a preventative measure.

Also it is important to not use HERA 300 EC more than twice a season on the winter oilseed rape. So, ZRMs proposed application scheme for HERA 300 EC against ALTEBA:

Apply the product according to one of the two application schedules given below.

1) use once at autumn application at BBCH 13-19 ~~and use once for spring application at BBCH 61-72.~~

Timing of application of the product:

- ✓ first *one treatment (autumn):* carry out treatment from the third leaf stage to the nine leaf stage or more (BBCH 13-19). Apply the product as a preventative measure or as soon as the first signs of disease are observed.
- ~~✓ *second treatment (spring):* carry out treatment from the beginning of flowering (open 10% of flowers on main inflorescence) to fruit development (Approximately 10% of the canes have reached typical size) as a preventative measure or as soon as the first symptoms of the disease are observed.~~

or

2) use twice per season for spring application at BBCH 61-72. Use as a preventive measure or as soon as the first signs of disease are visible, from the stage of 61 to 72 BBCH.

HERA 300 EC is recommended for a single autumn application against HIPERBR and LEPTMA at BBCH 13-19. HERA 300 EC against ALTEBA should be applied once in autumn at BBCH 13-19 or ~~and double~~ twice in spring application ~~against SCELSC~~ at BBCH 61-72 on winter oilseed rape. Control against SCLESC can be done only by twice applications of HERA300 EC in spring.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

According to FRAC active substance prothioconazole belongs to group 3 (DMI-fungicides). Its fungicidal properties are mainly attributed to prothioconazole ability to inhibit Lanosterol 14α-demethylase (CYP51A1) enzyme, which in fungi cells is required to biosynthesize ergosterol. Ergosterol is a key component in fungi cell membranes.

According to FRAC big differences in the activity spectra of DMI fungicides are known. For this type of fungicides, resistance in various fungal species are known. Couple of resistance mechanisms are known, among which there is target site mutation in cyp51 (erg 11) gene. We should accept the fact that cross resistance is present between DMI fungicides, which are active against the same fungus species. Fungicides of DMI group are Sterol Biosynthesis Inhibitors (SBIs), however they show no cross resistance to other SBI classes.
FRAC describes risk of resistance occurrence for this group as medium.

FRAC specific recommendations for DMIs (and in cereals are:

- The recommendations for the use of DMI and amine fungicides in mixture or alternation programmes with different mode of action fungicides remain unchanged. It needs to be emphasized that it is essential for resistance management purposes to follow strictly the manufacturer's and FRAC recommendations.
- Repeated application of DMI or amine fungicides alone should not be used on the same crop in one season against risky pathogens (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen.
- Reduced rates of DMIs can contribute to accelerate the shift to less sensitive populations. It is critical to use effective rates of DMIs in order to ensure robust disease control and effective resistance management. DMIs must provide effective disease control and be used at manufacturers' recommended rates.
- When used in mixture, recommended effective rates of the SBI must be maintained. Split and reduced rate programmes, using multiple repeated applications at dose rates below manufacturer's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.
- To ensure good performance and particularly resistance management in situations of even low disease pressure, it is essential to adhere to dosages and spray timings as recommended by manufacturers. Curative applications should be avoided. Application timing has to be appropriate to all mix partners' characteristics. Mixing with a non-cross resistant fungicide at effective dose rates contributes to a more effective disease control and resistance management.
- The amine fungicides are effective non-cross-resistant partner fungicides for DMIs on cereals for the control of pathogens included in the label recommendation of each respective product.
- Ramularia leaf spot (*Ramularia collo-cygni*) in barley: Given that there already exist populations of *Ramularia collo-cygni* in Europe resistant to all main site-specific modes of actions it is recommended to add precautionary a multi-site to ensure robust disease control and an effective resistance management in barley.

Comments for ZRMS:

Applicant did not presented the information on the occurrence or possible occurrence of the development of resistance in line to appropriate EPPO standard. So, for this reason ZRMs presented below widely characteristic of resistance against prothioconazole in cereals and rapeseed crops.

The risk of resistance to fungicides containing prothioconazole depends on various factors, including the type of pathogens, environmental conditions, agricultural practices, and the frequency of fungicide application. Prothioconazole is used against fungal diseases in agricultural crops such as wheat, corn, rapeseed, and fruits.

To minimize the risk of resistance development, it is recommended to implement diversified strategies for managing fungal diseases.

Here are some general recommendations:

- ***Fungicide Rotation***: Avoid using the same fungicides from the same chemical group too frequently. Rotating different active substances can reduce pressure on pathogens and decrease the risk resistance.
- ***Use of Mixtures***: Choose fungicides that contain combinations of different active substances. Mixtures may have a broader spectrum of action and can be more effective in preventing resistance.
- ***Integrated Pest Management (IPM)***: Implement strategies for managing fungal diseases within an overall IPM program, which may include field monitoring, use of resistant varieties, improvement of air circulation, proper fertilization, ant other cultivation practices.
- ***Education and Monitoring***: Regularly monitor fields for the presence of pathogens and assess the effectiveness of applied fungicides. Educate farmers and sustainable management practices.

It is also important for farmers to consult with local plant protection specialists and adhere to fungicide label recommendations and guidelines for resistance management.

The mode of action of prothioconazole is stated to be dementhylation inhibition (DMI). Resistance to DMI fungicides has been found for several pathogens including *Erysiphe graminis tritici*. The ZRMs considers the risk of resistance developing is high for powdery mildew of cereals (*Blumeria graminis*) and net blotch of barley (*Pyrenophora teres*) and is a moderate for septoria leaf blotch (*Zymoseptoria tritici*) for DMI fungicides including prothioconazole. A series of sensitivity studies have been carried throughout Europe to establish the baseline sensitivity of cereal mildew, net blotch leaf spot. In addition, a study was conducted to demonstrate cross-resistance between prothioconazole and a DMI fungicide for a range of cereal diseases.

Prothioconazole could be applied as a seed treatment and as a foliar spray to the same crop. However, the dose of prothioconazole applied in the seed treatment is low and would not be expected to produce significant selection of less sensitive strains of leaf, stem and ear diseases of cereals proposed for the spray formulation.

Prothioconazole is well known [cf. The Pesticide Manual, Fifteenth Edition, C.D.S. Tomlin (Ed.), 2009, BCPC Publications] as fungicide. Triazole fungicides including the fungicide Prothioconazole are well known as sterol biosynthesis inhibitors, see FRAC classification (FRAC website http://www/frac.info/), in particular subgroup 3 (legacy Gl). It is in particular known that triazoles fungicides including the fungicide Prothioconazole are inhibitors of fungal sterol C14 demethylase cyp51, which is a cytochrome P450 monooxygenase. However, so far the use of triazoles fungicides and in particular of the fungicide Prothioconazole as host defence inducer has never been reported before. The effect that Prothioconazole induces host defence responses and accumulation of salicylic acid is the more surprising since other triazole fungicides known as sterol biosynthesis inhibitors show a less substantial host defence response inducement and SA accumulation inducement.

Specific Recommendations by Crop / Pathogen for DMIs, Amines and KRIs (https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi):

- ✓ ***Cereals – DMIs and Amines***:

- The recommendations for the use of DMI and amine fungicides in mixture or alternation programmes with different mode of action fungicides remain unchanged. It needs to be emphasized that it is essential for resistance management purposes to follow strictly the manufacturer's and FRAC recommendations.
- Repeated application of DMI or amine fungicides alone should not be used on the same crop in one season against risky pathogens (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen.
- Reduced rates of DMIs can contribute to accelerate the shift to less sensitive populations. It is critical to use effective rates of DMIs in order to ensure robust disease control and effective resistance management. DMIs must provide effective disease control and be used at manufacturers' recommended rates.
- When used in mixture, recommended effective rates of the SBI must be maintained.
- Split and reduced rate programmes, using multiple repeated applications at dose rates below manufacturer's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.
- To ensure good performance and particularly resistance management in situations of even low disease pressure, it is essential to adhere to dosages and spray timings as recommended by manufacturers. Curative applications should be avoided. Application timing has to be appropriate to all mix partners' characteristics. Mixing with a non-cross resistant fungicide at effective dose rates contributes to a more effective disease control and resistance management.
- The amine fungicides are effective non-cross-resistant partner fungicides for DMIs on cereals for the control of pathogens included in the label recommendation of each respective product.
- Ramularia leaf spot (*Ramularia collo-cygni*) in barley: Given that there already exist populations of *Ramularia collo-cygni* in Europe resistant to all main site-specific modes of actions it is recommended to add precautionary a multi-site to ensure robust disease control and an effective resistance management in barley

✓ ***Oilseed rape*** (general recommendations)

- The SBI fungicides represent one of the most potent classes of fungicides available to the grower for the control of many economically important pathogens. It is in the best interest of all those involved in recommending and using these fungicides that they are utilised in such a way that their effectiveness is maintained
- The working group concentrates its resources on the major crop/pathogen targets from the point of view of resistance risk. Inevitably many, still important pathogens are omitted. To help in making recommendations for crops and pathogens not directly covered, the following general recommendations can be made:
- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended (see FRAC Code List on Download Page).
- Where alternation or the use of mixtures is not feasible because of a lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- If the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBIs should only be used in mixture or alternation with effective non cross-resistant partner fungicides.
- The introduction of new classes of chemistry offers opportunities for more effective resistance management. The use of different modes of action should be maximized for the most effective resistance management strategies.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance"

have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.

– Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.
– Exclusive frequency measurements of single cyp51 mutations are not sufficient to describe the sensitivity situation towards DMIs but can help to better understand the background of sensitivity shifts.

SBI fungicides have been characterized by FRAC (http://www.frac.info) as medium risk resistance but as pathogens have different risk levels, combination of both fungicide and pathogen resistance risk should also be investigated.

Diseases vary in their sensitivity towards fungicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. DMI fungicides have been tested and used worldwide for up to 30 years (or more), it is therefore difficult to find unexposed fungal populations. No true base line sensitivity data can therefore be established. FRAC has been monitoring the development in sensitivity in the most important diseases for a number of years.

In terms of agronomic practice, the selection pressure on the intended disease target for HERA 300 EC (product code: Protiokonazol 300 EC) may be medium to high in annual cereal crops like wheat (depending on whether a successful crop rotation system is applied or mono-cropping is carried out in the crop, respectively). The agronomic risk for HERA 300 EC is estimated as medium for prothioconazole.

The resistance management is coordinated by FRAC recommendation. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

<u>As part of a resistance management strategy, it is recommended to:</u>

– Do not apply the product at rates lower than dose recommended in the label;
– Use the product interchangeably with fungicides containing active ingredients from other chemical groups with a different mode of action;
– Apply the product a maximum of 2 times per growing season, in rotation with other fungicides fungicides containing active substances belonging to other groups according to the FRAC classification, with different mechanism of action FRAC classification, with a different mechanism of action;
– Adjust the dosage according to the level of disease severity or their predicted severity on the protected crop;
– Monitor the effects of the treatments performed.

In line to resistance strategy against powdery mildew and barley net blotch, ZRMs proposed following entry to label in the point of PRECAUTIONS AND SPECIFIC CONDITIONS OF USE:

[1] With recommendations of resistance strategy in mind, it would be reasonable to limit the use of the product to one treatment on cereals per season against powdery mildew in cereals and barley net blotch[or the second treatment should already be carried out with a product containing a fungicide from another FRAC group – with a different mechanism of action.

[2] If only one treatment is planned in the adopted protection programme HERA 300 EC, in order to achieve satisfactory efficacy this treatment should be carried out as a preventative measure.

3.4 Adverse effects on treated crops (KCP 6.4)

The applicant carried out 59 efficacy trials in which selectivity of the Protiokonazol 300 EC was assessed according to EPPO general and crop specific guidelines:
-10 trials in winter wheat
-2 trials in spring wheat

-2 trials in winter triticale
-2 trials in spring triticale
-3 trials in winter barley
-9 trials in spring barley
- 5 trials in rye
-16 trials in winter oilseed rape (autumn application)
-10 trials in winter oilseed rape (spring application)

EPPO PP 1/226(3) standard states - it is not required to conduct phytotoxicity trials for fungicides. However, phytotoxicity was evaluated in each type of the performed efficacy trials, also yield and its quality traits was evaluated according to EPPO guidelines.

All the trials have been presented in point 3.4 – 1.

Table 3.4-1: Presentation of trials (selectivity trials, transformation trials...)

Crop*	Country	Type of trial**	Number of trials (North-East zone)	Years	GEP, non-GEP, official***	Comments (any other relevant information)
Winter wheat	Czech Republic; Poland	Y + Q	10	2022	GEP	Yield assessment was performed, moisture, HLW and TGW was measured.
Spring wheat	Poland	Y + Q	2	2022	GEP	Yield assessment was performed, moisture, HLW and TGW was measured.
Winter triticale	Poland	Y + Q	2	2022	GEP	Yield assessment was performed, moisture, HLW and TGW was measured.
Spring triticale	Poland	Y + Q	2	2022	GEP	Yield assessment was performed, moisture, HLW and TGW was measured.
Winter barley	Poland	Y + Q	3	2022	GEP	Yield assessment was performed, moisture, HLW and TGW was measured.
Spring barley	Czech Republic; Poland	Y + Q	9	2022	GEP	Yield assessment was performed, moisture, HLW and TGW was measured.
Winter Rye	Poland	Y + Q	5	2022, 2023	GEP	Yield assessment was performed, moisture, HLW and TGW was measured.
Winter oilseed rape (autumn)	Poland	Y + Q	16	2021/2022, 2022/2023	GEP	Yield assessment was performed, moisture and oil content was measured.
Winter oilseed rape (spring)	Czech Republic; Poland	Y + Q	10	2022	GEP	Yield assessment was performed, moisture and oil content was measured.

Crop*	Country	Type of trial**	Number of trials (North-East zone)	Years	GEP, non-GEP, official***	Comments (any other relevant information)
TOTAL	-	Y + Q	**59**	-	-	

According to the GAP table

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

*** Official: carried out by a national official organisation

Table 3.4-2: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trial number	Crop(s)	Reference standards	Country(ies) where the product is registered[1]	Authorization number	Active substance(s) (a.s)	Formulation		Registered application rate[3]	Application rate in trials (per treatment)	Remark[4]
						Type[2]	Concentration of a.s.			
III 6.1.3/01 (E-WW-PL-2022-S22-03727-01) III 6.1.3/02 (E-WW-PL-2022-S22-03727-02) III 6.1.3/03 (E-WW-PL-2022-S22-03727-03) III 6.1.3/04 (E-WW-PL-2022-S22-03727-04) III 6.1.3/05 (E-WW-PL-2022-S22-03727-05) III 6.1.3/06 (E-WW-PL-2022-13GPSE2022-01) III 6.1.3/07 (E-WW-PL-2022-13GPSE2022-02)	Winter wheat	Polepo-sition 300 EC	PL	R-29/2020	Prothio-conazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applica-tions per season; 200-400 L/ha of spray vol-ume; foliar spray
III 6.1.3/08 (E-WW-PL-2022-13GPSE2022-03) III 6.1.3/09 (E-WW-PL-2022-13GPSE2022-04)	Winter wheat	Protendo 300 EC	PL	R-224/2019	Prothio-conazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applica-tions per season; 200-400 L/ha of spray vol-ume; foliar spray
III 6.1.3/10 (E-WW-PL-2022-CZOR-PSZ22-TRZAW-053NEC)	Winter wheat	ERA	CZ	5689-3	Prothio-conazole	EC	300 g/L	0.6 L/ha	0.6 L/ha	2. applica-tions per season; 200-400 L/ha of spray vol-ume; foliar spray
III 6.1.3/11 (E-SW-PL-2022-S22-03727-06) III 6.1.3/12	Spring wheat	Polepo-sition 300 EC	PL	R-29/2020	Prothio-conazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applica-tions per season;

Trial number	Crop(s)	Reference standards	Country(ies) where the product is registered[1]	Authorization number	Active substance(s) (a.s)	Formulation		Registered application rate[3]	Application rate in trials (per treatment)	Remark[4]
						Type[2]	Concentration of a.s.			
(E-SW-PL-2022-014GPSE2022-01)										200-400 L/ha of spray volume; foliar spray
III 6.1.3/13 (E-WT-PL-2022-S22-03727-07) III 6.1.3/14 (E-WT-PL-2022-15GPSE2022-01)	Wtinter triticale	Polepo-sition 300 EC	PL	R-29/2020	Prothio-conazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/15 (E-ST-PL-2022-S22-03727-08) III 6.1.3/16 (E-ST-PL-2022-16GPSE2022-01)	Spring triticale	Polepo-sition 300 EC	PL	R-29/2020	Prothio-conazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/17 (E-SB-PL-2022-S22-03727-10) III 6.1.3/18 (E-SB-PL-2022-S22-03727-11) III 6.1.3/19 (E-SB-PL-2022-S22-03727-12) III 6.1.3/20 (E-SB-PL-2022-S22-03727-13) III 6.1.3/21 (E-SB-PL-2022-S22-03727-14) III 6.1.3/22 (E-SB-PL-2022-19GPSE2022-01) III 6.1.3/23 (E-SB-PL-2022-19GPSE2022-02) III 6.1.3/24 (E-SB-PL-2022-19GPSE2022-03) III 6.1.3/25 (E-SB-PL-2022-19GPSE2022-04)	Spring barley	Polepo-sition 300 EC	PL	R-29/2020	Prothio-conazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/26 (E-WB-PL-2022-CZOR-PSZ22-HORVW-057NEC)	Winter barley	ERA	CZ	5689-3	Prothio-conazole	EC	300 g/L	0.6 L/ha	0.6 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/27 (E-WB-PL-2022-S22-03727-15) III 6.1.3/28 (E-WB-PL-2022-18GPSE2022-01)	Winter barley	Polepo-sition 300 EC	PL	R-29/2020	Prothio-conazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of

