

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: Diflufenikan 500 SC

Product name: -

Chemical active substance:

diflufenican, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Art. 33 - Extension of authorisation for professional user)

Applicant: Pestila Sp. z o.o.

Submission date: July 2024

MS Finalisation date: February 2025; July 2025

Version history

When	What
09.2023	ZRMs evaluated dRR updated by Applicant.
01.2024	The final Registration Report
04.2024	ZRMs made correction in line to MRiRW comments.
07.2024	Label extension acc. Art. 33 Reg (EC) 1107/2009 for professional user
02.2025	ZRMs assessed the possibility of the extension use on winter barley
07.2025	The final Registration Report

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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 are marked by grey colour). The assessment made for the extension of use on winter barley was marked by green.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Product can be extended for use on winter barley on the basis on submitted documentation by Applicant and assessment made by ZRMs.

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. *	Mem- ber state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fn G, Gn Gn p 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 ap- plications (days)	kg or L prod- uct / 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	Poland	Winter wheat, Winter tritcale Winter rye Winter barley	F	<p>Susceptible weeds (0.2L/ha): Shepherd's purse <i>Capsella bursa-pastoris</i> CAPBP; Field pansy <i>Viola arvensis</i> VI-OAR; Bird's-eye speedwell VERPE <i>Veronica persica</i></p> <p>Susceptible weeds (0.3L/ha): Shepherd's purse <i>Capsella bursa-pastoris</i> CAPBP; Cornflower <i>Centaurea cyanus</i> CENCY; Purple deadnettle <i>Lamium purpureum</i> LAMPU; Common chickweed <i>Stellaria media</i> STEME; Field pansy <i>Viola arvensis</i> VI-OAR; Bird's-eye speedwell VERPE <i>Veronica persica</i></p> <p>Moderately susceptible weeds (0.2L/ha): Silky apera <i>Apera spica-venti</i> APESV;</p>	broadcast spraying	BBCH 00-29 Autumn ap- plication pre- and post emergence	1 a) 1 b) 1	N/A	0.2 – 0.3 L/ha a) 0.3 L/ha b) 0.3 L/ha	100-150 g diflufenican a) 150 g diflufenican b) 150 g diflufenican	100-400 L/ha	not re- levant	not relevant	

			Purple deadnettle <i>Lamium purpureum</i> LAMPU Common chickweed <i>Stellaria media</i> STEME; Small-flower geranium GERPU <i>Geranium pusillum</i> Moderately susceptible weeds (0.3L/ha): Silky apera <i>Apera spica-venti</i> APESV; Small-flower geranium GERPU <i>Geranium pusillum</i> Wild chamomile MATCH <i>Matricaria chamomilla</i> Moderately resistant weeds (0.2L/ha): Cornflower <i>Centaurea cyanus</i> CENCY Tolerant weed (0.2 L/ha): Wild chamomile MATCH <i>Matricaria chamomilla</i>											
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* 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 Diflufenikan 500 SC according to Article 33 of Regulation 1107/2009. Diflufenikan 500 SC is a suspension concentrate (SC) formula, containing 500 g/L of active substance – diflufenican, to be used as a herbicide to control broad-leaved weeds in cereals (winter wheat, winter triticale, rye, winter barley). This is a core dossier in order to allow the approval of product Diflufenikan 500 SC in Poland (zRMS).

Description of active substances

Active substance in Diflufenikan 500 SC herbicide is: diflufenican (500 g/L) which are included into Annex I of Directive 91/414. Diflufenican are 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

Diflufenican is a selective, contact herbicide that has a bleaching action. Compound acts as residual and foliar herbicide which can be applied pre- and post-emergence. The symptom of the diflufenican used on weeds, bleaching, is caused by the inhibition of carotenoid biosynthesis, which limits or cancels completely the photosynthesis of the plants. Plant inability to perform photosynthesis causes plant death. Diflufenican belongs to the chemical group of pyridinecarboxamides, belonging to group 12 (Inhibition of phytoene desaturase) according to HRAC.

Table 3.2-1: Details of the active substances

Active substance	DIFLUFENICAN
Concentration	500 g/L
Chemical group	Carboxamides
Mode of action	Inhibition of phytoene desaturase
Biological action	Pre- and post-emergence herbicide

Description of the plant protection product

Diflufenikan 500 SC is a suspension concentrate (SC) containing 500 g/L diflufenican as active substance.

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, Winter rye Winter barley	Shepherd's purse <i>Capsella bursa-pastoris</i> CAPBP; Cornflower <i>Centaurea cyanus</i> CENCY; Purple deadnettle <i>Lamium purpureum</i> LAMPU; Common chickweed <i>Stellaria media</i> STEME; Field pansy <i>Viola arvensis</i> VIOAR; Silky apera <i>Apera spica-venti</i> APESV;	PL	0.2 – 0.3 L/ha	-

The applicant carried out efficacy trials on winter wheat, winter barley and winter triticale. Required selectivity trials are presented in point 3.4 – Adverse effects on treated crop.

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*
APESV	<i>Apera spica-venti</i>	Silky apera
BRSNW	<i>Brassica napus</i>	Oilseed rape
CAPBP	<i>Capsella bursa-pastoris</i>	Shepherd's purse
CENCY	<i>Centaurea cyanus</i>	Cornflower
CHEAL	<i>Chenopodium album</i>	Fat-hen
CIRAR	<i>Cirsium arvense</i>	Field thistle
GERPU	<i>Geranium pusillum</i>	Small-flower geranium
LAMPU	<i>Lamium purpureum</i>	Purple deadnettle
MATCH	<i>Matricaria chamomilla</i>	Wild chamomile
MATIN	<i>Tripleurospermum inodorum</i>	False chamomile
PAPRH	<i>Papaver rhoeas</i>	Common poppy
POAAN	<i>Poa annua</i>	Goosegrass
STEME	<i>Stellaria media</i>	Common chickweed
VERHE	<i>Veronica hederifolia</i>	Ivy-leaved speedwell
VERPE	<i>Veronica persica</i>	Bird's-eye speedwell
VIOAR	<i>Viola arvensis</i>	Field pansy

* optional

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

Total amount of area sown with cereals 7 200 000 ha.

Crop:	Crop yield (t):	Sowing area (ha):
Winter wheat	12 600 000	2 300 000
Winter barley	1 500 000	300 000
Rye	2 400 000	700 000
Winter triticale	5 400 000	1 200 000

The above presented numbers show that sown area of winter wheat, barley, rye and triticale in total exceeded 4.5 mln ha in 2022. Comparing to the year 2021: winter wheat area increased by 7%, rye area sown decreased by 13%, winter barley area increase was 4% and winter triticale decreased by 3%.

Hence, an appropriate protection in terms of weeds, fungal diseases and to control insects in the aforementioned crops, is inevitable. Chemical control of weeds is highly important in production of agricultural crops, especially in cereals because of its slower growing pace when compared to weeds. Most of weeds species, which are present in cereals, cause not only significant reduction of yield, but also deterioration of its quality parameters. Dicotyledonous (aka broadleaf) weeds are harmful for the crops, either because of their abundance, their competitiveness or difficulties involved in their control. Weeds are also known as intermediate host to many diseases and insects. In the case of some species, the problem is more due to their abundance (associated with a very large seed production and a high persistence of these seeds on the soil surface) rather than competitiveness with the crop. However, there are species, which produce high numbers of seeds although the competition with the crop can be quite high, especially in the early development stages of cereals. Other weeds have very fast-growing pace and can outcompete young cereal plants almost completely.

Weeds, which were present in field trials of Diflufenikan 500 SC are the known as serious cereals competitors. The results are showing that a lot of broadleaved weeds can be controlled by the product.

Weeds presented in field trials	Winter wheat, winter triticale, winter rye Dose rate (l/ha)
Silky apera <i>Apera spica-venti</i> APESV	0.2 ^{ms} -0.3 ^{ms}
Oilseed rape <i>Brassica napus</i> BRSNN	x
Shepherd's purse <i>Capsella bursa-pastoris</i> CAPBP	0.2-0.3
Cornflower <i>Centaurea cyanus</i> CENCY	0.2 ^{mr} -0.3
Fat-hen, <i>Chenopodium album</i> CHEAL	x
Field thistle <i>Cirsium arvense</i> CIRAR	x
Small-flower geranium <i>Geranium pusillum</i> GERPU	x
Purple deadnettle <i>Lamium purpureum</i> LAMPU	0.2 ^{ms} -0.3
Wild chamomile <i>Matricaria chamomilla</i> MATCH	x
False chamomile <i>Tripleurospermum inodorum</i> MATIN	x
Common poppy <i>Papaver rhoeas</i> PAPRH	x
Goosegrass <i>Poa annua</i> POAAN	x
Common chickweed <i>Stellaria media</i> STEME	0.2 ^{ms} -0.3
Ivy-leaved speedwell <i>Veronica hederifolia</i> VERHE	x
Bird's-eye speedwell <i>Veronica persica</i> VERPE	x
Field pansy <i>Viola arvensis</i> VIOAR	0.2-0.3

ms – moderately susceptible

mr –moderately resistant

r - resistant

x – not present

According to Statistics Poland means of production in agriculture in the farming year 2020 (latest year with sulfonylurea herbicides data available) such as herbicides, were commonly used in Poland. Sales of plant protection products (in commodity mass) such as herbicides, haulm destructors and moss killers aimed 69849.4 tonnes, out of which herbicides based on anilides, such as diflufenican, reached 1887.6 tonnes.

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, Winter triticale, Winter rye Winter barley	X		Mono- and dicotyle-donous weeds	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	Dicot and monocot weeds	Poland,	2020/2021; 2021/2022; 2022/2023	MED + E	5 (5)	GEP	-
Winter triticale	Dicot and monocot weeds	Poland	2021/2022	MED + E	2 (2)	GEP	-
Winter barley	Dicot and monocot weeds	Poland,	2021/2022	MED + E	2 (2)	GEP	-
TOTAL	Dicot and monocot weeds	Poland	2020/2021; 2021/2022; 2022/2023	MED + E	9 (9)	GEP	-

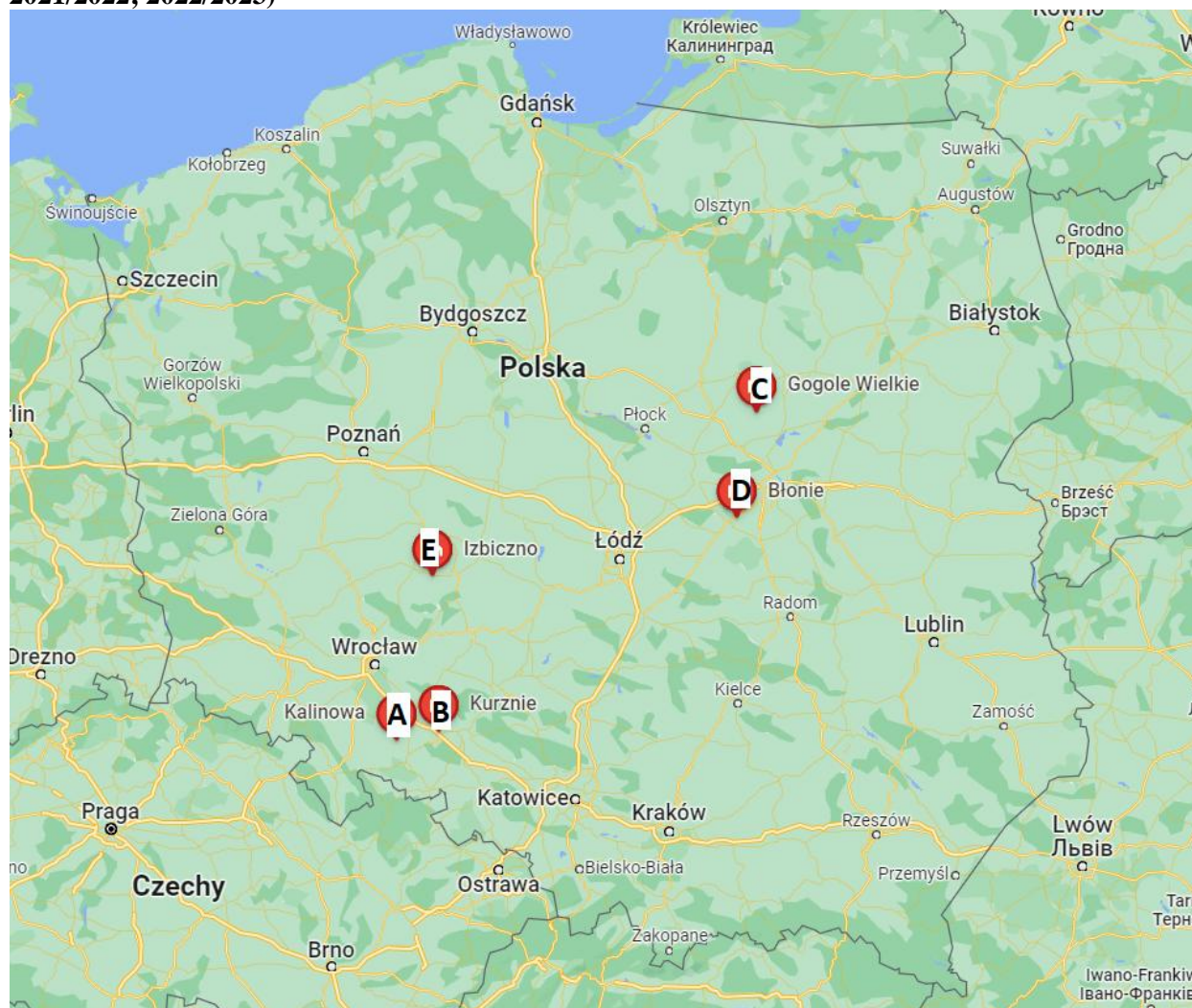
* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-emergence vs post-emergence, spring vs autumn).

