FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: MEZ-HER 100 SC

Product name: MECORN 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023, April 2024

MS Finalisation date: May 2024, August 2024

Version history

When	What
04.2024	Applicant's justification for carried efficacy trials in one season and bridging studies.
05.2024	ZRMs evaluated submitted dRR by Applicant.
08.2024	ZRMs added some information's during commenting period

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

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

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

Comments of zRMS:	Comments of ZRMs are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document were marked by grey colour and by turquoise during commenting period).

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

Abstract

Mecorn 100 SC (product code: MEZ-HER 100 SC) can be granted in Poland in line to accepted GAP table and label project. Detailed assessment is presented in commenting boxes 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, Fnp 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	Maize	F	**1L/ha Susceptible** ~~**Pigweed** *Amaranthus retroflexus* AMARE;~~ ~~**Field chamomile** *Anthemis arvensis* ANTAR;~~ **Shepherd's purse** *Capsella bursa-pastoris* CAPBP; ~~**Fat-hen** *Chenopodium album* CHEAL;~~ ~~**Common barnyard grass** *Echinochloa crus-galli* ECHCG;~~ **Cleavers** *Galium aparine* GALAP; ~~**Gallant soldier** *Galinsoga parviflora* GASPA;~~ ~~**Purple deadnettle** *Lamium purpureum* LAMPU;~~ ~~**Wild buckwheat** *Fallopia convolvulus* POLCO;~~ **Common chickweed** *Stellaria media* STEME; **Fanweed** *Thlaspi arvense* THLAR; **Field pansy** *Viola arvensis* VIOAR **1L/ha Moderarely susceptible** ~~**Common fumitory** *Fumaria officinalis* FUMOF;~~ **Fat-hen** *Chenopodium album* CHEAL;	broadcast spraying	BBCH 14-15 Spring, post emergence	1 a) 1 b) 1	N/A	1 L/ha a) 1 L/ha b) 1 L/ha	100g mesotri-one a) 100g meso-trione b) 100g meso-trione	200-300 L/ha	not re-levant	not relevant	Acceptable

				Common barnyard grass *Echinochloa crus-galli* ECHCG; **Volunteer rape seedlings** BRSNN *Brassica napus*										

* 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 MEZ-HER 100 SC according to Article 33 based on Article 34 of Regulation 1107/2009. MEZ-HER 100 SC is a water suspension concentrate (SC), containing 100 g/L of mesotrione to be used as a herbicide to protect maize. This is a core dossier in order to allow the approval of product MEZ-HER 100 SC in Poland (zRMS).

The reference product to the product under the code MEZ-HER 100 SC is Callisto 100 SC, that has been first registered in Poland according to authorisation Minister of Agricultural and Rural Development No. R-25/2009 of February, 27th 2009 which means, that data protection, for the data presented by Callisto 100 SC authorisation holder, for purposes of registration, has been expired.
In respect to the above and taking into account Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant provides six efficacy and five selectivity bridging, efficacy trial, to confirm that herbicidal properties of MEZ-HER 100 SC are comparable to properties of Callisto 100 SC in protection of maize against weeds.

The trials of MEZ-HER 100 SC have been performed in maize in 2022 season.
According to EPPO Standard PP 1/223 (2) *Efficacy evaluation of plant protection products*: the minimum number of trials required to establish acceptable efficacy depends on many factors, including: extent of knowledge of the active substance, extent of variability in the proposed area of use (e.g. plant health conditions, climatic differences, range of agricultural practices, uniformity of crops, importance of crop and target pest).
In common practice, trials on effectiveness and phytotoxicity (including, where relevant, measurement of yield) should be conducted over at least two growing seasons, unless results from a single season are considered to provide adequate confirmation of the validity of the proposed claims.
With this document applicant provided 11 efficacy and selectivity trials on maize performed in Poland territory in different regions with distinct environmental conditions. The results of those trials are comparable in efficacy and phytotoxicity so it has been assumed that they are adequate and sufficient for confirmation of the validity of the proposed claims.

Moreover, based on EPPO Standard PP 1/226 (3) *Number of efficacy trials*: the full number of trials is needed, particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought, or for intended uses for which no extrapolation of any aspect of efficacy from other uses is possible.
Mesotrione is well known and "old" active substance, which is common use for protection maize against several weeds. There are many plant protection products registered in Poland recommended to use as well in maize, in the same dose and against the same weeds, as proposed for MEZ-HER 100 SC, so extrapolation from knowledge provided by others applicants is possible.
At the same time, hence is has been assumed that the products MEZ-HER 100 SC and registered product Callisto 100 SC are comparable, using unprotected data of Callisto is possible for the purposes of evaluation of this application.