Trial number	Crop(s)	Reference standards	Country(ies) where the product is registered[1]	Authorization number	Active substance(s) (a.s)	Formulation		Registered application rate[3]	Application rate in trials (per treatment)	Remark[4]
						Type[2]	Concentration of a.s.			
										spray volume; foliar spray
III 6.1.3/29 (E-WOSR-PL-2022-S22-03740-01) III 6.1.3/30 (E-WOSR-PL-2022-S22-03740-02) III 6.1.3/31 (E-WOSR-PL-2022-S22-03740-03) III 6.1.3/32 (E-WOSR-PL-2022-S22-03740-04) III 6.1.3/33 (E-WOSR-PL-2022-S22-03740-05) III 6.1.3/34 (E-WOSR-PL-2022-020GP2022-01) III 6.1.3/35 (E-WOSR-PL-2022-020GP2022-02) III 6.1.3/36 (E-WOSR-PL-2022-020GPSE2022-03) III 6.1.3/37 (E-WOSR-PL-2022-020GPSE2022-04)	Winter oilseed rape	Polepoposition 300 EC	PL	R-29/2020	Prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.6 L/ha	Spring application. 2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/38 (E-WOSR-PL-2022-CZOR-PSZ22-BRSNN-045NEC)	Winter oilseed rape	ERA	CZ	5689-3	Prothioconazole	EC	300 g/L	0.6 L/ha	0.6 L/ha	Spring application. 2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/39 (E-WOSR-PL-2022-004GP202101) III 6.1.3/40 (E-WOSR-PL-2022-004GP202102) III 6.1.3/41 (E-WOSR-PL-2022-004GP202103) III 6.1.3/42 (E-WOSR-PL-2022-004GP202104) III 6.1.3/43 (E-WOSR-PL-2022-004GP202105) III 6.1.3/44 (E-WOSR-PL-2022-004GP202106)	Winter oilseed rape	Promino 300 EC	PL	R- 211/2019	Prothioconazole	EC	300 g/L	0.6 L/ha	0.6 L/ha	Autumn application. 2. application per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/45 (E-WR-PL-2022-017GPSE202201) III 6.1.3/46	Rye	Polepoposition 300 EC	PL	R-29/2020	Prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of

Trial number	Crop(s)	Reference standards	Country(ies) where the product is registered[1]	Authorization number	Active substance(s) (a.s)	Formulation		Registered application rate[3]	Application rate in trials (per treatment)	Remark[4]
						Type[2]	Concentration of a.s.			
(E-WR-PL-2022-S22-03727-09)										spray volume; foliar spray
III 6.1.3/47 (E-WR-PL-2023-007GPSE202301) III 6.1.3/48 (E-WR-PL-2023-007GPSE202302) III 6.1.3/49 (E-WR-PL-2023-007GPSE202303)	Rye	Protendo 300 EC	PL	R-224/2019	Prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/50 (E-WOSR-PL-2023-S22-07447-01) III 6.1.3/51 (E-WOSR-PL-2023-S22-07447-02)	Winter oilseed rape	Polepoposition 300 EC	PL	R-29/2020	Prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.6 L/ha	Autumn application. 2. applications per season; 200-400 L/ha of spray volume; foliar spray
III 6.1.3/52 (E-WOSR-PL-2023-006GPAE2022-01) III 6.1.3/53 (E-WOSR-PL-2023-006GPAE2022-02) III 6.1.3/54 (E-WOSR-PL-2023-006GPAE2022-03) III 6.1.3/55 (E-WOSR-PL-2023-006GPAE2022-04) III 6.1.3/56 (E-WOSR-PL-2023-006GPAE2022-05) III 6.1.3/57 (E-WOSR-PL-2023-006GPAE2022-06) III 6.1.3/58 (E-WOSR-PL-2023-006GPAE2022-07) III 6.1.3/59 (E-WOSR-PL-2023-006GPAE2022-08)	Winter oilseed rape	Tauron 240 EC	PL	R-32/2018	Prothioconazole, tebuconazole	EC	80 g/L (prothioconazole), 160 g/L (tebuconazole)	0,75 L/ha	0,75 L/ha	Autumn application. 2. applications per season; 200-400 L/ha of spray volume; foliar spray

(1) only on use(s) applied for (with the test product)
(2) e.g.WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) Dose / dose range authorized in the country
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application…)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Table 3.4-3: Phytotoxicity of product to winter wheat

Number of trials with…		Efficacy trials (10 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	10	10
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	10	10
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

10 trials were carried out on winter wheat in Poland and Czech Republic, in year 2022 on a wide range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 2x 0.65 L/ha of Protiokonazol 300 EC was used.

Table 3.4-4: Phytotoxicity of product to spring wheat

Number of trials with…		Efficacy trials (2 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

2 trials were carried out on spring wheat in Poland, in year 2022 on a range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on spring wheat, when proposed label rate of 2x 0.65 L/ha of Protiokonazol 300 EC was used.

Table 3.4-5: Phytotoxicity of product to winter triticale

Number of trials with…		Efficacy trials (2 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

2 trials were carried out on winter triticale in Poland, in year 2022 on a range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on winter triticale, when proposed label rate of 2x 0.65 L/ha of Protiokonazol 300 EC was used.

Table 3.4-6: Phytotoxicity of product to spring triticale

Number of trials with…		Efficacy trials (2 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

2 trials were carried out on spring triticale in Poland, in year 2022 on a range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on spring triticale, when proposed label rate of 2x 0.65 L/ha of Protiokonazol 300 EC was used.

Table 3.4-6: Phytotoxicity of product to spring barley

Number of trials with…		Efficacy trials (~~10~~ 9 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	9	9
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	9	9
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

~~10~~ 9 trials were carried out on spring barley in Poland, in year 2022 on a wide range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on spring barley, when proposed label rate of 2x 0.65 L/ha of Protiokonazol 300 EC was used.

Table 3.4-7: Phytotoxicity of product to winter barley

Number of trials with…		Efficacy trials (~~≥~~ 3 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	3	3
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

3 trials were carried out on winter barley in Czech Republic and Poland, in year 2022 on a range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on winter barley, when proposed label rate of 2x 0.65 L/ha of Protiokonazol 300 EC was used.

Table 3.4-7: Phytotoxicity of product to winter rye

Number of trials with…		Efficacy trials (5 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	5
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	5	5
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

5 trials were carried out on winter ~~barley~~ rye in Poland, in year 2022 and 2023 on a range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on winter rye, when proposed label rate of 2x 0.65 L/ha of Protiokonazol 300 EC was used.

Table 3.4-8: Phytotoxicity of product to winter oilseed rape (spring application)

Number of trials with…		Efficacy trials (10 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	10	10
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	10	10
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

10 trials were carried out on winter oilseed rape in Poland and Czech Republic, in year 2022 on a wide range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on winter oilseed rape, when proposed label rate of 2x 0.6 L/ha of Protiokonazol 300 EC was used.

Table 3.4-9: Phytotoxicity of product to winter oilseed rape (autumn application)

Number of trials with…		Efficacy trials (~~2~~ 16 trials)	
		Test product	Standard 1
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	16	16
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	16	16
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

16 trials with autumn application of the product were carried out on winter oilseed rape in Poland on a wide range of commercially grown varieties.

No phytotoxicity effect of Protiokonazol 300 EC at target rate of 0.6 L/ha was observed.

Comments for ZRMS:

Both EU Directive (EU, 1991) and EPPO PP 1/226 – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 – Phytotoxiicty assessment states: "*EPPO Standards on fungicides, insecticides and plant growth regulators, on the other hand, include only a relatively simple special section on phytotoxicity as-assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent'. Selectivity trials were not*

required, which is in ac-accordance with EPPO 1/135 (3).”

The crop safety of applying HERA 300 EC (product code: Protiokonazol 300 EC) at recommended dose of 0.5-0.65 L/ha for cereals and 0.6 L/ha for winter oilseed rape (spring and autumn application).

Applicant presented efficacy trials in which phytotoxic effect was assessed and an assessment of the impact on the yield and its quality has been carried out. Trials for winter wheat, spring wheat, winter triticale, spring triticale, spring barley, winter rye, winter oilseed rape (autumn and spring application) were carried out in Poland (N-E EPPO zone). Trials from winter barley were performed in CZ (1 trials) and PL (2 trials) and for winter oilseed rape for spring application in CZ (1 trial) and PL (9 trials).

- ***Winter wheat***: 10 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ***Spring wheat***: 2 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ***Winter triticale***: 2 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ***Spring triticale*** : 2 trials .No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ***Winter barley***: 3 trials No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ***Spring barley***: 9 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ***Winter rye***: 5 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates and st. ref. product (at dose 0.6 L/ha). Dose 0.5-0.65 L/ha was studied in 2 trials. During 2 trials doses: 0.25 L/ha; 0.33 L/ha and 0.65 L/ha was studied.
- ***Winter oilseed rape*** **(autumn application)*:*** 16 trials. No symptoms of phytotoxiicty were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.6 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ***Winter oilseed rape*** **(spring application)**: 10 trials. No symptoms of phytotoxiicty were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.6 L/ha) and st. ref. product (at dose 0.6 L/ha).

Summary: No phytotoxicity symptoms assessed in terms of general injury (PHYGEN) caused by HERA 300 EC (product code: Protiokonazol 300 EC) at the proposed rate (0.5-0.65 L/ha for cereals and 0.6 L/ha for winter oilseed rape) in efficacy trials were recorded in all trials (59). Those results were comparable to standard reference products.

For Poland, documentation is sufficient for registration HERA 300 EC for use on winter cereals (wheat, triticale, barley, rye) and spring cereals (wheat, triticale, barley) and winter oilseed rape. Lack of trials for spring oilseed rape is accepted as its registration is on the basis on the Article 51 (as a minor crop).

In conclusion, no negative influence of the product HERA 300 EC (product code: Protiokonazol 300 EC) is to be expected when at the intended rate and used according to the label recommendations.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Not relevant. This part concerns only trials in pest-free conditions.

Comments for ZRMS:

- ✓ **Cereals:** Yield was studied during efficacy trials (59). Below, ZRMs presented results for each crop and each dose studied. The yield must be specified or, if it is not specified, it is necessary to provide justification. The fresh weight content and moisture content of the harvested grain. The yield should be calculated in t/ha or dt/ha according to the established level of moisture content (specified national standard or international) and is compared to the yield obtained for the control object or preparation comparison in line to EPPO 1/26.