** 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 Diflufenican 500 SC herbicide were carried out during three growing seasons – 2020/2021, 2021/2022 and 2022/2023 in different regions of Poland. Maps below presents locations of the trials in each crop.

Picture 1. A map of efficacy trial locations in winter wheat performed in Poland (seasons 2020/2021; 2021/2022; 2022/2023)



From total of nine trials, five Diflufenikan 500 SC trails were set in winter wheat during 2020/2021, 2021/2022 and 2022/2023 seasons. All of them were performed in Poland. Trials were set in four voivode-ships: Masovian, Opolskie, Lower Silesia and Greater Poland.

Trials were set in 2020/2021, 2021/2022 and 2022/2023 and conducted by Agreco, Green & Property Consulting and Fertico in the locations below:

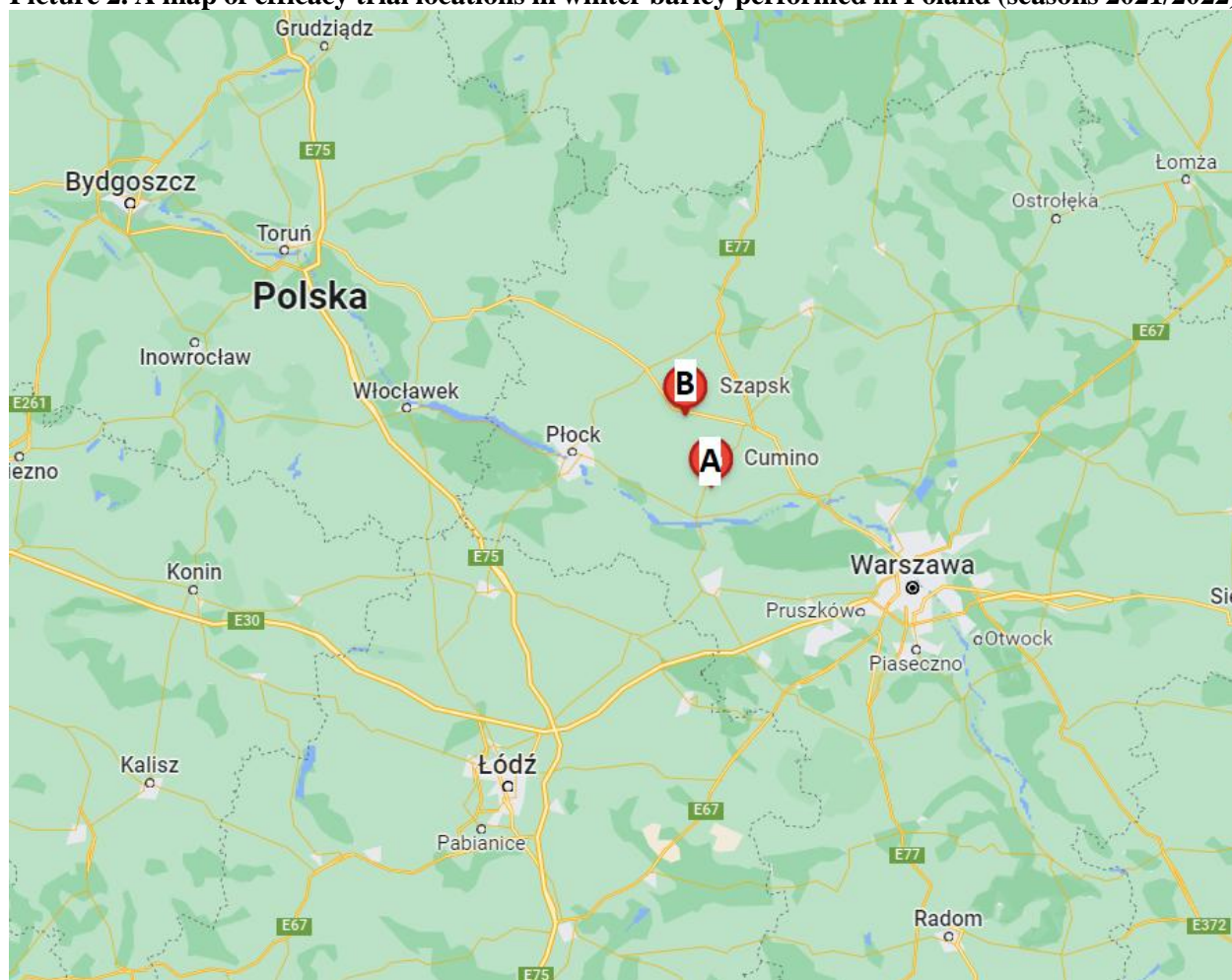
	Year	Country	Trial ID	Location	Variety	Soil type	pH
A	2020/2021	PL	21PRO0821-1	Kalinowa	Sailor	Sandy loam	6.2
B	2022/2021	PL	21PRO0821-2	Kurznie	Arkadia	Loamy sand	6.3
C	2021/2022	PL	001GP202103	Gogole Wielkie	Julius	Sandy clay loam	6.2
D	2021/2022	PL	001GP202104	Błonie	Belissa	Sandy clay	6.91
E	2022/2023	PL	347_01_F22_060	Izbicno	Hondia	Sandy clay	5.8

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary weed infestation levels assessments were done in trials where post-emergence application was done, during crop BBCH 12 and 13.

First assessment after application were performed when crop reached the BBCH 13-14 stage.

Second assessment was done during tillering (BBCH 23-29). Evaluations were done in accordance with EPPO PP 1/93 (3) "Weeds in cereals" guideline.

Picture 2. A map of efficacy trial locations in winter barley performed in Poland (seasons 2021/2022)



From total of nine trials, two Diflufenikan 500 SC trials were set in winter barley during 2021/2022 season. All of them were performed in Poland. Trials were set one voivodeships – Masovian.

Trials were set in 2021/2022 and conducted by Green & Property Consulting in the locations below:

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2021/2022	PL	002GP202102	Cumino	KWS Morris	Sandy loam	7.2
B	2021/2022	PL	002GP202103	Szapsk	KWS Morris	Sandy clay loam	6.9

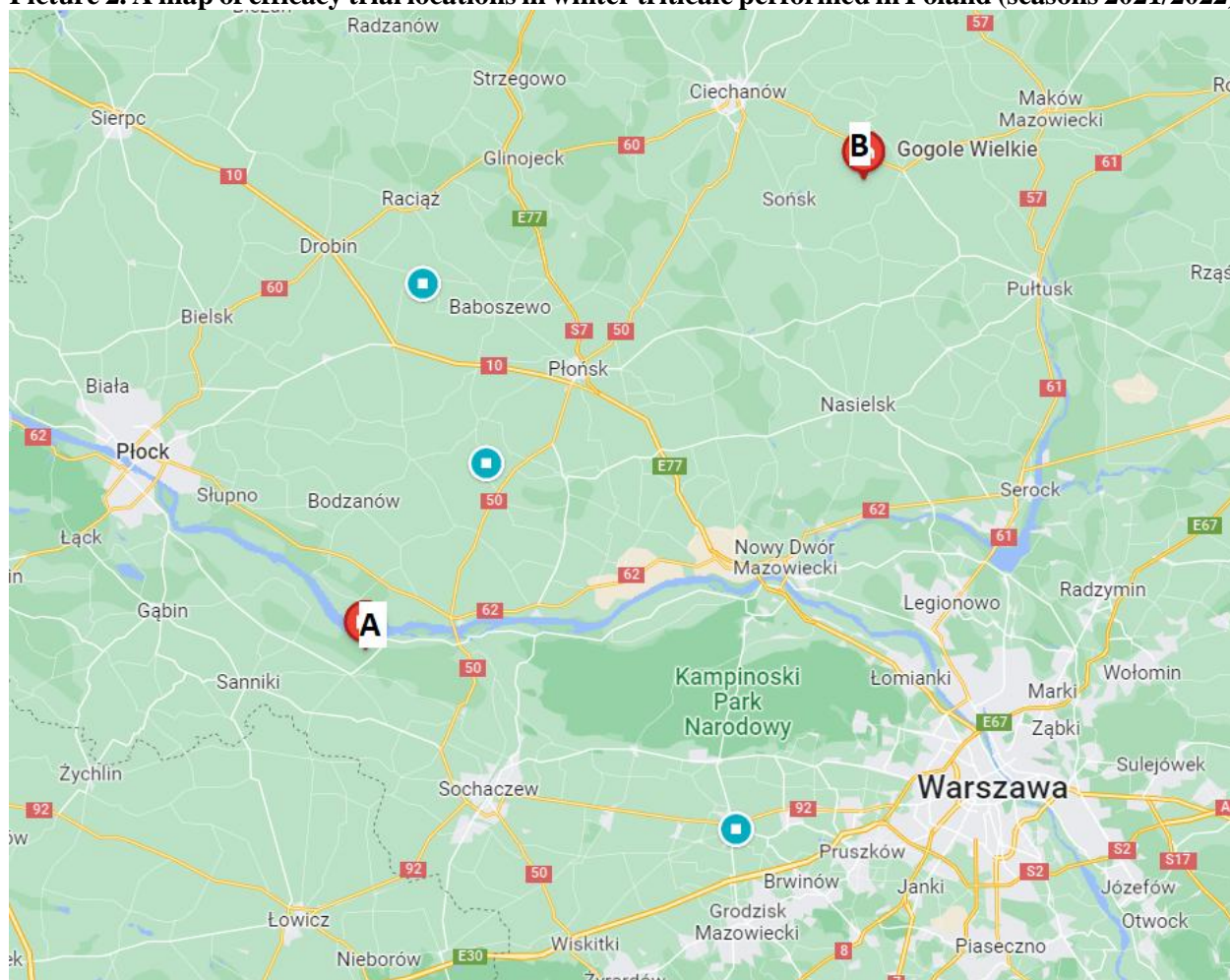
All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary weed infestation levels assessments were done in trials where post-emergence application was done, during crop BBCH 12 and 13.

First assessment after application were performed when crop reached the BBCH 14 stage.

Second assessment was done during tillering (BBCH 23-25). Evaluations were done in accordance with EPPO PP 1/93 (3) “Weeds in cereals” guideline.

According to Polish guidelines on possibility of extrapolation in registration herbicides it is not require to perform efficacy trials since extrapolation form one specie of winter cereal is possible to another specie of winter cereal. However these two trials performed in winter barley have been provided in support of the first registration in winter wheat and can be use in current application for label extension.

Picture 2. A map of efficacy trial locations in winter triticale performed in Poland (seasons 2021/2022)



From total of nine trials, two Diflufenikan 500 SC trails were set in winter triticale during 2021/2022 season. All of them were performed in Poland. Trials were set one voivodeships – Masovian.

Trials were set in 2021/2022 and conducted by Green & Property Consulting in the locations below:

	Year	Country	Trial ID	Location	Variety	Soil type	pH
A	2021/2022	PL	003GP202102	Rakowo	Borwo	Sandy clay loam	5.8
B	2021/2022	PL	003GP202103	Gogole Wielkie	Fredro	Sandy loam	6

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary weed infestation levels assessments were done in trials where post-emergence application was done, during crop BBCH 11 and 13.

First assessment after application were performed when crop reached the BBCH 14-16 stage.

Second assessment was done during tillering (BBCH 21). Evaluations were done in accordance with EPPO PP 1/93 (3) “Weeds in cereals” 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; Winter triticale; Winter barley	Hukkata 500 SC	PL	R-37/2021	diflufenican	SC	500 g/L;	0.2-0.375 L/ha	0.3 L/ha	1. application per season; 200-400 L/ha of spray volume; foliar spray
Winter wheat	Legato 500 SC	PL	R-165/2015	diflufenican	SC	500 g/L;	0.2-0.3 L/ha	0.3 L/ha	1. application per season; 200-300 L/ha of spray volume; foliar spray

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable 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 of zRMS:	<p>This document summarizes the information related to the efficacy of the plant protection product – Diflufenikan 500 SC. The formulation of this product is a solid active ingredient dispersed in water (SC) and it is containing one active substance: diflufenican (500 g/l). For now, this mentioned active substance is on the list of approved active substances.</p> <p>The applicant has provided some details about active substance - diflufenican. As stated above, diflufenican is a pyridinecarboxamide, belonging to group 12 (Inhibition of phytoene desaturase) according to HRAC. Nearly 20 years pass since diflufenican was registered on the domestic market. Undeniably, its advantage is that it effectively combats violets and common chickweed, i.e., low-story weeds that are dangerous at mass emergence simultaneous with cereal emergence. In addition, it fights well against sea mayweed as well as catchweed bedstraw and shepherd's purse. However, this is not the only reason for its ever-growing popularity.</p> <p>The mode of action of diflufenican is a bleaching action, due to the inhibition of carotenoid biosynthesis, thereby preventing photosynthesis and leading to plant death. The specificity is obtained. Diflufenican is approved for use for example on barley, durum wheat, rye, triticale, wheat. Although diflufenican is effective on its own, it is also sold in a variety of premixed formulations to give a wider spectrum of control. Combination mixes include: pendimethalin, mecoprop-P, chlorotoluron, bromoxynil and ioxynil sodium, flufenacet, flurtamone, iodosulfuron Methyl sodium, glyphosate, oxadiazon, isoproturon, mcpa, mesosulfuron-methyl. In some of these various combinations, diflufenican can be applied to amenity turf and areas with unwanted vegetation. It should be remembered that it is a substance with an intrinsic soil action, hence, regardless of the date of application during treatment, the soil should be moist and the weeds as young as possible.</p> <p>The applicant has provided some information on the target weeds. However, no information on the importance of each of the target weeds (major or minor) has been provided.</p> <p>In Poland 80 plant protection products with diflufenican as active compound are registered, according to register of plant protection products (dated 31.08.2023).</p> <p>Poland is a ZRMs, cMS were not relevant. The dossier for the product Diflufenican 500 SC (code name H-01-2020) is jointly owned in part B3 (including B3 BAD) by Pestila Sp. z o.o.</p>
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	Evaluation of extending registration to winter barley: This document was prepared by Applicant for the extension of registration DANUBIS (product code: Diflufenikan 500 SC) for use on winter barley. DANUBIS is already registered on the Polish market (R – 99/2024 dated 26.06.2024) for use on winter wheat, winter triticale and winter rye against weeds. Previous assessment in this commenting box is still valid. All necessary information's about tested plant protection product, active substance, studied weeds, reference products, etc. were correctly presented in this dRR by Applicant. In Poland 74 PPPs with diflufenican as an active compound (single or in tank mix) are registered for use in winter barley for control weeds (in line with plant protection products search engine).
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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 of Diflufenikan 500 SC, diflufenican, has been commonly used in agricultural practice for many years.

Comments of zRMS:	Preliminary range-finding tests are not required since 'Diflufenikan 500 SC' contains diflufenican, which is an approved active substance and commonly use in 80 PPP in Poland against weeds. Evaluation of extending registration to winter barley: Previous assessment is still valid for the extension. Preliminary tests are not required.
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3.2.2 Minimum effective dose tests (KCP 6.2)

Minimum effective dose tests were not carried out. However, several doses of Diflufenikan 500 SC 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 dicotyledonous weeds

9 field trials were established to present the control of the mono and dicotyledonous weeds in cereals. Diflufenikan 500 SC was tested in rates from 0.15 L/ha to 0.3 L/ha (75-150 g/ha of diflufenican) in order to determine the minimum effective dose in cereals for the control of mono and dicotyledonous weeds. The rates reflect the proposed label rates, 50% and 66% of the lowest recommended rate, which in this case was 0.15 L/ha and 0.2 L/ha, of Diflufenikan 500 SC, in accordance with the EPPO standard PP 1/225 (2) '*Minimum effective dose*'.

For the BBCH 10-29, the 0.15 L/ha dose of Diflufenikan 500 SC provided inferior control when compared to 0.2-0.3 L/ha of Diflufenikan 500 SC in 9 trials out of 9 trials.

Table 3.2-7: Minimum effective dose. Efficacy of Di flufenikan 500 SC at proposed label rates, at 50% and 66% of the lowest recommended dose rate at BBCH 10-29 against mono and dicotyledonous weeds in winter cereals.

Group- ing *	Number of trials	Infestation of the un- treated control (unit)		% control with Di flufenikan 500 SC					
				0.15 L/ha (50% of the lowest recom- mended rate)		0.2 L/ha (The lowest recommended rate)		0.3 L/ha (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
APESV	5	8.06	5-16.8	62.02	25-91.3	71.18	38.8-91.3	81.88	67.8-92.5
BRSSNN	2	5.25	5-5.5	62.5	60-65	72.5	72.5-72.5	81.25	8--82.5
CAPBP	4	5.4	5-5.8	90.45	79-100	94.13	86.5-100	95	90-100
CENCY	4	11.5	5-25	72.23	62.5-88.8	67.6	52-78.3	89.33	85.2-97.5
CHEAL	1	8	8-8	77.5	77.7-77.5	87.5	87.5-87.5	92.5	92.5-92.5
CIRAR	1	5	5-5	78.8	78.8-78.8	83.8	83.8-83.8	90	90-90
GERPU	3	9.93	7-14	66.67	20-90	71.2	32.5-92.3	81.43	58.3-93.5
LAMPU	4	5.83	5.3-6.5	75.78	61.8-83.8	83.65	76.3-93.3	90.95	82.5-100
MATCH	3	7.6	6.5-9	61.25	20-77.5	52.43	36.3-73.5	71.77	62.5-86.5
MATIN	2	4.5	4-5	61.25	55-67.5	76.3	73.8-78.8	85.65	85-86.3
PAPRH	3	6.93	5.8-8	45	0-77.5	55.03	12.5-86.3	68.5	25-98
POAAN	1	5.3	5.3-5.3	33.8	33.8-33.8	56.3	56.3-56.3	70	70-70
STEME	4	6	5.5-7	74.78	66.3-81.5	80.65	73.8-87.5	89.45	83.8-100
VERHE	1	5.8	5.8-5.8	42.5	42.5-42.5	74.5	74.5-74.5	88.5	88.5-88.5
VERPE	2	4.65	4-5.3	79.9	76.3-83.5	86.05	78.8-93.3	93.75	87.5-100
VIOAR	5	10.62	5.5-25	80.02	62.5-92	89.28	76.3-100	93.8	83.8-100

Results presented in the tables above are combined for all winter cereals (tab. 3.2-7) on which trials were performed. Winter cereals were: winter wheat, winter barley, winter triticale. Within winter cereals group, results for each weed species can be extrapolated between species of each group (f.e. from winter wheat to winter triticale, winter barley to winter wheat etc.). National PPP regulations of Poland, extrapolation tables to be precise, allow such situation when applicant submits required number (listed in the abovementioned extrapolation tables) of selectivity trials – full number for main crop, and 3-4 (according to extrapolation tables) for each crop for which extrapolation is used.

Summary was done based on A2 assessments, which was done accordingly to EPPO PP 1/93, so during tillering of the crop (BBCH 21-29).

Summary and conclusions on the minimum effective dose

According to the presented results, 0.2-0.3 L/ha dosage of Di flufenikan 500 SC provided the optimum overall control (higher dose is to be used when demanding weed species occur or infestation level is high) and should be considered as effective against dicotyledonous and monocotyledonous weeds in winter wheat and winter triticale, for which activity of Di flufenikan 500 SC is claimed.

As a result, the proposed rate of 0.2 L/ha should be considered as the minimum effective dose to deliver broad spectrum control of mono and dicotyledonous weeds under a wide range of environmental conditions.

Comments of zRMS:	The active substance diflufenican is the active ingredient of many herbicides and in consequence the effective doses are known and well proven.
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	<p>EPPO PP1/225 states that in the case of multiple target pests ‘Information is required for a range of targets which are the most important, and for which control provides the major agricultural benefit. It should be noted that where the proposed use is across a substantive geographical area such as an authorization zone (as defined in PP 1/278 Principles of zonal data production and evaluation), the major target species and/or the major crop may vary and there may be differences in population pressures. Therefore, particular consideration should be given to trials location.’ Therefore, the applicant properly assessed the minimum effective dose of the ‘Diflufenikan 500 SC’.</p> <p>The trials submitted to support the MED of ‘Diflufenikan 500 SC’ are the same as the efficacy trials described under section 3.2.3. (Efficacy tests). All the MED data were produced in the North-East EPPO zone (PL-9). The zRMS considers that a minimum population of 5 weeds/m² or 2% ground cover is required for a trial to be considered sufficiently challenging and valid.</p> <p>Following weed species were studied during trials: APESV (5), BRSNN (2), CAPBP (4), CENCY (4), CHEAL (1), CIRAR (1), GERPU (3), LAMPU (4), MATCH (3), MATIN (2), PAPRH (3), POAAN (1), STEME (4), VERHE (1), VERPE (2) and VIOAR (5).</p> <p>During the efficacy studies Applicant used 3 different doses of herbicide – ‘Diflufenikan 500 SC’: 0.15 l/ha (0.5N), 0.20 l/ha (lower N) and 0.30 l/ha (N dose). So, in the appropriate research of efficacy were tested different doses and to register was chosen the lowest effective 0.20 l/ha – which should be use in the case of lower infestation and good weather conditions and dose 0.3 L/ha which should be use in the case of high infestation and/or worse weather conditions.</p> <p>Applicant showed that the reduced dose (0.20 l/ha) is characterized by similar efficacy to the higher dose (0.30 l/ha). A reduction in the registered dose is proposed due to unacceptable risk to aquatic organisms for the higher dose of 0.30 l/ha (which may occur).</p> <p>The 0.2-0.3 L/ha dosage of Diflufenikan 500 SC provided the optimum overall control (higher dose is to be used when demanding weed species occur or infestation level is high) and should be considered as effective against dicotyledonous and monocotyledonous weeds in winter wheat, winter rye and winter triticale, for which activity of ‘Diflufenikan 500 SC’ is claimed.</p> <p>Evaluation of extending registration to winter barley:</p> <p>Previous assessment is still valid for the extension on winter barley, especially if Applicant did not submit any new efficacy trials carried out on winter barley or other winter cereal (like wheat, triticale or rye). List of accepted weed species and their scale of sensitivity not require any changes. So, MED dose for previous accepted winter cereals (wheat, triticale and rye) is also recommended for winter barley as the most effective. In accordance with the Polish harmonization meetings no efficacy trials are required for the extrapolation of results from winter cereal to winter barley. Only 3-4 selectivity trials carried out on winter barley are needed. Applicant properly presented 4 valid selectivity trials carried out in PL on winter barley, so possibility of the extension of registration on winter barley is accepted by ZRMs.</p>
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3.2.3 Efficacy tests (KCP 6.2)

A total of 9 trials were carried out in seasons 2020/2021, 2021/2022 and 2022/2023 to evaluate the efficacy of Diflufenikan 500 SC for the control of weeds in winter wheat, winter barley and winter triticale in four different regions of Poland 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 200-400 litres of working solution per hectare. All trials were conducted in compliance with GEP principles and following appropriate EPPO guidelines: EPPO PP 1/93 (3), EPPO PP 1/135 (4), EPPO PP 1/152 (4), EPPO PP 1/181 (4).