Yield (t/ha) noted in efficacy trials on fungal diseases on winter and spring cereals

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	6.63	n.a	n.a	6.80	6.97	7.05	6.95
spring wheat	2	4.89	n.a	n.a	5.29	5.01	5.08	5.14
winter triticale	2	6.72	n.a	n.a	6.89	6.77	6.89	7.02
spring triticale	2	4.89	n.a	n.a	5.29	5.01	5.08	5.14
winter rye	2	6.52	n.a	n.a	7.20	7.00	7.25	7.06
	3	5.88	6.07	6.16	n.a	n.a	6.22	6.23
winter barley	3	7.73	n.a	n.a	8.16	8.13	8.26	8.26
spring barley	9	4.58	n.a	n.a	4.89	5.00	5.23	5.06

Hera 300 EC at the proposed label rate had positive effect on the yield on the studied cereals. Hera 300 EC is assumed to have no negative effects on the yield of treated plants. Results were compared to un-treated control and st. reference product.

- ✓ ***Winter oilseed rape***: Recording yields can be useful. For make it easier to harvest the crop and reduce losses, you should divide the rows before the 71-78 developmental stage on the BBCH. The yield should be calculated in kg ha-1 according to the established moisture level (according to national or international standards), and in relative to a control plot or preparation comparison. Useful information can also be obtained by measuring the weight of 1,000 grains (g) and measuring oil content. In line to EPPO 1/78.

Yield (t/ha) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	3.15	3.38	3.47	3.57	3.49

Hera 300 EC at the proposed label rate had positive effect on the yield on the studied winter oilseed rape (spring application). Hera 300 EC is assumed to have no negative effects on the yield of treated plants. Results were compared to untreated control and st. reference product.

Yield (t/ha) noted in efficacy trials on fungal diseases on winter oilseed rape (autumn application)

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.20 L/ha	HERA 300 EC at dose 0.3 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (autumn application)	6	3.63	3.66	3.63	3.63	3.65

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.3 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Poleposition 300 EC at dose 0.6 L/ha
winter oilseed rape (autumn application)	2	3.54	3.52	3.67	3.82	3.79

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
winter oilseed rape (autumn application)	8	3.77	3.94	3.88	3.97	3.95

Hera 300 EC at the proposed label rate had positive effect on the yield on the studied winter oilseed rape (autumn application). Hera 300 EC is assumed to have no negative effects on the yield of treated plants. Results were compared to untreated control and st. reference product.

In conclusion, no negative impact of the product – Hera 300 EC (product code: Protiokonazol 300 EC) on the yield is to be expected when applied at the intended rate and used according to the label recommendation's.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

59 efficacy studies conducted in 2021 and 2022 seasons in Czech Republic and Poland on winter and spring wheat, winter and spring triticale, winter and spring barley, rye and winter oilseed rape. Trials have showed that Protiokonazol 300 EC fungicide had no negative impact on treated plants, their yield and yield quality traits. Protiokonazol 300 EC applied twice (or once in case of autumn application done on winter oilseed rape) in rate 0.6 L/ha (winter oilseed rape) and 0.65 L/ha (cereals) did not cause any adverse effects on yield quantities and quality traits which were analyzed in efficacy trials of the product.

In none of the trials done, no phytotoxic effect (f.e.changes in growth, plant height, tillering, dates of succeeding growth stages, thinning out of plants, discolorations, necroses, deformations) caused by any tested rate of Protiokonazol 300 EC was recorded.

Comments for ZRMS:

Quality of yield was assessed during 59 efficacy trials. Below, ZRMs presented results for each crop and each dose studied for quality of yield.

- ✓ ***Cereals:***

Moisture (%) noted in efficacy trials on fungal diseases on winter and spring cereals

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	13.025	n.a.	n.a.	13.013	13.073	13.098	13.043
spring wheat	2	12.35	n.a.	n.a.	12.35	12.35	12.30	12.20
winter triticale	2	11.55	n.a.	n.a.	11.65	11.55	11.60	11.55
spring triticale	2	12.25	n.a.	n.a.	12.35	12.40	12.35	12.20
winter rye	2	14.70	n.a	n.a.	14.80	14.80	14.85	14.80
	3	13.01	13.1	13.11	n.a	n.a	13.22	13.03
winter barley	3	12.67	n.a.	n.a.	12.20	12.10	12.20	12.20
spring barley	9	12.31	n.a.	n.a.	12.32	12.34	12.38	12.30

Hera 300 EC at the proposed label rate had positive effect on the moisture content (%) on the studied cereals. Hera 300 EC is assumed to have no negative effects on the quality of yield (moisture) of treated

plants. Results were compared to untreated control and st. reference product.

Weight of 1000 grains (g) noted in efficacy trials on fungal diseases on winter and spring cereals

Cereal	No. trials	Un-treated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	42.614	n.a	n.a.	43.019	43.049	43.099	43.241
spring wheat	2	36.385	n.a	n.a.	36.74	37.295	36.32	36.44
winter triticale	2	39.205	n.a	n.a.	39.26	37.87	39.305	39.23
spring triticale	2	34.67	n.a	n.a.	34.84	35.255	35.065	34.285
winter rye	2	32.79	n.a	n.a	32.58	32.27	32.80	32.68
	3	31.29	31.59	31.42	n.a	n.a.	31.53	31.27
winter barley	3	46.63	n.a	n.a.	47.40	47.70	47.69	47.92
spring barley	9	45.27	n.a	n.a.	45.26	45.26	45.70	45.49

Hera 300 EC at the proposed label rate had positive effect on the weight of 1000 grains (g) on the studied cereals. Hera 300 EC is assumed to have no negative effects on the quality of yield (weight of 1000 grains) of treated plants. Results were compared to untreated control and st. reference product.

Test weight (kg/hl) noted in efficacy trials on fungal diseases on winter and spring cereals

Cereal	No. trials	Un-treated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	77.932	n.a.	n.a.	78.159	78.079	77.916	78.122
spring wheat	2	73.335	n.a.	n.a.	73.51	73.67	73.675	73.67
winter triticale	2	73.95	n.a.	n.a.	73.97	74.56	74.255	74.28
spring triticale	2	58.68	n.a.	n.a.	58.69	58.55	58.77	58.74
winter rye	2	74.25	n.a	n.a	74.5	74.03	75.0	74.74
	3	68.75	69.43	69.03	n.a	n.a	68.78	69.14
winter barley	3	67.99	n.a.	n.a.	68.27	68.14	68.73	68.40
spring barley	9	68.65	n.a.	n.a.	68.46	68.25	68.64	68.8

Hera 300 EC at the proposed label rate had positive effect on the test weight (kg/hl) on the studied cereals. Hera 300 EC is assumed to have no negative effects on the quality of yield (test weight) of treated plants. Results were compared to untreated control and st. reference product.

- ✓ ***Winter oilseed rape***:

Recording yields can be useful. For make it easier to harvest the crop and reduce losses, you should divide the rows before the 71-78 developmental stage on the BBCH. The yield should be calculated in kg ha-1 according to the established moisture level (according to national or international standards), and in relative to a control plot or preparation comparison. Useful information can also be obtained by measuring the weight of 1,000 grains (g) and measuring oil content in line to EPPO 1/78.

Moisture (%) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	3.15	3.38	3.47	3.57	3.49

Weight of 1000 grains (g) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	4.35	4.39	4.40	4.67	4.42

Oil content (%) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	42.05	42.10	42.24	42.16	42.37

Hera 300 EC at the proposed label rate had positive effect on the quality of yield on the studied winter oilseed rape (spring application). Hera 300 EC is assumed to have no negative effects on the quality of yield (moisture, weight of 1000 grains, oil content) of treated plants. Results were compared to untreated control and st. reference product.

Moisture (%) noted in efficacy trials on fungal diseases on winter oilseed rape (autumn application)

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.20 L/ha	HERA 300 EC at dose 0.3 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (autumn application)	6	7.30	7.28	7.33	7.32	7.40

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.3 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Poleposition 300 EC at dose 0.6 L/ha
winter oilseed rape (autumn application)	2	6.10	6.25	6.15	6.15	6.20

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
winter oilseed rape (autumn application)	8	8.10	8.12	8.17	8.13	8.13

Oil content (%) noted in efficacy trials on fungal diseases on winter oilseed rape (autumn application)

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.20 L/ha	HERA 300 EC at dose 0.3 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (autumn application)	6	42.07	42.45	42.78	41.85	42.13

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.3 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Poleposition 300 EC at dose 0.60 L/ha
winter oilseed rape (autumn application)	2	43.38	44.01	44.88	45.09	44.73

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
winter oilseed rape (autumn application)	8	41.74	41.95	42.07	41.96	41,64

Hera 300 EC at the proposed label rate had positive effect on the quality of yield on the studied winter oilseed rape (autumn application). Hera 300 EC is assumed to have no negative effects on the quality of yield (moisture and oil content) of treated plants. Results were compared to untreated control and st. reference product.

In conclusion, no negative impact of the product – Hera 300 EC (product code: Protiokonazol 300 EC) on the quality of yield is to be expected when applied at the intended rate and used according to the label recommendation's.

3.4.4 Effects on transformation processes (KCP 6.4.4)

According to the EPPO guideline PP 1/243(1) " […] regulation (e.g. Commission Regulation 284/2013, EU, 2013) may require investigation of possible adverse effects if there are indications that the use of a plant protection product could have an influence on transformation processes (e.g. use of plant growth regulators or fungicides close to harvest or after harvest), or where use of similar products has been found to have an adverse influence. [...] If the applicant can demonstrate that residues are undetectable, or that any residues will not affect yield, a reasoned case may be sufficient to address these requirements."

For Protiokonazol 300 EC no processing trials were performed. There is no indication from agricultural practice that fungicides containing the active substance prothioconazole have affected the processing of harvested cereal grains in the past. Furthermore, the test product is intended for application in BBCH 29-65 of cereals and, for oilseed rape, BBCH 13-19 and 61-72. With plenty of time to commercial harvest and very short period of prothioconazole dissipation in plant matrix, product is considered as having no effects on transformation processes.

According to DAR for prothioconazole (Section 6, December 2017) under conditions designed to mimic pasteurisation, baking, brewing, boiling and sterilization there was no significant hydrolysis of prothioconazole following incubation at different pH values and temperatures. Prothioconazole is stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation, and no additional metabolites are formed in processed commodities as compared to raw agricultural commodities.

Comments for ZRMS:

In general, fungicides containing prothioconazole are used to protect cereals from fungal diseases. They are also used on rape seed and other crops. Thus active substance can impact grain processing, especially if used in excessive amounts or not in accordance with the label's recommendations.

Below, ZRMs presented general pieces of information regarding the influence of these fungicides on cereal processing:

- ***grain quality***: The use of fungicide can help maintain better grain quality by controlling fungal diseases. However, if used excessively, it may potentially affect the physical and chemical characteristics of the grain.
- ***mycotoxin content***: Fungicides can assist in reducing the occurrence of mycotoxins produced by certain fungal species, thereby affecting the food safety. Nevertheless, in the case of excessive fungicide use, there is a risk that some mycotoxins may still be present in the grain.
- ***processing efficiency***: If fungicides application is appropriately balanced and in line with recommendations, it can contribute to maintaining the efficiency of cereal processing. They protect plants from diseases, which can impact the quantity and quality of yields.
- ***compliance with regulations***: It is crucial to adhere to local and international regulations regarding pesticide residue levels in food. Non-compliance with these regulations may result in rejection of product batches.

The impact of fungicides on cereal processing will depend on various factors such as the applied dosage, grain type, growing conditions, and protection period. It is always recommended to strictly follow the label's recommendations and consult with experts in plant protection and food processing to minimize potential adverse effects.

No indication from agricultural practice is known that fungicides with the active substance – prothioconazole have affected cereals or oilseed rape for propagation purposes. No negative of the product – HERA 300 EC on the yield, quality and processing procedure is expected. So, no negative impact of the product HERA 300 EC (product code: Protiokonazol 300 EC) is to be expected when applied at the intended dose rate and used according to the label recommendations. Furthermore, the test product is intended for application in BBCH 29-65 of cereals and, for oilseed rape, BBCH 13-19 and 61-72. With plenty of time to commercial harvest and very short period of prothioconazole dissipation in plant matrix, product is

considered as having no effects on transformation processes. According to DAR for prothioconazole (Section 6, December 2017) under conditions designed to mimic pasteurisation, baking, brewing, boiling and sterilization there was no significant hydrolysis of prothioconazole following incubation at different pH values and temperatures. Prothioconazole is stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation, and no additional metabolites are formed in processed commodities as compared to raw agricultural commodities.

Since the market introduction no effects on transformation processes have been recorded for any of these products, nor prothioconazole containing products have any label restriction concerning their use on crops destined for processing. In the opinion of ZRMs, no undesirable effects are expected on the transformation processes.

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

59 studies conducted in 2021, 2022 and 2023 seasons in Czech Republic and Poland on winter and spring wheat, winter and spring triticale, winter and spring barley, rye and winter oilseed rape revealed no negative impact of Protiokonazol 300 EC on propagation material – cereal seed and rape seeds.

Summary and conclusion

No adverse effects on treated plants such as phytotoxicity symptoms, negative impact on yield quality/ quantity and transformation processes were observed in efficacy trials of Protiokonazol 300 EC.

Comments for ZRMS:

Prothioconazole is a fungicide used to protect cereals from fungal diseases. The impact of this substance on reproductive goals in cereals may depend on several factors, such as the applied dosage, application period, type of cereals, environmental conditions, and other agricultural practices.

Below, ZRMs presented some general aspects to consider:

- ***disease protection***: Prothioconazole are effective in combating various fungal diseases, such as rust, fusarium and powdery mildew. Protecting plants from these diseases can contribute to better plant health, influencing their ability to reproduce.
- ***impact on yield***: Protecting plants from diseases using fungicides can improve yield as healthier plants are less susceptible to losses caused by diseases. Increased yield can affect the availability of seed for the reproduction processes.
- ***effect on seed quality***: Proper use of fungicide can influence the quality of cereal seeds, which, in turn, is essential for reproductive processes. Preventing fungal diseases can contribute to obtaining healthy seeds.
- ***sustainable application***: It is important to use fungicides in accordance with the label's recommendations and adopt a sustainable approach to their use. Excessive use or failure to adhere to recommendations may lead to potential side effects.
- ***protection against environmental stress***: Fungicides can assist plants in overcoming environmental stresses, such as attacks by pathogenic fungi. Protection against stress can support reproductive processes by maintaining healthy plants.

In conclusion, no negative impact of the product – HERA 300 EC on the yield, quality and processing procedure is to be expected. No indication from agricultural practice is known that fungicides with the active substance – prothioconazole have affected cereals or oilseed rape used for propagating purposes. No negative impact of the product – HERA 300 EC is to be expected when applied at the intended dose rate and used according to the label recommendations.

No phytotoxicity symptoms occurring during the field trials suggested that product application in accordance with label recommendations has no negative impact on parts of plant used for propagating purposes. Also, the fungicides containing prothioconazole have been allowed to use for many years. Based on the expert knowledge about prothioconazole, it can be concluded to accept the information's provided by Applicant. According to the above statement, additional studies are not required in this range, in the opinion of ZRMs.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Protiokonazol 300 EC (containing prothioconazole) is not harmful for succeeding plants since its active substance decomposes in very fast pace (According to PPDB by University of Hertfordshire[1], soil degradation DT_{90} ranges between 3.9 and 5.9 days for prothioconazole in field studies done on 8 different soils). Consequently, the product decomposes within the growing season without making any damage to succeeding plants. It is concluded that after the appropriate application of Protiokonazol 300 EC in winter and spring cereals, all the possible crops and catch crops can be grown when usual crop rotation and seedbed preparation is used.

Considering raised arguments and the fact that the literature does not say anything about the adverse impact on succeeding crops after application of fungicides containing this active substance, no specific plant-back restrictions related to Protiokonazol 300 EC are required. In case of the need to sift the treated plantation (as a result of crop damage by frost, disease or pest), every crop can be grown after performing 25cm ploughing.

Comments for ZRMS:

Applicant did not provide a sufficient level of information to address the impact on succeeding crops in accordance with EPPO PP 1/207. Normally, no special data for fungicides are prepared and submitted for that point if no persistence of the product is known or in discussion. Some data can be described at other parts of this section or in other sections (persistence situation of the applied substance). However, problems from authorisations of prothioconazole products at cereals and rape seed have not been reported.

Lack of phytotoxicity symptoms recorded during the field trials suggested that product (HERA 300 EC) application in accordance with label recommendations shall not adversely impact on succeeding crops.

The half-life of prothioconazole in soils was lower than it metabolites, with the DT_{50} of ranging from 16.6 to 99.6 days, 15.8 and 50.7 days for M01 and M04 under aerobic condition, respectively.

A review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggest that product application in line to label, shall not adversely impact on succeeding crops. Also, based on the absence of any adverse effects in typical cropping situations, it was concluded that the fungicide – HERA 300 EC (product code: Protiokonazol 300 EC) poses no risk to succeeding crops.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

None of the efficacy trials reported any effects on adjacent crops or plants. Application of Protiokonazol 300 EC when done according to the requirements of "Good Agricultural Practice" excludes lapses, e.g. overspray of boundary stripes, overdose or applications in other than the registered crops or at other appli-

[1] http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/559.htm

cation times. Furthermore, GAP rules say that to avoids spray drift to adjacent crops the wind speed (maximum allowed wind speed during application of PPP in Poland 4 m/s), the droplet size and positioning of the spray boom have to be taken into account.

Therefore, it is not expected that appropriate applications of Protiokonazol 300 EC will lead to adverse effects on adjacent crops.

Tank cleaning

There are no special requirements for cleaning application equipment and protective clothing. Normal procedures should be followed for the cleaning and use of protective clothing and equipment.

Comments for ZRMS:

The Applicant initially did not provide any data for the impact on adjacent crops. Fungicides containing prothioconazole are used to protect cultivated plants, especially cereals from fungal diseases. However, they can also affect neighbouring plants, referred to as companion plants.