Table 3.2-10: 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 1/93 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	19.5-24 m ²
	Number of replications	4
Crop	Trials per crop	Winter wheat (5)
	Varieties per crop	Winter wheat: Arkadia, Belissa, Hondia, Julius, Sailor
	Sowing period	Winter wheat: 14.10-16.10.2020; 15.09-17.10.2021; 05.11.2022
Application	Crop stage (BBCH)* at application	Winter wheat: BBCH 12-13
	Timing Pest stage at application (1)	APESV 10-12 BRSNN 16 CAPBP 10-16 CENCY 10-12 CHEAL 11 CIRAR 12 GERPU 10-11 LAMPU 10-12 MATCH 10-12 MATIN 10 PAPRH 10-11 POAAN 10-11 STEME 10-16 VERHE 10-11 VERPE 10-11 VIOAR 10-12
	Number of applications	1
	Intervals between applications	N/A
Assessment	Spray volumes	200-350 L/ha
	Assessment types	weeds infestation level (no/m ²)
	Assessment dates	A1: 7.12.2020; 24.10.2021, 24.11.2021; 23.12.2022 A2: 21.04.2021; 11.11.2021, 11.12.2021; 03.04.2023;
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Loamy sand, sandy clay, sandy clay loam, sandy loam pH 5.8-6.91
	e.g. Natural / artificial inoculation...	Natural
	e.g. Field / Greenhouse...	Field

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

Table 3.2-11: 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 1/93 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	27-28,5 m ²
	Number of replications	4
Crop	Trials per crop	Winter barley (2)
	Varieties per crop	Winter barley: KWS Morris

	Sowing period	Winter barley: 12.09-19.09.2021
Application	Crop stage (BBCH)* at application	Winter barley: BBCH 12-13
	Timing Pest stage at application (1)	APESV 12 BRSNW 15 CENCY 12 GERPU 14-16 LAMPU 14 MATIN 12 PAPRH 12
	Number of applications Intervals between applications	1 N/A
	Spray volumes	250-400 L/ha
Assessment	Assessment types	weeds infestation level (no/m ²)
	Assessment dates	A1: 23.10.2021, 24.20.2021 A2: 11.11.2021, 12.11.2021
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Sandy clay, sandy clay loam pH: 6.9-7.2
	e.g. Natural / artificial inoculation...	Natural
	e.g. Field / Greenhouse...	Field

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

Table 3.2-12: Details on methodology of efficacy trials in winter triticales

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/93 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	24 m ²
	Number of replications	4
Crop	Trials per crop	Winter triticales (2)
	Varieties per crop	Winter triticales: Borwo, Fredro
	Sowing period	Winter triticales: 14.09-26.09.2021
Application	Crop stage (BBCH)* at application	Winter triticales: BBCH 11-13
	Timing Pest stage at application (1)	APESV 12 CAPBP 13 CENCY 12 LAMPU 12 PAPRH 13 VIOAR 13
	Number of applications Intervals between applications	1 N/A
	Spray volumes	300-400 L/ha
Assessment	Assessment types	weeds infestation level (no/m ²)
	Assessment dates	A1: 23.10.2021, 07.11.2021 A2: 20.11.2021
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Sandy loam, sandy clay loam pH 5.8-6
	e.g. Natural / artificial inoculation...	Natural
	e.g. Field / Greenhouse...	Field

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

Table 3.2-13: Efficacy of active substance components in Diflufenikan 500 SC trials in winter cereals

Grouping *	Number of trials	Infestation of the un- treated control (num- ber of plants)		% control								No of trials where Diflufenikan 500 SC at full recommended dose is >, <, = compared to stand- ard(s)**
				Diflufenikan 500 SC Diflufenikan 75 g/ha		Diflufenikan 500 SC Diflufenikan 100 g/ha		Diflufenikan 500 SC Diflufenikan 150 g/ha		Legato 500 SC/Hukkata 500 SC Diflufenikan 150 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	Plants/m²	Plants/m²	%	%	%	%	%	%	%	%	[-]
APESV	5	8.06	5-16.8	62.02	25-91.3	71.18	38.8-91.3	81.88	67.8-92.5	82.22	67.3-93.8	2 trial > 2 trial < 1 trial =
BRSNN	2	5.25	5-5.5	62.5	60-65	72.5	72.5-72.5	81.25	80-82.5	80	77.5-82.5	1 trial > 1 trial =
CAPBP	4	5.4	5-5.8	90.45	79-100	94.13	86.5-100	95	90-100	95	90-100	4 trial =
CENCY	4	11.5	5-25	72.23	62.5-88.8	67.6	52-78.3	89.33	85.2-97.5	88.03	83.8-97.5	2 trial > 2 trial =
CHEAL	1	8	8-8	77.5	77.7-77.5	87.5	87.5-87.5	92.5	92.5-92.5	92.5	92.5-92.5	1 trial =
CIRAR	1	5	5-5	78.8	78.8-78.8	83.8	83.8-83.8	90	90-90	90	90-90	1 trial =
GERPU	3	9.93	7-14	66.67	20-90	71.2	32.5-92.3	81.43	58.3-93.5	83.1	58-97.5	1 trial > 2 trial <
LAMPU	4	5.83	5.3-6.5	75.78	61.8-83.8	83.65	76.3-93.3	90.95	82.5-100	90.95	83.8-100	1 trial > 2 trial < 1 trial =
MATCH	3	7.6	6.5-9	61.25	20-77.5	52.43	36.3-73.5	71.77	62.5-86.5	72.17	62.5-86.5	1 trial < 2 trial =
MATIN	2	4.5	4-5	61.25	55-67.5	76.3	73.8-78.8	85.65	85-86.3	84.8	83.8-85.8	2 trial >
PAPRH	3	6.93	5.8-8	45	0-77.5	55.03	12.5-86.3	68.5	25-98	68.93	26.3-98	1 trial < 2 trial =
POAAN	1	5.3	5.3-5.3	33.8	33.8-33.8	56.3	56.3-56.3	70	70-70	68.3	68.3-68.3	1 trial >
STEME	4	6	5.5-7	74.78	66.3-81.5	80.65	73.8-87.5	89.45	83.8-100	90.58	83.8-100	1 trial > 1 trial < 2 trial =
VERHE	1	5.8	5.8-5.8	42.5	42.5-42.5	74.5	74.5-74.5	88.5	88.5-88.5	88	88-88	1 trial >
VERPE	2	4.65	4-5.3	79.9	76.3-83.5	86.05	78.8-93.3	93.75	87.5-100	93.15	86.3-100	1 trial > 1 trial =
VIOAR	5	10.62	5.5-25	80.02	62.5-92	89.28	76.3-100	93.8	83.8-100	94.04	83.8-100	1 trial < 4 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 above table, results of the A2 efficacy assessment was used, according to EPPO 1/93 A2 assesment should be performed when crop is tillering (BBCH 21-29). According to statistical analysis, data assessed in trials demonstrated that the efficacy of Diflufenikan 500 SC in control of weeds in winter cereals at the proposed rate of 0.3 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of reference products used in the same rate.

Minor use

Not relevant.

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

Not relevant.

Summary and conclusion

9 trials total were conducted to confirm efficacy of Diflufenikan 500 SC in control of dicotyledonous and monocotyledonous weeds in winter cereals. Diflufenikan 500 SC showed its effectiveness in control of weed species listed below, in winter cereals at the proposed label rates:

0.2 L/ha –

Susceptible weeds:

Shepherd's purse (*Capsella bursa-pastoris*), Field pansy (*Viola arvensis*)

Moderately susceptible weeds:

Silky apera (*Apera spica-venti*), Purple deadnettle (*Lamium purpureum*), Common chickweed (*Stellaria media*)

Moderately resistant weeds:

Cornflower (*Centaurea cyanus*)

0.3 L/ha –

Susceptible weeds:

Shepherd's purse (*Capsella bursa-pastoris*), Cornflower (*Centaurea cyanus*), Purple deadnettle (*Lamium purpureum*), Common chickweed (*Stellaria media*), Field pansy (*Viola arvensis*)

Moderately susceptible weeds:

Silky apera (*Apera spica-venti*)

Comments of zRMS:	<p>All details about efficacy methodology used during efficacy trials (9 in total) are presented above by Applicant. The trials were performed in the North-East EPPO zone (PL-9) in varied soil, environmental and climatic conditions with the use of different agricultural practice. The experiment was established on a set of complete randomized blocks in 4 replications, statistical methods and observation dates were applied. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.</p> <p>The number of efficacy of the product presented in this dossier is in accordance with the basic number of trials defined in EPPO PP/226 (6–15 trials) for winter cereals. For winter wheat Applicant submitted only 5 trials carried out in 3 different growing</p>
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	<p>seasons (2020/2021; 2021/2022 and 2022/2023). However, in the opinion of ZRMs reduction number from 6 to 5 can be acceptable. 80 PPP with diflufenican as an active substance are on the Polish market, so its efficacy is known. Diflufenican (DFF) is now a substance that is very commonly prevalent in the protection of cereals against weeds. In the 2022 agricultural crop protection program, the most popular herbicide chemicals are diflufenican and flufenacet used singly and in mixtures. Diflufenican is a contact-active substance. After application, it remains on the soil surface for a long time, producing a thin layer that has a contact effect on emerging young, actively growing weeds. Protection time after herbicide application is about 8 weeks. Diflufenican remains active in the soil for many weeks after treatment, resulting in the maintenance of high herbicidal efficacy even afterwards.</p> <p>The results showed that as the dose increases, the effectiveness of the product increases. And the results proved to be quite consistent. Winter triticale and winter rye were characterized by not enough number of trials. However, Applicant submitted 3 selectivity trials for those crops. So, in the opinion of ZRMs extrapolation of results is possible. Especially since a group of plants (winter cereals) and not individual crops was used to classify weeds.</p> <p>The Applicant did not provide any scale of efficacy/susceptibility of studied weeds. So, Evaluator applied the efficacy scale of efficacy/susceptibility weeds due to existing Member State requirements for expressing levels of control for weeds and the practice of preparations by Polish farmers:</p> <ul style="list-style-type: none"> •S (susceptible) > 85% (within each trial the average must be higher than 85%) •MS (moderately susceptible) 70-85% •MT (moderately tolerant) 60-70% •T (tolerant) < 60% <p>We are dealing with the active substances used commonly for many years in many countries. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations. Only trials with appropriate level of infestation (5 weeds/m²) were used for evaluation.</p> <p>According to PP 1/226, major weeds should be supported with at least 6 trials and minor weeds with at least 2 trials. However, according to Polish rules for major weeds at least 4 trials are required and for minor – 2 trials. Most of the studied weed species did not meet the minimum necessary number of tests.</p> <p>The weeds were treated at BBCH stage 10-16 in POST application. The water volume ranged from 300 to 400 l/ha.</p> <p>Applicant correctly presented results. All studied weed species were characterized by enough number of trials and level of infestation.</p> <p>Early post-emergence uses on winter cereals crops against accepted weeds species (on the basis of 9 trials: winter wheat-5 trials, winter barley-2 trials, winter triticale – 2 trials):</p> <ul style="list-style-type: none"> ✓ APESV – major weed – 5 trials – MT at 0.15 L/ha and MS at 0.2 and 0.3 L/ha ✓ CAPBP – minor weed – 4 trials – S at all studied doses (0.15 L/ha; 0.2 L/ha and 0.3 L/ha) ✓ CENCY – major weed – 4 trials – MS at 0.15 L/ha; MT at 0.2 L/ha and S at 0.3 L/ha. ✓ GERPU – minor weed – 3 trials – MT at 0.15 L/ha and MS at 0.2 and 0.3 L/ha.
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	<p>✓ LAMPU – minor weed – 4 trials – MS at 0.15 and 0.2 L/ha and S at 0.3 L/ha</p> <p>✓ MATCH – minor weed – 3 trials – MT at 0.15 L/ha; T at 0.2 L/ha and MS at 0.3 L/ha</p> <p>✓ STEME – minor weed – 4 trials -MS at 0.15 and 0.2 L/ha and S at 0.3 L/ha</p> <p>✓ VERPE – minor weed – 2 trials – MS at 0.15 L/ha and S at 0.2 and 0.3 L/ha</p> <p>✓ VIOAR – major weed – 5 trials – MS at 0.15 L/ha and S at 0.2 and 0.3 L/ha</p> <p>Obtained results were comparable to standard reference product. The most effective dose for most studied weed species for post-emergence use was dose: 0.3 L/ha. However, dose 0.2 L/ha was characterized only less effective than dose 0.3 L/ha.</p> <p>Following major weeds should be excluded from GAP table and label project due to not enough trials (at least 4 are required): BRSNN (2 trials), MATIN (2 trials), PAPRH (3 trials).</p> <p>Weeds species represented only by one trial were also excluded from GAP table and label project: CHEAL, CIRAR, POAAN, VERHE.</p> <p><u>In Polish label following weeds species can be included for winter wheat, winter triticale and winter rye:</u></p> <ul style="list-style-type: none"> • Dose 0,2 L/ha: <i>Susceptible weeds:</i> CAPBP, VERPE, VIOAR; <i>Moderately susceptible weeds:</i> APESV, GERPU, LAMPU and STEME; <i>Moderately tolerant weeds</i> CENCY; <i>Tolerant weeds:</i> MATCH. • Dose 0,3 L/ha: <i>Susceptible weeds:</i> CAPBP, CENCY, LAMPU, STEME, VERPE, VIOAR; <i>Moderately susceptible weeds:</i> APESV, GERPU, MATCH. <p>This plant protection product ‘Diflufenikan 500 SC’ can be used on winter cereals (wheat, triticale and rye) against weed species included in GAP table and label project. Product can be use post-emergence at BBCH 10-29 at autumn application.</p> <p>The trials are acceptable for PL (N-E EPPO zone). In the opinion of ZRMs submitted documentation will be not sufficient for cMS from other EPPO zone. However, final decision is left to cMS.</p> <p><u>Evaluation of extending registration to winter barley:</u></p> <p>Previous assessment is still valid for the extension on winter barley, especially if Applicant did not submit any new efficacy trials carried out on winter barley or other winter cereal (like wheat, triticale or rye). List of accepted weed species and their scale of sensitivity not require any changes. In accordance with the Polish harmonization meetings – no efficacy trials are required for the extrapolation of results from winter cereal to winter barley. Only 3-4 selectivity trials carried out on winter barley are needed. Applicant properly presented 4 valid selectivity trials carried out in PL on winter barley, so possibility of the extension of registration on winter barley is accepted by ZRMs.</p>
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

According to the HRAC code list, active substance of Diflufenikan 500 SC - diflufenican belongs to group 12 (Inhibition of phytoene desaturase) according to HRAC. Diflufenican is a selective, contact herbicide that has a bleaching action. Compound acts as residual and foliar herbicide which can be applied pre- and post-emergence. The symptom of the diflufenican used on weeds, bleaching, is caused by the inhibition of

carotenoid biosynthesis, which limits or cancels completely the photosynthesis of the plants. Plant inability to perform photosynthesis causes plant death. Diflufenican belongs to the chemical group of anilides, belonging to group 12 (Inhibition of phytoene desaturase) according to HRAC.

Diflufenican was introduced in mid-80 of the XX century. Since then this phytoene desaturase herbicide is being used in all major agronomic crops and have been widely adopted due to their low dose rates and high efficacy against a broad spectrum of weeds. According to weedscience.org only 5 cases of resistance to the HRAC group 12 herbicides was discovered worldwide. None of the cases have occurred in Europe (closest case was described in Israel). Since risk of resistance occurrence in Europe can be described as low, preventive practices should be implemented, like rotation (use of herbicides with different modes of action), mixing herbicides (at least two different modes of action) and use of weed control methods other than chemical (f.e. mechanical).

Comments of zRMS:	<p>Diflufenican belongs to the pyridinecarboxamide group. Applied early post-emergence, diflufenican is effective on some important broadleaf weeds. This compound typically affects susceptible weeds at the early stages.</p> <p>Diflufenican is persistent in soil (DT₅₀= 224 days) thus a prolonged exposure to weed populations may occur. The herbicidal effects of diflufenican are primarily due to its inhibition of carotenoid biosynthesis at the phytoene desaturase step (PDS).</p> <p>Due to the primary target site and the chemical subgroup, diflufenican is classified as a HRAC group F1 herbicide (inhibition of carotenoid biosynthesis at the phytoene desaturase step (PDS)). In the WSSA resistance classification system the pyridinecarboxamides are classified as group 12. The other chemical groups in HRAC group F1 are: Pyridazinones and other.</p> <p>Some naturally occurring weed biotypes resistant to F1 herbicides may exist through normal genetic variability in any weed population. The resistant biotypes are unusual. A PDS mutation leading to resistance has been identified. Also, non-target-site resistance has been suggested.</p> <p>HRAC group F1 herbicides are used for weeding control in agricultural crops for more than 20 years. Since the first years these products were used no weeds resistant to Carotenoid biosynthesis inhibitors have been reported in central Europe.</p> <p>The applicant has not provided a resistance risk assessment in accordance with EPPO PP 1/213.</p> <p>Resistance to diflufenican has been reported in 3 weed species, consisting of 5 individual cases of resistance being observed. These include the 4 stated above by the applicant along with a more recent observation in <i>Senecio vernalis</i> in Israel in 2014. The full list of resistance cases to diflufenican are shown in the table below, taken from http://www.weedsience.org:</p> <p>Reported cases of resistance to diflufenican</p> <table><tr><th>#</th><th>Year</th><th>Species</th><th>Country</th><th>MOAs</th><th>Actives</th><th>Contacts</th></tr><tr><td>1</td><td>1998</td><td><i>Raphanus raphanistrum</i></td><td>Australia (Western Australia)</td><td>ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12)</td><td>chlorsulfuron, diflufenican, metosulam</td><td>Abul Hashem</td></tr><tr><td>2</td><td>2006</td><td><i>Raphanus raphanistrum</i></td><td>Australia (South Australia)</td><td>ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12), Synthetic Auxins (O/4)</td><td>2,4-D, diflufenican, MCPA, triasulfuron</td><td>Christopher Preston, Peter Boutsalis</td></tr></table>	#	Year	Species	Country	MOAs	Actives	Contacts	1	1998	<i>Raphanus raphanistrum</i>	Australia (Western Australia)	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12)	chlorsulfuron, diflufenican, metosulam	Abul Hashem	2	2006	<i>Raphanus raphanistrum</i>	Australia (South Australia)	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12), Synthetic Auxins (O/4)	2,4-D, diflufenican, MCPA, triasulfuron	Christopher Preston, Peter Boutsalis
#	Year	Species	Country	MOAs	Actives	Contacts																
1	1998	<i>Raphanus raphanistrum</i>	Australia (Western Australia)	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12)	chlorsulfuron, diflufenican, metosulam	Abul Hashem																
2	2006	<i>Raphanus raphanistrum</i>	Australia (South Australia)	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12), Synthetic Auxins (O/4)	2,4-D, diflufenican, MCPA, triasulfuron	Christopher Preston, Peter Boutsalis																

3	2011	<i>Sisymbrium orientale</i>	Australia (Victoria)	Carotenoid biosynthesis inhibitors (F1/12)	diflufenican	Christopher Preston, Peter Boutsalis
4	2010	<i>Raphanus raphanistrum</i>	Australia (Western Australia)	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12), EPSP synthase inhibitors (G/9), Synthetic Auxins (O/4)	2,4-D, chlorsulfuron, diflufenican, glyphosate, imazethapyr, MCPA, metosulam, sulfometuron-methyl	Stephen Powles, Michael Ashworth
5	2014	<i>Senecio vernalis</i>	Israel	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12), Photosystem II inhibitors (C1/5), PPO inhibitors (E/14), PSII inhibitor (Ureas and amides) (C2/7)	carfentrazone-ethyl, diflufenican, diuron, imazamox, metribuzin	Baruch Rubin, Maor Matzrafi

Diflufenican has been authorised as an herbicide in Europe for decades and despite its widespread use in cereals, no resistance to this active substance has yet been reported in Europe. There is currently no resistance to any Group F1 herbicides in Europe. Additionally, no cross resistance to diflufenican is known.

The only target weed with reported resistance to diflufenican is RAPRA, although this was reported outside of Europe. *Senecio vernalis* is also of the same genus as the target weed SENVU.

The zRMS would consider that inherent risk of resistance developing to diflufenican to be low. Some of the target weeds e.g. STEME and PAPRH have an inherently high risk of developing resistance; however, there has been no resistance to any of the target weeds except RAPRA. The resistance to this weed was outside of Europe and this is not usually considered to be a high risk weed. 'Diflufenican 500 SC' is restricted to 1 use per season and there are other herbicides that can control the target weeds in cereals, along with non-chemical control such as cultivation or rotation.

Overall, the zRMS considers that the risk of resistance developing to diflufenican from the proposed use of 'Diflufenican 500 SC' is low. No specific resistance management strategy is considered necessary for the PL label.

ZRMs approved the proposed label provision about strategies to minimize the risk of occurrence and the development of weed resistance against diflufenican.

To minimize the risk of occurrence and development of weed resistance to herbicides, according to Good Agricultural Practice:

- ✓ follow strictly the directions on the crop protection product label - apply the product at the recommended dose, at the recommended time to ensure optimal weed control,
- ✓ adjust the choice of herbicide and the decision to carry out the treatment to the prevailing (possibly potential) weed infestation, taking into account the dominant species and pest thresholds,
- ✓ use a rotation of herbicides (active substances) with different mechanisms of action,
- ✓ use a mixture of herbicides (active substances) with different mechanism of action,
- ✓ use in rotation and/or mixture herbicides acting on several life processes of weeds (with different mechanism of action),
- ✓ apply an herbicide with a given mechanism of action only once during the

	<p><i>growing season of the crop,</i></p> <ul style="list-style-type: none"> ✓ <i>adjust tillage operations to field conditions, especially to the type and severity of weeds,</i> ✓ <i>use various methods of weed control, including crop rotation, etc.,</i> ✓ <i>use certified seed,</i> ✓ <i>clean agricultural machinery to prevent the transfer of weed propagating material to other sites,</i> ✓ <i>inform the permit holder of unsatisfactory weed control,</i> ✓ <i>for more information, contact your advisor, the permit holder or the permit holder's representative.</i> <p>Evaluation of extending registration to winter barley:</p> <p>Previous assessment is still valid for the extension on winter barley. The risk of resistance development is influenced more by the frequency and type of herbicide application than by the crop itself (e.g. winter barley, wheat or rye). However, winter barley is often grown in tight rotations with limited herbicide diversity, which increases the selection pressure for resistance. The risk of resistance may be slightly higher in winter barley than in cereals such as oats or rye, which are less frequently treated with diflufenican or have a different herbicide regime.</p> <p>The potential for resistance to diflufenican in winter barley is not inherently higher than in other winter cereals. However, cropping systems and herbicide management practices used in winter barley often increase the risk. Resistance management strategies, including diverse herbicide use and integrated weed control, are crucial regardless of the cereal crop.</p> <p>ZRMs approved the proposed label provision about strategies to minimize the risk of occurrence and the development of weed resistance against diflufenican. Those strategy is still valid for winter barley and not require any changes.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

The applicant carried out:

- 4 selectivity trials in winter wheat
- 3 selectivity trials in winter rye
- 3 selectivity trials in winter triticale
- 4 selectivity trials in winter barley

EPPO PP 1/226(3) standard states - it is required to conduct at least 8 phytotoxicity trials per major crop, usually within 2 years/2 growing seasons. However, national addendum of Poland demands 4-5 selectivity trials conducted within 1 season – for known substances, and 5-8 selectivity trials for new substance/new use of known substance/new composition, conducted during 2 growing seasons. The applicant also has to mention about the Poland's extrapolation tables for PPP registration purposes, which allows extrapolations between different winter cereal species and extrapolations between different spring cereal species. In case of use of such extrapolations, the applicant is obligated to conduct reduced number of 3-4 selectivity trials, for each of the additional crop species which is requested in the application.

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	Poland	S	9	2021; 2022; 2023	GEP	
		S + Y	4			
		S + Y + Q	4			
Winter rye	Poland	S	3	2023	GEP	
		S + Y	3			
		S + Y + Q	3			
Winter triti- cale	Poland	S	5	2022; 2023	GEP	
		S + Y	3			
		S + Y + Q	3			
Winter bar- ley	Poland	S	6	2021; 2022	GEP	
		S + Y	4			
		S + Y + Q	4			
TOTAL	-	S	23	-	-	
		S + Y	14			
		S + Y + Q	14			

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)	Refer- ence stand- ards	Coun- try(ies) where the product is regis- tered ⁽¹⁾	Authorization number	Active sub- stance(s) (a.s)	Formulation		Registered application rate ⁽³⁾	Appli- cation rate in trials (per treat- ment)	Re- mark ⁽⁴⁾
						Type ⁽²⁾	Concentra- tion of a.s.			
III 6.1.4/01 S-WW-PL-2021- 21PRO822-1 III 6.1.4/02 S-WW-PL-2022- 22PRO974-3 III 6.1.4/03 S-WW-PL-2022- 22PRO974-4 III 6.1.4/04 S-WW-PL-2023- 348_01_F22_061 III 6.1.4/05 S-WR-PL-2023- 06GPAS202201 III 6.1.4/06 S-WR-PL-2023- 06GPAS202202 III 6.1.4/07	Winer wheat, Winter rye, Winter triticale Winter barley	Hukkata 500 SC Legato 500 SC	Poland	R-229/2021b R-165/2015	dIfIufe- nican	SC	500 g/L	0.2-0.375 L/ha	0.3-0.6 L/ ha	

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.			
S-WR-PL-2023-06GPAS202203 III 6.1.4/08 S-WT-PL-2023-06GPAS202204 III 6.1.4/09 S-WT-PL-2023-06GPAS202205 III 6.1.4/10 S-WT-PL-2023-06GPAS202206 III 6.1.4/11 S-WB-PL-2022-22PRO975-1 III 6.1.4/12 S-WB-PL-2022-22PRO975-2 III 6.1.4/13 S-WB-PL-2022-22PRO975-3 III 6.1.4/14 S-WB-PL-2022-22PRO975-4										

(1) only on use(s) applied for (with the test product)

(2) e.g. WP (wetable 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...		Selectivity trials (4 trials)				Efficacy trials (5 trials)	
		Test product		Standard 1		Test product	Standard 1
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	4	4	4	5	5
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	4	4	4	4	5	5
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

9 trials were carried out on winter wheat in Poland, in years 2020/2021, 2021/2022 and 2022/2023 on a wide range of commercially grown varieties.