Below, ZRMs presented several potential impacts on these plants (adjacent):

- **drift:** During fungicide application, the phenomenon of drift, where active substance particles are carried by the wind, can occur. This may lead to the unintentional delivery of fungicides to neighbouring plants. Therefore, it is important to exercise caution during application and use appropriate techniques to minimize the risk of drift. Such information should be added to label: "*During the application of the substance, prevent the drift of the spray onto neighbouring crops*".
- ***allergic reactions and toxicity***: Companion plants may be exposed to the active substances in fungicides, leading to allergic reactions or toxicity, especially if these substances come into contact with the leaves or roots of neighbouring plants.
- ***changes in soil microflora***: Fungicides can influence soil microflora, disrupting the balance of microorganism at both the soil level and in the rhizosphere, the area around plant roots. This can impact the health and functions of neighbouring plants.
- ***effects on soil fauna***: Fungicides can also affect organisms living in the soil, such as bacteria, fungi, or small animals. Disturbances in the soil ecosystem can influence neighbouring plants.
- ***disease protection***: On the other hand, fungicides used to protect cultivated plants can also provide benefits to companion plants by shielding them from potential pathogens transmitted by wind or soil.

It is crucial for farmers to apply fungicides in line with the label's recommendations and local regulations. Adhering to pesticide application standards, employing suitable application techniques, and considering environmental factors can help minimize potential adverse effects on neighbouring plants.

The following provision on the label should be done:

When applying the product, do not allow spray to drift onto neighbouring crops

Tank cleaning procedure: ZRMs accepted the procedure proposed by Applicant and included in the label project. So, normal procedure tank cleaning should be made.

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

In efficacy trials no adverse effects of Protiokonazol 300 EC on beneficial organisms were observed. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

Comments for ZRMS:

Data and information on the safety of HERA 300 SC (product code: Protiokonazol 300 EC) to beneficial and other non-target organisms can be found in the Ecotoxicology section.

3.5.4 Compatibility with current management practices including IPM

This is not an EC data requirement/not required by Regulation 1107/2009.

Summary and conclusion

Products which are containing prothioconazole, has been used for many years, not only in Poland and Czech Republic (where efficacy trials were done) but also in other European countries. According to current knowledge, the active substance present in the product Protiokonazol 300 EC does not pose any unacceptable risk to other plants also there was no adverse impact on beneficial organisms.

3.6 Other/special studies

Not relevant.

Comments for ZRMS:

ZRMs agree with Applicant. Other studies are not required.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
Eurofins Agroscience Services Sp. z o.o.	ul. Parkowa 6 64-530 Kaźmierz, Poland	Yes
Green & Property Consulting Anna Huszcza-Podgórska	ul. Na stoku 6/6 26-601 Radom, Poland	Yes
Zkušební stanice Nechanice	Štolbova 319 503 15 Nechanice, Czech Republic	Yes

GŁÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENNICTWA

Tadeusz Kłos

WO-505-11/15

Warszawa, dnia 10.08.2015 r.

DECYZJA Nr 8/2015

Na podstawie art. 17 ust. 2 i ust. 8 pkt 2 w związku z art. 79 ust. 3 ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin (Dz.U. z 2015 r. poz. 547) oraz art. 104 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2013 r. poz. 267 z późn.zm.), po rozpatrzeniu wniosku z dnia 29 czerwca 2015 r., uzupełnionego pismem z dnia 29 lipca 2015 r., rozszerzam zakres upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin wydanego w drodze decyzji Nr 28/2005 (z 20.12.2005 r.), zmienioną decyzjami Nr 6/2009 (z 16.09.2009 r.) oraz Nr 4/2010 (z 14.05.2010 r.), w zakresie prowadzenia badań skuteczności działania środka ochrony roślin z użyciem herbicydów, repelentów, fungicydów, insektycydów i regulatorów wzrostu w uprawach i drzewostanach leśnych iglastych i liściastych w leśnictwie oraz w produkcjach szkółkarskich.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

Upoważniam

Eurofins Agroscience Services Sp. z o.o.

(Kaźmierz, ul. Parkowa 6; 64-530 Kaźmierz)

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy akarycydów, fungicydów, herbicydów, insektycydów, moluskocydów, nematocydów, regulatorów wzrostu, repelentów, rodentycydów oraz adiuwantów w uprawach polowych, pod osłonami, w uprawach sadowniczych, w pomieszczeniach magazynowych oraz w pomieszczeniach przeznaczonych do uprawy grzybów jadalnych. Badania prowadzone będą w uprawach roślin zbożowych, rzepaku i innych roślin oleistych, kukurydzy, buraków, ziemniaków, roślin pastewnych i włóknistych, warzyw (kapustne, cebulowe, liściowe, korzeniowe, dyniowate, psiankowate, strączkowe), drzew i krzewów owocowych, roślin jagodowych, ziół, roślin ozdobnych, a także na terenach nieużytkowanych (odłogi, ugory) oraz na ścierniskach.

Ponadto Eurofins Agroscience Services Sp. z o.o. może prowadzić badania skuteczności działania środka ochrony roślin z grupy herbicydów, repelentów, fungicydów, insektycydów i regulatorów wzrostu w uprawach i drzewostanach leśnych iglastych i liściastych w leśnictwie oraz w produkcjach szkółkarskich.

Uzasadnienie

Eurofins Agroscience Services Sp. z o.o. (Kaźmierz, ul. Parkowa 6; 64-530 Kaźmierz), pismem z dnia 29 czerwca 2015 r., uzupełnionym pismem z dnia 29 lipca br., zwróciła się do Głównego Inspektora Ochrony Roślin i Nasiennictwa o rozszerzenie zakresu decyzji Nr 28/2005 (z 20.12.2005 r.), zmienionej decyzjami Nr 6/2009 (z 16.09.2009 r.) oraz Nr 4/2010 (z 14.05.2010 r.), upoważniającej do prowadzenia badań skuteczności działania środka ochrony roślin o możliwość prowadzenia takich badań z użyciem herbicydów, repelentów, fungicydów, insektycydów i regulatorów wzrostu w uprawach i drzewostanach leśnych iglastych i liściastych w leśnictwie oraz w produkcjach szkółkarskich.

Eurofins Agroscience Services Sp. z o.o. spełnia wymagania dobrej praktyki doświadczalnej w rozumieniu art. 3 pkt 20 rozporządzenia Parlamentu Europejskiego i Rady (WE) Nr 1107/2009 z dnia 21 października 2009 r. dotyczącego wprowadzania do obrotu środków ochrony roślin i uchylającego dyrektywy Rady 79/117/EWG i 91/414/EWG (Dz.Urz. UE L 309 z 24.11.2009 str. 1 z późn.zm.), co zapewnia prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

Rozpatrując prośbę dotyczącą zmiany zakresu upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin Główny Inspektor uwzględnił również informację (pismo znak: L.dz. 68/w/2015 z 23.06.2015 r.) o zmianie siedziby Spółki z miejscowości Gałowo (ul. Wierzbowa 12; 64-500 Szamotuły) do miejscowości Kaźmierz (ul. Parkowa 6; 64-530 Kaźmierz) .

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.

Pobrano opłatę skarbową zgodnie z częścią I ust. 36c załącznika do ustawy z dnia 16 listopada 2006 r. o opłacie skarbowej (Dz.U. z 2015 r. poz. 783) w wysokości 1000 zł .

Małgorzata Kukuła – gł. specjalista w Głównym Inspektoracie Ochrony Roślin i Nasiennictwa

lingua-franca.pl

niedziela, 11 grudnia 2016
Arkadiusz Kaczorowski - Tłumacz przysięgły języka angielskiego TP/619/05
Tłumaczenie uwierzytelnione z języka angielskiego

1

[Początek tłumaczenia]
MAIN INSEPCTORATE OF PLANT HEALTH AND SEED INSPECTION

Tadeusz Kłos
WO-505-11/15

Warsaw, August 10, 2015

Decision no 8/2015

Pursuant to art. 17 (2) and (8) 2 and in relation to art. 79 (3) of the act of March 8, 2013 on plant protection agents (Journal of Laws of 2015, item 547) and in relation to art. 104 of the act of June 14, 1960 - Code of administrative procedure (Journal of Laws of 2013, item 267 with amendments), having examined the application of June 29, 2015 supplemented with the letter of July 29, 2015 please be advised that this authority has extended the permit to conduct efficacy studies of a plant protection agent granted by the decision no 28/2005 (of December 20, 2005) amended with decision 6/2009 (of September 16, 2009) and decision 4/2010 (of May 14, 2010) within the scope of efficacy studies of a plant protection agent with the use of herbicides, repellents, fungicides, insecticides and growth regulators in cultivation of deciduous and coniferous trees in plant nurseries.

This is to authorize Eurofins Agroscience Services Sp. z o.o. Kaźmierz, ul. Parkowa 6; 64-530 Kaźmierz to conduct studies on the efficacy of a plant protection product

from the subgroup of acaricides, fungicides, herbicides, insecticides, moluscocides, nematocides, plant growth regulators, repellents, rodenticides, adjuvants in field, indoors, orchards, warehouses and in edible mushroom facilities cultivation. The research shall be conducted in the cultivation of crops, rape and other oil plants, corn, beet, potatoes, plants used for animal feed production, fiber plants, vegetables (brassicaceae, bulbous vegetables, potherbs, root vegetables, cucurbitaceae, solanaceae, leguminous), fruit trees and shrubs, berries, herbs, ornamental plants and in wastelands such as idle lands, fallows and stubble fields.

Moreover, Eurofins Agroscience Services Sp. z o.o. Kaźmierz, ul. Parkowa 6; 64-530 Kaźmierz is authorized to conduct said studies with a plant protection agent from the group of herbicides, repellents, fungicides, insecticides and growth regulators in the cultivation of deciduous and coniferous trees in plant nurseries.