No phytotoxicity symptoms caused by Diflufenikan 500 SC at the proposed dose rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not caused phytotoxicity.

Table 3.4-4: Phytotoxicity of product to winter rye

Number of trials with...		Selectivity trials (3 trials)				Efficacy trials (0 trials)	
		Test product		Standard 1		Test product	Standard 1
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3	3	3	0	0
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	3	3	3	3	0	0
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

3 trials were carried out on winter rye in Poland, in years 2022/2023 on a wide range of commercially grown varieties.

No phytotoxicity symptoms caused by Diflufenikan 500 SC at the proposed dose rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not caused phytotoxicity.

Table 3.4-5: Phytotoxicity of product to winter tritcale

Number of trials with...		Selectivity trials (3 trials)				Efficacy trials (2 trials)	
		Test product		Standard 1		Test product	Standard 1
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3	3	3	2	2
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	3	3	3	3	2	2
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

5 trials were carried out on winter tritcale in Poland, in years 2021/2022 on a wide range of commercially grown varieties.

No phytotoxicity symptoms caused by Diflufenikan 500 SC at the proposed dose rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not caused phytotoxicity.

Table 3.4-6: Phytotoxicity of product to winter barley

Number of trials with...		Selectivity trials (4 trials)				Efficacy trials (2 trials)	
		Test product		Standard 1		Test product	Standard 1
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	4	4	4	2	2
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	4	4	4	4	2	2
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Six trials (4 selectivity new trials and 2 efficacy trials assessed at previous registration) were carried out on winter barley in Poland, in years 2021/2022 on a wide range of commercially grown varieties.

No phytotoxicity symptoms caused by Diflufenikan 500 SC at the proposed dose rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not caused phytotoxicity.

Comments of zRMS:	<p>EPPO 1/226 indicates that typically at least 8 specific crop safety trials per major crop are required, to cover the range of conditions of use, including soil types and weather conditions that are likely to be encountered. Research should be conducted in the Poland or/and in other countries from the North-East EPPO zone or neighbouring countries not belonging to the zone. According to the Polish guidelines for well-known active substance should be submitted at least 4-5 phytotoxicity studies performed in two growing seasons on 3-4 varieties. Also, Applicant can use CIRCA for the assessment, but into account must be taken issues related to data protection. Alternatively, Applicant can use the data from the records of other / neighbouring countries – but the justification for using this part by Applicant must be submitted.</p> <p>The applicant has submitted 10 selectivity trials from North-East EPPO zone (PL) carried out on winter wheat (4 trials), winter rye (3 trials) and winter triticale (3 trials). In the opinion of Evaluator, the Applicant submitted enough phytotoxicity trials for winter wheat at early post-emergence use. For other cereals: winter rye and winter triticale selectivity trials can be extrapolated, especially when the Applicant presented an appropriate number of confirmatory tests (3 for each use) for rye and triticale at early post-emergence use.</p> <p>Selectivity studies on herbicide were performed in total in 10 trials by companies authorized to conduct studies on efficacy of plant protection products. The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. The herbicide has been used in two doses: N and 2N. In all trials studied product was compared to the standard reference containing the same active ingredient. Statistical analysis of the data was performed. Also, phytotoxicity effect was assessed during efficacy trials. No phytotoxicity symptoms caused by Diflufenikan 500 SC at the proposed dose rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not cause phytotoxicity.</p> <p>Evaluation of extending registration to winter barley:</p>
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	Applicant submitted 4 additional selectivity trials carried out in Poland (N-E EPPO zone) on winter barley in 2022. During those trials dose N (0.3 L/ha) and 2N (0.6 L/ha) was studied in line to appropriate EPPO standard. HUKKATA 500 SC at dose N (0.3 L/ha) and 2N (0.6 L/ha) was used as a st. ref. product. Following varieties of winter barley: Carmina, KWS Faro and KWS Meridian (2 trials) were studied during those trials. The appropriate experimental design was applied. Statistical analysis of the data was performed. Also, phytotoxicity effect was assessed during 2 efficacy trials assessed at previous registration.
	No phytotoxicity symptoms caused by Danubis (product code: Diflufenikan 500 SC) at the proposed dose rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not cause phytotoxicity.
	In accordance with the Polish harmonization meetings – no efficacy trials are required for the extrapolation of results from winter cereal to winter barley. Only 3-4 selectivity trials carried out on winter barley are needed. Applicant properly presented 4 valid selectivity trials carried out in PL on winter barley, so possibility of the extension of registration on winter barley is accepted by ZRMs.

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

Table 3.4-4: Relationship between phytotoxicity and yield

In field trials on winter wheat Diflufenikan 500 SC was used in single rate of 0.3 L/ha and doubled rate of 0.6 L/ha did not have significant adverse effect on yield. No phytotoxicity effects were observed in all of the five performed trials. Treatments in 1N, nor 2N, had no influence on yield amount and its parameters. Statistical analysis of the yield and its parameters showed no significant statistical differences between each treatment.

In field trials on winter rye Diflufenikan 500 SC was used in single rate of 0.3 L/ha and doubled rate of 0.6 L/ha did not have significant adverse effect on yield. No phytotoxicity effects were observed in all of the five performed trials. Treatments in 1N, nor 2N, had no influence on yield amount and its parameters. Statistical analysis of the yield and its parameters showed no significant statistical differences between each treatment.

In field trials on winter triticale Diflufenikan 500 SC was used in single rate of 0.3 L/ha and doubled rate of 0.6 L/ha did not have significant adverse effect on yield. No phytotoxicity effects were observed in all of the five performed trials. Treatments in 1N, nor 2N, had no influence on yield amount and its parameters. Statistical analysis of the yield and its parameters showed no significant statistical differences between each treatment.

In field trials on winter barley Diflufenikan 500 SC was used in single rate of 0.3 L/ha and doubled rate of 0.6 L/ha did not have significant adverse effect on yield. No phytotoxicity effects were observed in all of the five performed trials. Treatments in 1N, nor 2N, had no influence on yield amount and its parameters. Statistical analysis of the yield and its parameters showed no significant statistical differences between each treatment.

Comments of zRMS:	The effect of the test product on winter cereals (winter wheat – 4 trials, winter triticale – 3 trials, winter rye – 3 trials) yield was assessed in ten selectivity trials carried out in the North-East EPPO zone (PL). Dose N and 2N was studied during selectivity trials. Submitted trials are sufficient. The evaluation was carried out in accordance with EPPO guidelines. No negative effect on the winter cereals grain yield was observed. Detailed results are presented in each report from selectivity trials. ‘Diflufenikan 500 SC’ can be considered as safe for winter cereals (wheat, triticale and rye) crops on the basis on the submitted documentation
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	by Applicant.
	Evaluation of extending registration to winter barley:
	The effect of the test product on winter barley yield was assessed in four selectivity trials carried out in the North-East EPPO zone (PL). Dose N and 2N was studied during selectivity trials. Submitted trials are sufficient. The evaluation was carried out in accordance with EPPO guidelines. No negative effect on the winter barley grain yield was observed. Detailed results are presented in each report from selectivity trials. 'Diflufenikan 500 SC' can be considered as safe for winter cereals (wheat, triticale and rye- previous assessed and winter barley – assessed now) crops on the basis on the submitted documentation by Applicant.

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

14 selectivity studies conducted in 2020/2021, 2021/2022 and 2022/2023 seasons in Poland, on winter wheat, winter rye and winter triticale as well as winter barley revealed that the product Diflufenikan 500 SC had no negative impact on quality of plants. Application of Diflufenikan 500 SC in a dose of 0.3 L/ha (and 2N rate of 0.6 L/ha), caused no adverse effects on yield quantity and quality (grain yield, the weight of thousand grain, moisture content of grain) in selectivity trials.

Moreover, in 14 out of 14 trials, no phytotoxic effect (changes in growth, plant height, tillering, dates of succeeding growth stages, thinning out of plants, discolorations, necroses, deformations) of Diflufenikan 500 SC, was recorded in efficacy trials.

Comments of zRMS:	The evaluation was carried out in accordance with EPPO guidelines. Parameters such as grain yield, the weight of thousand grain, moisture content of grain was assessed during 10 trials. Quality of yield of winter cereals in recommended dose of tested product – 'Diflufenikan 500 SC' were similar to objects, which used standard reference product. Detailed results are presented in each report from selectivity trials. Diflufenikan 500 SC' can be considered as safe for winter cereals (wheat, rye and triticale) crops on the basis on the submitted documentation by Applicant.
	Evaluation of extending registration to winter barley:
	The effect of the test product on winter barley quality of yield was assessed in four selectivity trials carried out in the North-East EPPO zone (PL). Dose N and 2N was studied during selectivity trials. Submitted trials are sufficient. The evaluation was carried out in accordance with EPPO guidelines. No negative effect on the winter barley quality of yield was observed. Detailed results are presented in each report from selectivity trials. 'Diflufenikan 500 SC' can be considered as safe for winter cereals (wheat, triticale and rye- previous assessed and winter barley – assessed now) crops on the basis on the submitted documentation by Applicant.

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 Diflufenikan 500 SC no processing trials were performed. There is no indication from agricultural practice that herbicides with the active substance diflufenikan have affected the processing of harvested cereal grains in the past. Furthermore, the test product is intended for application in BBCH 10-29 of cereals

and, not close to harvest or after harvest.

Comments of zRMS:	<p>No data were presented to address the risk to transformation processes in accordance with EPPO 243 Effects of plant protection products on transformation processes. Considering that product is applied at early stage (up to BBCH 29 for winter cereals) of the crop, before inflorescence emergence and heading, and as the active ingredients (diflufenican) are not systemic it could be agreed that no negative impact on processing is expected.</p> <p>Evaluation of extending registration to winter barley:</p> <p>Previous assessment is still valid for winter barley. <i>Considering that product is applied at early stage (up to BBCH 29 for winter cereals) of the crop, before inflorescence emergence and heading, and as the active ingredients (diflufenican) are not systemic it could be agreed that no negative impact on processing is expected.</i></p>
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

14 studies conducted in 2020/2021, 2021/2022 and 2022/2023 seasons in Poland on winter wheat, winter rye and winter triticale **as well as winter barley** revealed no negative impact of Diflufenikan 500 SC on propagation material – cereal seed.

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 and selectivity trials of Diflufenikan 500 SC.

Comments of zRMS:	<p>EPPO PP1/135 (3) indicates that data are needed for foliar applied herbicides where application is made at or after seed initiation e.g., for cereals when the first node is detectable or where detectable residues occur in harvested seed. The proposed latest time of application is up to BBCH 29 for winter cereals, which for cereals is after seed initiation. Special trials to investigate this purpose or reasoned case were not submitted. Therefore, either restrictions/warnings based on absence of data or conclusions from other similar diflufenican products out of protection should be implemented.</p> <p>Evaluation of extending registration to winter barley:</p> <p>Previous assessment is still valid for winter barley</p>
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

The product decomposes over the growing season without making any damage to succeeding plants. In case of the need to sift the treated plantation, do not grow beetroots, oilseed rape, oats, onions and brassica-cabbage. Other crops can be grown after the performance of ploughing (at least 20cm depth).