Grounds

Eurofins Agroscience Services Sp. z o.o. Kaźmierz, ul. Parkowa 6; 64-530 Kaźmierz, in its application of June 29, 2015 supplemented with the letter of July 29, 2015 requested that this

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niedziela, 11 grudnia 2016
Arkadiusz Kaczorowski - Tłumacz przysięgły języka angielskiego TP/619/05
Tłumaczenie uwierzytelnione z języka angielskiego

2

authority had extended the permit to conduct efficacy studies of a plant protection agent granted by the decision no 28/2005 (of December 20, 2005) amended with decision 6/2009 (of September 16, 2009) and decision 4/2010 (of May 14, 2010) authorizing it to conduct efficacy studies of a plant protection agent with the use of herbicides, repellents, fungicides, insecticides and growth regulators in cultivation of deciduous and coniferous trees in plant nurseries.

Eurofins Agroscience Services Sp. z o.o. meets the technical and organizational criteria as provided for in the Principles of Good Experimental Practice as laid down in art. 3 (20) of the 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 Directives 79/117/EEC and 91/414/EEC, therefore it is capable of conducting the efficacy studies on the plant protection product in the appropriate manner.

When evaluating the application for the extension of the permit to conduct studies with a plant protection product, this authority has also considered the information of the change of the applicant's headquarter (ref# L.dz. 68/w/2015 of June 23, 2015). Former headquarter of Eurofins Agroscience Services Sp. z o,o. , Gałowo, ul. Wierzbowa 12, 64-500 Szamotuły moved to a new address: Eurofins Agroscience Services Sp. z o.o. Kaźmierz, ul. Parkowa 6; 64-530 Kaźmierz.

Having regard to the above, it has been decided as stated hereinabove.

You cannot appeal against this decision. However, if you are not satisfied with it, you may reapply to the Main Inspectorate of Plant Health and Seed Inspection within 14 day of the service hereof as prescribed in art. 127 (3) of the Code of Administrative Procedure.

Treasury fee collected in the amount of PLN 1000 as prescribed in Part I, paragraph 36c of the act of November 16, 2006 on treasury fees (Journal of Laws of 2015, item 783).

Małgorzata Kukuła – a principal specialist with the Main Inspectorate of Plant Health and Seed Inspection.
[Round seal of the Main Inspectorate of Plant Health and Seed Inspection with the national emblem of Poland]
[illegible signature]

[Koniec tłumaczenia]

Ja, Arkadiusz Kaczorowski, tłumacz przysięgły języka angielskiego zaświadczam, że niniejszy dokument jest pełnym i wiernym tłumaczeniem oryginału okazanego mi w dniu 11 December 2016 r.
Sporządzono, odczytano i opatrzono pieczęcią w Poznaniu w dniu 11 December 2016 r.
Poz. rep.: F:\2016\189_7215_2016

ul. Poznańska 57/9a, 60-852 Poznań, Poland Tel: +48 61 8427626 Fax: +48 61 8427626
www.lingua-franca.pl

GŁÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENNICTWA

Andrzej Chodkowski

BORiN.510.7.2022 Warszawa, 12 maja 2022 r.

DECYZJA Nr 7/2022

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. – Kodeks postępowania administracyjnego (Dz. U. z 2021 r. poz. 735, z późn. zm.) w związku z art. 17 ust. 8 pkt 2 ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin (Dz. U. z 2020 r. poz. 2097), po rozpatrzeniu wniosku Pani Anny Huszcza-Podgórskiej prowadzącej działalność gospodarczą pod firmą Green & Property Consulting Anna Huszcza-Podgórska (ul. Na stoku 6/6; 26-601 Radom) z dnia 19 kwietnia 2022 r., uzupełnionego pismem z dnia 9 maja 2022 r., zmieniam decyzję Nr 14/2021 z dnia 12 sierpnia 2021 r. w ten sposób, że rozstrzygnięciu decyzji nadaję następujące brzmienie:

Upoważniam Panią Annę Huszcza-Podgórską prowadzącą działalność gospodarczą pod firmą Green & Property Consulting Anna Huszcza-Podgórska do prowadzenia badań skuteczności działania środków ochrony roślin z grupy fungicydów, herbicydów, insektycydów, regulatorów wzrostu oraz bakteriocydów w uprawach polowych zbóż (*pszenica jara i ozima, jęczmień jary i ozimy, pszenżyto jare i ozime, żyto ozime, owies*), kukurydzy, rzepaku ozimego, roślin okopowych (*ziemniak, burak cukrowy*), warzyw (*kapusta głowiasta*), uprawach sadowniczych (*jabłoń, grusza, śliwa, wiśnia, czereśnia, truskawka, malina*) oraz na terenach nieużytkowanych rolniczo.

Uzasadnienie

Wnioskiem z dnia 19 kwietnia 2022 r., uzupełnionym pismem z dnia 9 maja 2022 r. Pani Anna Huszcza-Podgórska prowadząca działalność gospodarczą pod firmą Green & Property Consulting Anna Huszcza-Podgórska (ul. Na stoku 6/6; 26-601 Radom) zwróciła się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z prośbą o zmianę zakresu upoważnienia do prowadzenia badań skuteczności działania środków ochrony roślin Nr 14/2021 z dnia 12 sierpnia 2021 r. Wnioskowane zmiany dotyczą możliwości prowadzenia takich badań w uprawach polowych ziemniaka i buraka cukrowego, w uprawach warzywnych - kapusta głowiasta oraz w uprawach sadowniczych - śliwa, wiśnia, czereśnia, malina.

Mając na uwadze przepis art. 15zzzzy ust. 1 ustawy z dnia 2 marca 2020 r. o szczególowych rozwiązaniach związanych z zapobieganiem, przeciwdziałaniem i zwalczaniem COVID-19, innych chorób zakaźnych oraz wywołanych nimi sytuacji kryzysowych (Dz. U. z 2021 r. poz. 2095, z późn. zm.), która czasowo wyłącza niektóre obowiązki wynikające z ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin, Główny Inspektor Ochrony Roślin i Nasiennictwa przed dokonaniem zmiany zakresu upoważnienia do prowadzenia badań skuteczności działania środków ochrony roślin

odstąpił od przeprowadzenia kontroli, o której mowa w art. 17 ust. 6 ustawy o środkach ochrony roślin.

Stwierdzenie spełnienia wymagań dobrej praktyki doświadczalnej przez Panią Annę Huszcza-Podgórską prowadzącą działalność gospodarczą pod firmą Green & Property Consulting Anna Huszcza-Podgórska dokonano na podstawie dokumentów dołączonych do wniosku.

Mając powyższe na uwadze postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy, w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 kpa.

W trakcie biegu terminu do złożenia wniosku ponowne rozpatrzenie sprawy strona może zrzec się tego prawa wobec organu administracji publicznej, który wydał decyzję. Z dniem doręczenia Głównemu Inspektorowi Ochrony Roślin i Nasiennictwa oświadczenia o zrzeczeniu się prawa do złożenia wniosku o ponowne rozpatrzenie sprawy, decyzja staje się ostateczna i prawomocna, co oznacza, iż decyzja podlega natychmiastowemu wykonaniu i brak jest możliwości zaskarżenia decyzji do Wojewódzkiego Sądu Administracyjnego.

Jeżeli strona nie uważa, że decyzja jest zgodna z jej wnioskiem, a nie chce skorzystać z prawa zwracania się z wnioskiem o ponowne rozpatrzenie sprawy, może wnieść do Wojewódzkiego Sądu Administracyjnego w Warszawie skargę na decyzję w terminie 30 dni od dnia doręczenia decyzji stronie. Skargę wnosi się za pośrednictwem Głównego Inspektora Ochrony Roślin i Nasiennictwa.

Zgodnie z § 2 ust. 1 pkt 2 rozporządzenia Rady Ministrów z dnia 16 grudnia 2003 r. w sprawie wysokości oraz szczegółowych zasad pobierania wpisu w postępowaniu przed sądami administracyjnymi (Dz. U. z 2021 r. poz. 535) wpis stały bez względu na przedmiot zaskarżonego aktu lub czynności w sprawach skarg na akty lub czynności z zakresu administracji publicznej dotyczące uprawnień lub obowiązków wynikających z przepisów prawa wynosi 200 zł.

Na wniosek strony złożony przed wszczęciem lub w toku postępowania sądowego może być stronie przyznane prawo pomocy, w zakresie całkowitego lub częściowego zwolnienia od kosztów sądowych oraz ustanowienia adwokata lub radcy prawnego, gdy strona wykaże, że nie jest w stanie ponieść jakichkolwiek lub pełnych kosztów postępowania.

Została pobrana opłata skarbowa w wysokości 1 000 zł .

Otrzymują:
1. Pani Anna Huszcza-Podgórska
   ul. Na stoku 6/6
   26-601 Radom
2. a/a

GŁÓWNY INSPEKTOR OCHRONY ROŚLIN I NASIENNICTWA

Z upoważnienia
GŁÓWNEGO INSPEKTORA
Tadeusz Łączyński

Certified Translation from the Polish Language

[Polish National Emblem]

Chief Inspector of Plant Protection and Seed Inspection
Andrzej Chodkowski

Our ref.: BORiN.510.7.2022 Warszawa, 12 May 2022

DECISION No. 7/2022

On the basis of Article 155 of the Act of 14 June 1960 – the Administrative Procedure Code (Journal of Laws of 2021, item 735, as amended) in conjunction with Article 17 section 8 point 2 of the Act of 8 March 2013 on plant protection products (Journal of Laws of 2020, item 2097), after considering an application submitted by Mrs Anna Huszcza-Podgórska running a business activity under the name *Green & Property Consulting Anna Huszcza-Podgórska* (address: ul. Na Stoku 6/6, 26-601 Radom) of 19 April 2022 completed by a letter of 9 May 2022, I change my decision No. 14/2021 of 12 August 2021 in such a way that the operative part of the decision reads as follows:

"I authorize Mrs Anna Huszcza-Podgórska running a business activity under the name *Green & Property Consulting Anna Huszcza-Podgórska* to carry out efficacy tests of plant protection products in the following categories: fungicides, herbicides, insecticides, plant growth regulators and bactericides in the field crops *(spring and winter wheat, spring and winter barley, spring and winter triticale, winter rye and oat)*, corn, winter rape, root crops *(potato, sugar beet)*, vegetables (*head cabbage)*, orchard cultivation *(apple tree, pear tree, plum tree, sour cherry tree, cherry tree, strawberry, raspberry*) and non-agricultural land".

Justification

In her application of 19 April 2022, completed by a letter of 9 May 2022, Mrs Anna Huszcza-Podgórska running a business activity under the name *Green & Property Consulting Anna Huszcza-Podgórska* (address: Na Stoku 6/.6) asked the Chief Inspector of Plant Protection and Seed Inspection to change the scope of authorization to carry out efficacy tests of plant protection products No. 14/2021 of 12 August 2021. The requested changes concern a possibility of carrying out such tests in field crops of potato and sugar beet, vegetable crops of head cabbage and orchard cultivation of plum, sour cherry, cherry and raspberry.

Taking into account the regulation of Article 15zzzzy section 1 of the Act of 2 March 2020 on special solutions related to preventing, counteracting and combating COVID-19, other infectious diseases and the resulting crisis (Journal of Laws of 2021, item 2095, as amended), which temporarily relieves some obligations arising from the Act of 8 March 2013 on plant protection products, the Chief Inspector of Plant Protection and Seed Inspection, before changing the scope of authorization to carry out efficacy tests of plant protection products, refrained from the inspection, referred to in Article 17 section 6 of the Act on plant protection products.

TŁUMACZ PRZYSIĘGŁY
JĘZYKA ANGIELSKIEGO
mgr Renata Gocławska
26-600 Radom, ul. Żwirki i Wigury 38 m. 46
NIP 796-103-76-92, Regon: 670075944

R. Gocławska

On the basis of the documents attached to the application it was found that Mrs Anna Huszcza-Podgórska running a business activity under the name *Green & Property Consulting Anna Huszcza-Podghórska* mets the requirements of good experimental practice.

In view of the above said it has been decided like in the operative part of the decision.

Instructions

The party has no right to appeal from this decision. In accordance with Article 127 § 3 of the Administrative Procedure Code, the Party that is not satisfied with the decision can apply to the Chief Inspector of Plant Protection and Seed Inspection to re-consider the case within 14 days from following its receipt.

Within the time limit for submitting the application for re-consideration of the case, the Party can waive this right. On the day the Chief Inspector of Plant Protection and Seed Inspection is served the waiver, the decision becomes final and valid which means that it cannot be contested before the Provincial Administrative Court.

If the Party does not think that the decision is in line with the application but does not want to exercise the right to apply for re-consideration of the case, it can file a complaint with the Provincial Administrative Court in Warszawa within 30 days following its receipt. The complaint shall be filed via the Chief Inspector of Plant Protection and Seed Inspection.

Pursuant to §2 section 1 point 2 of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules of collecting a fee for an entry in the register in the proceedings before the administrative courts (Journal of Laws of 2021, item 535), the court fee, regardless of the subject of the contested act (…), amounts to PLN 200.

At the request of the party concerned made prior to the initiation of the proceedings or during the proceedings, the party may be granted assistance in the form of full or partial exemption from a court fee and appointment of a lawyer or legal advisor, if the party proves that it is not able to incur any or full costs of the proceedings.

Stamp duty of PLN 1 000 was collected.

Signed and stamped by: /-/ Tadeusz Łączyński
p p the Chief Inspector

(round official seal with the Polish National Emblem and inscription in the rim: Główny Inspektor Ochrony Roślin i Nasiennictwa (Chief Inspector of Plant Protection and Seed Inspection))

Copies to:
1. Anna Huszcza-Podgórska
   ul. Na Stoku 6/6
   26-601 Radom
2. To files

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
Entry No. 655/2022 in the Sworn Translator's Register

TŁUMACZ PRZYSIĘGŁY
JĘZYKA ANGIELSKIEGO
mgr Renata Gocławska
26-600 Radom, ul. Żwirki i Wigury 38 m. 46
NIP 796-103-76-92, Regon: 670075944

R. Gocławska

I, the undersigned, Danuta Gocławska, Sworn Translator for English, registered with the Ministry of Justice of the Republic of Poland (Entry No TP/6127/05), do hereby certify that the foregoing is a true and exact translation of the original document in Polish presented to me. In witness whereof I have hereunto set my hand and seal of office this 1st day of December 2022.

TŁUMACZ PRZYSIĘGŁY
JĘZYKA ANGIELSKIEGO
mgr Danuta Gocławska
26-600 Radom, ul. Żwirki i Wigury 38 m. 46
NIP 796-103-76-92, Regon: 670075944

D. Gocławska

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 122942/2021 ze dne 20. 7. 2021

OSVĚDČENÍ

GEP/NEC/2021

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnická osoba: **ZKUŠEBNÍ STANICE NECHANICE, s.r.o.**

sídlo právnické osoby: Štolbova 319, 503 15 Nechanice

IČ právnické osoby: 25283669

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- trvalé kultury / *high crops*
- skleníky a jiné kryté prostory / *protected areas and storage rooms*

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 2 -

Ing. Pavel Minář, Ph.D.
ředitel odboru

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/01	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-01 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/02	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-02 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/03	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-03 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/04	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-04 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/05	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-05 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/06	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter wheat for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 013GPSE202201 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/07	Figurski R	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter wheat for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 013GPSE202202 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/08	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Winter Wheat. Poland 2022. Green & Property Poland; Report No.: 013GPSE202203 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/09	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Winter Wheat. Poland 2022. Green & Property Poland; Report No.: 013GPSE202204 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/10	Čáp J.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in cereals. Czech Republic, 2022 Zkušební stanice Nechanice, Czech Republic; Report No.: CZOR-PSZ22-TRZAW-053NEC GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/11	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-06 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/12	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring wheat for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 014GPSE202201 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/13	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter triticale. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-07 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/14	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter triticale for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 015GPSE202201 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/15	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring triticale. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-08 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/16	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring triticale for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 016GPSE202201 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/17	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-10 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/18	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-11 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/19	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-12 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/20	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-13 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/21	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-14 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/22	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring barley for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 019GPSE202201 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/23	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring barley for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 019GPSE202202 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/24	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Spring Barley. Poland 2022. Green & Property Poland; Report No.: 019GPSE202203 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/25	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Spring Barley. Poland 2022. Green & Property Poland; Report No.: 019GPSE202204 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/26	Čáp J.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in cereals. Czech Republic, 2022 Zkušební stanice Nechanice, Czech Republic; Report No.: CZOR-PSZ22-HORVW-057NEC GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/27	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-15 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/28	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter barley for the control of fungal diseases, Poland 2022. Green & Property Poland; Report No.: 018GPSE202201 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/29	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-01 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/30	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-02 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/31	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-03 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/32	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-04 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/33	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-05 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/34	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter OSR for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 020GP202201 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/35	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter OSR for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 020GP202202 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/36	Ławiński K.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Green & Property Poland; Report No.: 020GPSE202203 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/37	Ławiński K.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Green & Property Poland; Report No.: 020GPSE202203 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/38	Čáp J.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Czech Republic 2022 Zkušební stanice Nechanice, Czech Republic; Report No.: CZOR-PSZ22-BRSNN-045NEC GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/39	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202101 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/40	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202102 GEP: Yes Published: No	N	Pestila* ProAgri**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 3.2/41	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202103 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/42	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202104 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/43	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202105 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/44	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202106 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/45	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter rye for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 017GPSE 202201 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/46	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter rye. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland Report No.: S22-03727-09 GEP: Yes Published: No	N	Pestila* ProAgri**

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KCP 3.2/47	Springer M.	2023	Efficacy evaluation of Protiokonazol 300 EC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 007GPSE202301 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/48	Huszcza-Podgórska A.	2023	Efficacy evaluation of Protiokonazol 300 EC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 007GPSE202302 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/49	Figurski R.	2023	Efficacy evaluation of Protiokonazol 300 EC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 007GPSE202303 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/50	Głowacki G.	2023	Determination of efficacy of Protiokonazol 300 EC applied in the autumn, in winter rape against fungal diseases. Poland 2022 Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-07447-01 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/51	Głowacki G.	2023	Determination of efficacy of Protiokonazol 300 EC applied in the autumn, in winter rape against fungal diseases. Poland 2022 Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-07447-02 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/52	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-01 GEP: Yes Published: No	N	Pestila* ProAgri**

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KCP 3.2/53	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-02 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/54	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-03 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/55	Figurski R.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-04 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/56	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-05 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/57	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-06 GEP: Yes Published: No	N	Pestila* ProAgri**

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KCP 3.2/58	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-07 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/59	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-08 GEP: Yes Published: No	N	Pestila* ProAgri**

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The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

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