Comments of zRMS:	<p>The evaluation of any possible effects on rotational (succeeding) or replacement crops was not carried out according to the stepwise approach in EPPO PP 1/207 'Effects on succeeding crops'. To examine whether the active substance of – Diflufenikan 500 SC can cause negative effects on crops grown after cereals treated</p>
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	<p>with the product a bioassay on representative crops should be conducted.</p> <p>Half decomposition in soil (DT₅₀): <i>laboratory tests</i> – 44.3-237.9 days; <i>field tests</i> 224-621 days.</p> <p>The Applicant proposed provisions for the effect on succeeding plants. it is in line with the provisions found on labels of plant protection products containing diflufenican as an active substance. Diflufenican is used in 80 PPP registered in PL, so its effect on succeeding crops is known. ZRMs accepted that: <i>“The product decomposes over the growing season without making any damage to succeeding plants. In case of the need to sift the treated plantation, do not grow beetroots, oilseed rape, oats, onions and brassica-cabbage. Other crops can be grown after the performance of ploughing (at least 20cm depth).”</i></p> <p>Evaluation of extending registration to winter barley:</p> <p>Previous assessment is still valid for winter barley</p>
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

None of the efficacy/crop safety trials reported any effects on adjacent crops or plants. Application of Diflufenikan 500 SC 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 application times. Furthermore, GAP avoids spray drift to adjacent crops by taking into account the wind speed, the droplet size and positioning of the spray boom. As Diflufenikan 500 SC is intended for control of dicotyledonous weeds, the product may cause damages on dicotyledonous adjacent crops if it is misused. Therefore, it is not expected that appropriate applications of Diflufenikan 500 SC will lead to adverse effects on adjacent crops.

Comments of zRMS:	<p>An application of Diflufenikan 500 SC in respect of the GAP should not present an unacceptable risk for non-target terrestrial plants when risk mitigation measures are considered. Generally, the product is a foliar herbicide effective on broadleaved weeds. Therefore, warnings to avoid spray drift on adjacent crops should appear on the label.</p> <p>No negative impact on adjacent crops is expected when 5 m no spray buffer zone is maintained. Nevertheless, Diflufenikan 500 EC is an herbicide that provides both contact and residual control with residual activity lasting for up to 8 weeks under favourable growing conditions. Therefore, standard warning to avoid spray drift to neighbouring crops and fields should appear on the label.</p> <p>Evaluation of extending registration to winter barley:</p> <p>Previous assessment is still valid for winter barley</p>
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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 of zRMS:	<p>ZRMs agree with Applicant.</p> <p>Evaluation of extending registration to winter barley:</p> <p>Previous assessment is still valid for winter barley</p>
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

In efficacy and phytotoxicity trials no adverse effects of Diflufenikan 500 SC 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).

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 diflufenican, has been used for many years (substance is known from 1985), not only Poland but also in other European countries. According to current knowledge, Diflufenikan 500 SC does not pose any unacceptable risk to other plants also there was no adverse impact on beneficial organisms.

Comments of zRMS:	For detailed consideration of risks to beneficial organisms please see the ecotoxicology section Part B section 9.
	Evaluation of extending registration to winter barley:
	Previous assessment is still valid for winter barley

3.6 Other/special studies

Not relevant.

Comments of zRMS:	ZRMs agree.
	Evaluation of extending registration to winter barley:
	Previous assessment is still valid for winter barley

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)
AGRECO Sp. z o.o.	al. Lipowa 21, lok. 1, 53-124 Wrocław	Yes
Fertico Sp. z o.o.	Goliany 43, 05-620 Błędów	Yes
Green & Property Consulting Anna Huszcza-Podgórska	Na stoku 6/6, 26-601 Radom	Yes

AGRECO Sp. z o.o.



**GŁÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**

Andrzej Chodkowski

BORiN.510.3.2021

Warszawa, 15 kwietnia 2021 r.

DECYZJA Nr 3/2021

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. - Kodeks postępowania administracyjnego (Dz. U. z 2020 r. poz. 256, 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 AGRECO Sp. z o. o. z dnia 29 marca 2021 r., zmienionego pismem z dnia 7 kwietnia 2021 r., zmieniam decyzję Nr 5/2010, z dnia 14 maja 2010 r., zmienioną decyzjami Nr 5/2012, z dnia 16 kwietnia 2012 r., Nr 4/2013, z dnia 11 marca 2013 r., Nr 4/2016, z dnia 30 maja 2016 r., Nr 7/2017, z dnia 9 czerwca 2017 r. oraz Nr 3/2018, z dnia 20 kwietnia 2018 r., w sprawie udzielenia upoważnienia do prowadzenia badań skuteczności działania środków ochrony roślin, w ten sposób, że rozstrzygnięcie decyzji otrzymuje następujące brzmienie:

„Upoważniam AGRECO Sp. z o. o. (Al. Lipowa 21 lok. 1; 53-124 Wrocław) do prowadzenia badań skuteczności działania środka ochrony roślin z grupy akarycydów, bakteriocydów, fungicydów, herbicydów, insektycydów, moluskocydów, regulatorów wzrostu i repelentów w uprawach polowych (zboża, kukurydza, ziemniak, burak cukrowy, rzepak, soja, łubin, bób, koniczyna, facelia, wyka, rośliny zielarskie, słonecznik, warzywa: pomidor, papryka, marchew, ogórek gruntowy, kapusta, kalafior, sałata, cebula, pietruszka, groch, fasola, burak, seler, por, czosnek, dyniowate), sadowniczych (jabłoń, grusza, śliwa, wiśnia, czereśnia, brzoskwinia, morela, porzeczka, malina, truskawka, winorośl, agrest, borówka), pod osłonami (truskawki i maliny, rośliny zielarskie, warzywa: pomidor, ogórek, sałata, papryka, dyniowate), w uprawach roślin ozdobnych w gruncie i pod osłonami (rośliny jednoroczne i dwuletnie, byliny, rośliny doniczkowe, rośliny uprawiane na kwiaty cięte), w uprawach roślin przemysłowych w gruncie i pod osłonami (chmiel, tytoń, wiklina), w młodnikach i drzewostanach dojrzałych drzew i krzewów iglastych i liściastych, na trawnikach, użytkach zielonych, łąkach, pastwiskach, ugorach i odłogach, ścierniskach i terenach nieużytkowanych rolniczo, w pomieszczeniach magazynowych (przechowywanie owoców i warzyw), w pomieszczeniach przeznaczonych do uprawy grzybów jadalnych, na torach i nasypach kolejowych, placach magazynowych, parkingach oraz chodnikach.”

Uzasadnienie

Wnioskiem z dnia 29 marca 2021 r., zmienionym pismem z dnia 7 kwietnia 2021 r., spółka AGRECO Sp. z o. o. (Al. Lipowa 21 lok. 1; 53-124 Wrocław) zwróciła się do

Głównego Inspektora Ochrony Roślin i Nasiennictwa o rozszerzenie zakresu upoważnienia do prowadzenia badań skuteczności działania środków ochrony roślin Nr 5/2010 (z 15.05.2010 r.), zmienionego decyzjami Nr 5/2012 (z 16.04.2012 r.), Nr 4/2013 (z 11.03.2013 r.), Nr 4/2016 (z 30.05.2016 r.), Nr 7/2017 (z 09.06.2017 r.) oraz Nr 3/2018 (z 20.04. 2018 r.), o możliwości prowadzenia takich badań w uprawach polowych soi, łubinu, bobu, koniczyny, facelii, wyki, roślin zielarskich, w uprawach warzyw w gruncie (rośliny dyniowate), pod osłonami: rośliny zielarskie oraz warzywa dyniowate, a także na torach i nasypach kolejowych, placach magazynowych, parkingach oraz chodnikach.

Mając na uwadze przepis art. 15zzzzy ust.1 ustawy z dnia 2 marca 2020 r. o szczególnych rozwiązaniach związanych z zapobieganiem, przeciwdziałaniem i zwalczaniem COVID-19, innych chorób zakaźnych oraz wywołanych nimi sytuacji kryzysowych (Dz. U. z 2020 r. poz. 1842, 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 środka ochrony roślin, odstąpił od przeprowadzenia kontroli, o której mowa w art. 17 ust. 8 pkt 2 ustawy o środkach ochrony roślin.

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 szczególnych zasad pobierania wpisu w postępowaniu przed sądami administracyjnymi (Dz. U. Nr 221 poz. 2193, z późn. zm.) 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.

Pobrano opłatę skarbową zgodnie z częścią I ust. 36c załącznika do ustawy z dnia 16 listopada 2006 r. o opłacie skarbowej (Dz.U. z 2020 r. poz. 1546, z późn. zm.) w wysokości 1 000 zł.

Otrzymują:

1. AGRECO Sp. z o.o.
Al. Lipowa 21 lok. 1
53-124 Wrocław
2. a/a



MAIN INSPECTOR OF PLANT HEALTH AND SEED INSPECTION

Andrzej Chodkowski

BORIN.510.3.2021

Warsaw, 15 April 2021

DECISION NO 3/2021

Pursuant to Article 155 of the Act as of 14 June 1960, the Administrative Procedure Code (Journal of Laws of 2020, item 256, as amended) in conjunction with Article 17(8)(2) of the Act as of 8 March 2013 concerning plant protection products (Journal of Laws of 2020, item 2097), having examined an application filed on 29 March 2021 by AGRECO Sp. z o.o., changed by a letter of 7 April 2021, I hereby change Decision No 5/2010 of 14 May 2010 changed with Decisions No 5/2012 of 16 April 2012, No 4/2013 of 11 March 2013, No 4/2016 of 30 May 2016, No 7/2017 of 9 June 2017 and No 3/2018 of 20 April 2018, on the authorisation to conduct the research on the effectiveness of plant protection products in such a way that the operative part of the decision shall read as follows:

"I authorise AGRECO Sp. z o.o. (Al. Lipowa 21 lok. 1, 53-124 Wrocław) to conduct studies on the effectiveness of plant protection products from the group of acaricides, bactericides, fungicides, herbicides, insecticides, molluscicides, growth regulators and repellents in field crops (cereals, corn, potato, sugar beet, oilseed rape, soy, lupin, broad bean, clover, phacelia, vetch, herbs and sunflower; vegetables: tomato, pepper, carrot, pickling cucumber, cabbage, cauliflower, lettuce, onion, parsley, pea, bean, beetroot, celeriac, leek, garlic and cucurbits; orcharding (apple, pear, plum, morello cherry, cherry, peach, apricot, currant, raspberry, strawberry, grapevine, gooseberry and whortleberry); covered crops (strawberries and raspberries; herbs; vegetables: tomato, cucumber, lettuce, pepper and cucurbits), in ornamental plants grown in the field and under cover (annual and biennial plants, perennials, pot plants and plants grown for cut flowers); industrial crops grown in land and under cover (hops, tobacco and wicker); tree nursery and forest stands with mature trees and coniferous and deciduous shrubs, on grass (lawns), green lands, meadows, pastures, fallow land and set-asides; on stubble fields and non-agricultural land; in store rooms (fruit and vegetable repository) and rooms designated for growing edible mushrooms; on railway tracks and embankments, stockyards, parking lots and pavements."

Grounds for the Decision

With the application of 29 March 2021, changed by the letter of 7 April 2021, AGRECO Sp. z o.o. (Al. Lipowa 21 lok. 1; 53-124 Wrocław) requested an extension of the scope of the authorisation to the Main Inspector of Plant Health and Seed Inspection to conduct studies on the effectiveness of plant protection products No 5/2010 (of 15/05/2010), changed by Decisions No 5/2012 (of 16/04/2012), No 4/2013 (of 11/03/2013), No 4/2016 (of 30/05/2016), No 7/2017 (of 09/06/2017) and No 3/2018 (of 20/04/2018) to allow such studies on the effectiveness on field crops of soy, lupin, broad bean, clover, phacelia, vetch and herbs; field grown vegetables (cucurbits); under cover: herbs and cucurbits; and on railway tracks and embankments, stockyards, parking lots and pavements.

Taking into account Article 155(1) of the Act of 2 March 2020 on the detailed solutions related to the prevention, counteraction and eradication of COVID-19, other infectious diseases and crisis situations caused by them (Journal of Laws of 2020, item 1842, as amended), which temporarily excludes certain obligations arising from the Act of 8 March 2013 on plant protection products, the Main Inspector of Plant Health and Seed Inspection, before amending the scope of the authorisation to conduct the studies on the effectiveness of a plant protection product, abandoned the inspection referred to in Article 17(8)(2) of the Plant Protection Products Act.

Instructions:

There is no right of appeal against this decision. The party dissatisfied with the decision may apply to the Main Inspector of Plant Health and Seed Inspection for re-examination, within 14 days of the decision delivery date, pursuant to Article 127(3) of the Administrative Procedure Code.

During the time limit for filing the request for re-examination of the case, the party may waive this right before the public administration body which issued the decision. As of the date of delivery to the Main Inspector of Plant Health and Seed Protection of a statement on the waiver of the right to file the



CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

request for the case to be re-examined, the decision becomes final and legally valid, which means that the decision is subject to immediate enforcement and there is no possibility to appeal the decision to the Regional Administrative Court.

If the party does not believe that the decision is consistent with the request and does not wish to exercise the right to request re-examination of the case, it may file a complaint against the decision with the Regional Administrative Court in Warsaw within 30 days of delivery of the decision to the party. The complaint is filed through the Main Inspector for Plant Health and Seed Inspection.

Pursuant to Section 2(1)(2) of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules for collecting the entry fee in proceedings before administrative courts (Journal of Laws No. 221, item 2193, as amended), the fixed entry, regardless of the subject matter of the appealed act or action in cases concerning complaints against acts or actions in the field of public administration concerning rights or obligations arising from legal regulations, is PLN 200.

At the request of the party filed prior to the commencement of or in the course of court proceedings, the party may be granted the right to be assisted with complete or partial exemption from court costs and appointment of an advocate or a legal adviser if the party demonstrates that it is not able to bear any or all costs of the proceedings.

A stamp duty was collected in accordance with Part I item 36c of the Annex to the Act of 16 November 2006 on stamp duty (Journal of Laws of 2020, item 1546, as amended) of PLN 1,000.

Copies to:

1. AGRECO Sp. z o.o.
Al. Lipowa 21 lok. 1
53-124 Wrocław
2. For our files

[round seal of the Main Inspector of Plant Health and Seed Inspection the national emblem of the Republic of Poland]

[illegible signature]

END OF THE TRANSLATION

This is to certify that the foregoing is a true translation of the document in the Polish language; in witness whereof, I have subscribed my name and affixed my seal of office hereto.

Izabela Mazur, sworn translator of the English language entered in the list of sworn translators kept by the Minister of Justice of Poland; Entry No. TP/1885/06.

Records of Translations No. 269/2021
Ruda Śląska, Poland. 17 May 2021



Fertico Sp. z o.o.



**GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**

Tadeusz Kłós

WO-505- 17 /2011

Warszawa, dnia 26. 04.2011 r.

DECYZJA Nr 13/2011

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2000 r. Nr 98, poz. 1071 ze zm.) i art. 40 ust. 1 ustawy z dnia 18 grudnia 2003 r. o ochronie roślin (Dz.U. 2008 r. Nr 133, poz. 849 ze zm.), po rozpatrzeniu wniosku z dnia 13 kwietnia 2011 r., **zmieniam decyzję Nr 8/2008 z dnia 29 września 2008 r., zmienioną decyzjami: Nr 1/2009 z dnia 27 stycznia 2009 r., Nr 2/2010 z dnia 31 marca 2010 r. oraz Nr 1/2011 z dnia 12 stycznia 2011 r.**

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

upoważniam

FERTICO Sp. z o.o.

Goliany 43; 05-620 Błędów

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy akarycydów, bakteriocydów, fungicydów, herbicydów, insektycydów, moluskocydów, regulatorów wzrostu, repelentów i semiozwiązków w uprawach sadowniczych: jabłoni, gruszy, śliwy, wiśni, czereśni, brzoskwinia, leszczyna, aronia, agrest, truskawka, malina, porzeczka czarna, porzeczka kolorowa, borówka wysoka, w uprawach polowych: zboża, buraki, kukurydza, ziemniaki, rośliny strączkowe, rzepak, kapusta pastewna, gorczyca, chmiel, rośliny energetyczne, w uprawach polowych i pod osłonami: warzywa kapustne, cebulowe, liściowe, korzeniowe, psiankowate, dyniowate, rzepowate, strączkowe, wieloletnie i różne: – kukurydza cukrowa, koper ogrodowy, szparag lekarski oraz w pomieszczeniach magazynowych.

Niniejsze upoważnienie, zgodnie z art. 50 ustawy z dnia 4 marca 2010 r. o świadczeniu usług na terytorium Rzeczypospolitej Polskiej (Dz.U. Nr 47 poz. 278), jest upoważnieniem wydanym na czas nieokreślony.

Uzasadnienie

Pismem z dnia 13 kwietnia 2011 r. FERTICO Spółka z o.o. (Goliany 43; 05-620 Błędów), zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Nr 8/2008 z dnia 29 września 2008 r., zmienionej decyzjami

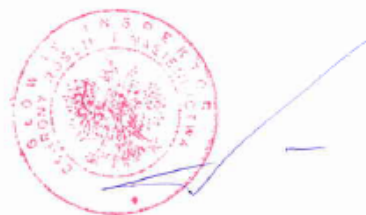
Nr 1/2009 z dnia 27 stycznia 2009 r., Nr 2/2010 z dnia 31 marca 2010 r. oraz Nr 1/2011 z dnia 12 stycznia 2011 r., upoważniającej do prowadzenia badań skuteczności działania środka ochrony roślin o możliwość prowadzenia badań z użyciem środków ochrony roślin z grupy moluskocydów we wszystkich uprawach wyszczególnionych w upoważnieniu Głównego Inspektora Ochrony Roślin i Nasiennictwa.

FERTICO Sp. z o.o. spełnia warunki organizacyjno-techniczne, zwane „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniające prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

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.



DOROTA WILAND

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[*national emblem of the Republic of Poland*]-----

GENERAL INSPECTOR FOR PROTECTION OF PLANTS AND SEED
PRODUCTION-----

TADEUSZ KŁOS-----

[Ref. No.] WO-505- 17/2011 -----

Warsaw, 26 April 2011 -----

DECISION No. 13/2011 -----

According to Art. 155 of the Act of 14 June 1960 – Code of
Administrative Proceedings (Journal of Laws 2000 No. 98 item 1071, as
amended) and Art. 40 para 1 of the Act of 18 December 2003 on the
Protection of Plants (Journal of Laws 2008 No. 133 item 849, as
amended), having reviewed the Application of 13 April 2011, I hereby
change Decision No. 8/2008 of 29 September 2008, as amended by
decisions No. 1/2009 of 27 January 2009, No. 2/2010 of 31 March 2010
and No. 1/2011 of 12 January 2011.-----

The Decision shall now read:-----

I HEREBY AUTHORIZE-----

FERTICO Sp. z o.o.-----

Goliany 43, 05-620 Błędów-----

TO TEST THE EFFICACY OF THE PESTICIDE -----

classified as acaricides, bactericides, fungicides, herbicides, insecticides,
molluscicides, plant growth regulators, repellents and semi-compounds in
the orchard cultivations of apple, pear, plum, sour cherry, cherry, peach,
hazel, chokeberry, gooseberry, strawberry, raspberry, black currant,
white/red currant, highbush blueberry; in the arable farming of cereals,



beet, maize, potato, legumes, rape, kale, mustard, hop, energy crops; in the arable farming and under roof cultivation of brassicas, and bulb, leaf, root, solanaceous, cucurbit, leguminous, perennial plants and miscellaneous plants: sweet corn, dill, asparagus; and in the storage facilities. -----

The term of this authorization, under Art. 50 of the Act of 4 March 2010 on Providing Services in the Territory of the Republic of Poland (Journal of Laws No. 47 item 278), is unspecified. -----

JUSTIFICATION -----

By the letter of 13 April 2011, FERTICO Spółka z o.o. (Goliany 43, 05-620 Błędów) requested that Decision No. 8/2008 of 29 September 2008, as amended by Decisions No. 1/2009 of 27 January 2009, No. 2/2010 of 31 March 2010 and No. 1/2011 of 12 January 2011, authorizing it to test the efficacy of pesticides, be extended so that it includes carrying out the tests using molluscicides in all the types of crops specified in the authorization from the General Inspector of Plant Protection and Seed Production. -----

FERTICO Sp. z o.o. meets the organizational and technical conditions defined in the Good Experimental Practice (GEP), which ensures proper testing of the pesticide efficacy. -----

Given the above, it is decided as stated above. -----

Notice: -----

This decision is not subject to appeal. However, if the party is not satisfied with this Decision, it may request the General Inspector of Plant Protection and Seed Production to reconsider the case within 14 days of the date this decision is served, according to Art. 127 § 3 of the Code of Administrative Proceedings. -----



(-) [illegible signature] -----

[Official round seal, bearing the national emblem of the Republic of
Poland in the centre and a circumscription reading: General Inspector of
Plant Protection and Seed Production] -----

The foregoing is a true translation of the original document made in the
Polish language. In witness whereof I, Dorota Wiland, sworn translator of
the English language, registered under number TP/3674/2005 on the List
of Sworn Translators and Interpreters kept by the Polish Ministry of
Justice, have hereunto subscribed my name and affixed my official seal at
Pruszków, Poland this 3rd day of February 2012.

Record No. 89/2012



Dorota Wiland

Green & Property Consulting



GLÓWNY INSPEKTOR OCHRONY ROŚLIN I NASIENICTWA

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 (*jabłoni, 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. 15zzzzz ust. 1 ustawy z dnia 2 marca 2020 r. o szczególnych 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 żrzec 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 skarbową w wysokości 1 000 zł.

Otrzymują:

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



Zupoważnienia
GŁÓWNEGO INSPEKTORA
Tadeusz Łęczyński

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 15zzzzz 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.

TLUMACZ PRZYSIĘGŁY
JĘZYKA ANGIELSKIEGO
mgr Danuta Gocławska
26-600 Radom, ul. Zwirki i Wigury 38 m.46
NIP 796-103-76-92, REGON: 676075944

D. 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-Podgórska* meets 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))

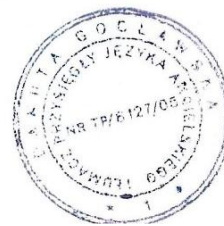
Copies to:

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

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

TLUMACZ PRZYSIĘGLY
JĘZYKA ANGIELSKIEGO
mgr Beata Goctawska
26-600 Radom, ul. Zwirki i Wigury 38 m. 46
NIP 796-103-76-92, Regon: 670075944

B. Goctawska



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.

TLUMACZ PRZYSIĘGLY
JĘZYKA ANGIELSKIEGO
mgr Danuta Gocławska
26-600 Radom, ul. Żwirki i Wigury 38 m. 46
NIP 796-103-76-92, Regon: 67003944

D. Gocławska



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	Kukuła A.	2021	Efficacy of H-01-2020 for the control of weeds in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0821-1 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/02	Kukuła A.	2021	Efficacy of H-01-2020 for the control of weeds in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0821-2 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/03	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter wheat. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 001GP202103 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/04	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter wheat. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 001GP202104 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	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter barley. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 002GP202102 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/06	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter barley. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 002GP202103 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/07	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter triticales. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 003GP202102 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/08	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter triticales. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 003GP202103 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.2/09	Szemendera A.	2023	Efficacy of H-01-2020 in weed control in winter wheat, Poland 2022; Fertico Sp. z o.o., Poland; Report No.: 347_01_F22_060 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/01	Kukuła A.	2021	Selectivity of H-01-2020 in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0822-1 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 3.4/02	Kukuła A.	2022	Selectivity of H-01-2020 in winter wheat. 2022; AGRECO Sp. z o.o., Poland; Report No.: 22PRO0974-3 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/03	Kukuła A.	2022	Selectivity of H-01-2020 in winter wheat. 2022; AGRECO Sp. z o.o., Poland; Report No.: 22PRO0974-4 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/04	Szemendera A.	2023	Selectivity of H-01-2020 applied in control of weeds in winter wheat, Poland 2022; Fertico Sp. z o.o., Poland; Report No.: 348_01_F22_061 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/05	Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202201 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/06	Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202202 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/07	Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202203 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 3.4/08	Figurski R.	2023	Selectivity of H-01-2020 in winter triticales. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202204 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/09	Figurski R.	2023	Selectivity of H-01-2020 in winter triticales. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202205 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/10	Figurski R.	2023	Selectivity of H-01-2020 in winter triticales. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202206 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/11	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-3 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/12	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-4 GEP: Yes Published: No	N	Pestila* ProAgri**
KCP 3.4/13	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-1 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 3.4/14	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-2 GEP: Yes Published: No	N	Pestila* ProAgri**

*Pestila Spółka z ograniczoną odpowiedzialnością (short name Pestila Sp. z o. o.)

**ProAgri International Sp. z o. o. or ProAgri Sp. z o. o.

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

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