Considering the above, it was assumed, that the safety and effectiveness of the plant protection product MEZ-HER 100 SC, against ~~fungal diseases~~ weeds for uses in cereals (maize), was confirmed on the basis of the studies submitted by the applicant, and knowledge about the active substance mesotrione.

Description of active substances

The active substance of the herbicide MEZ-HER 100 SC is mesotrione, well known and commonly used in Poland and other EU countries. The efficacy of the substance has been proved in many trials and in crop protection practice.

Mode of action

Mesotrione is an organic compound used as selective, systemic herbicide. Target plants absorb it through the leaves and translocated acropetally and basipetally. It is inspired by the substance that occurs naturally – leptospermone – a phytotoxin which occurs in the plant called Californian bottlebrush. Mesotrione works by inhibition of the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme in target plants. Aforementioned enzyme is necessary in the process of biosynthesis of alpha-tocopherol and plastoquinone (which is made from tyrosine) – substances essential for carotenoid production in the plants. When carotenoid synthesis in the chlorophyll pathway is disrupted, which causes degradation of chlorophyll. This causes bleaching effect to happen, which later leads to plant death.

Mesotrione belongs to inhibitors of hydroxyphenyl pyruvate dioxygenase group of herbicides and belongs to HRAC group 27 (legacy F2 group).

Table 3.2-1: Details of the active substances

Active substance	Mesotrione
Concentration	100 g/L
Chemical group	Phenoxy-carboxylates
Mode of action	Mimix auxins on molecular level
Biological action	Post-emergence herbicide

Description of the plant protection product

MEZ-HER 100 SC is a suspension concentrate (SC) containing 100 g/L mesotrione 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)			
Maize	Silky apera (*Apera spica*-venti) APESV, Shepherd's purse (*Capsella bursa*-pastoris) CAPBP, Cornflower (*Centaurea cyanus*) CENCY, Cleavers (*Galium aparine*) GALAP, Common deadnettle (*Lamium amplexicaule*) LAMAM, Purple deadnettle (*Lamium purpureum*) LAMPU, Field chamomile (*Matricaria chamomila*) MATCH, False chamomile (*Tripleurospermum indorum*) MATIN, Common poppy (*Papaver rhoeas*) PAPRH, Common chickweed (*Stellaria media*) STEME, Fanweed (*Thlaspi arvense*) THLAR, Ivy-leaved speedwell (*Veronica hederifolia*) VERHE, Bird's eye speedwell (*Veronica persica*) VERPE Field pansy (*Viola arvensis*) VIOAR,	PL	1 L/ha	-Accepted of weeds species and their sensitivity classification are presented in GAP and label project by ZRMs

The applicant carried out efficacy trials on ~~winter wheat, winter barley, winter triticale, winter rye, spring wheat, spring barley, sprint triticale, oat~~ maize. ~~SE EPPO zone trials were performed on winter wheat.~~ 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*
AMARE	***Amaranthus retroflexus***	**Pigweed**
ANTAR	*Anthemis arvensis*	Field chamomile
BRSNN	***Brassica napus***	**Oilseed rape**
CAPBP	***Capsella bursa-pastoris***	**Shepherd's purse**
CHEAL	***Chenopodium album***	**Fat-hen**
ECHCG	***Echinochloa crus-galli***	**Common barnyard grass**
FUMOF	*Fumaria officinalis*	Common fumitory
GALAP	***Galium aparine***	**Cleavers**
GASPA	***Galiinsoga parviflora***	**Gallant soldier**
LAMPU	*Lamium purpureum*	Purple deadnettle
MATIN	***Tripleurospermum inodorum***	**False chamomile**
POLCO	***Fallopia convolvulus***	**Wild buckwheat**
STEME	***Stellaria media***	**Common chickweed**
THLAR	***Thlaspi arvense***	**Fanweed**
VIOAR	***Viola arvensis***	**Field pansy**

* optional

In **bold** font weed species which have occurred in the efficacy trials submitted by the applicant.

Agricultural crop production has been the main branch of plant production in Poland for years. According to Statistics Poland, total amount of sown area in Poland reached 10 891 000 ha in 2021 (latest year available).

Maize in Poland, neither for grain nor for forage has a large proportion in the sown area structure of crops, it still has a great impact on agriculture in Poland. Maize is the most important fodder plant in our climatic zone, especially in terms of feed for dairy cattle. However in Poland, majority of area used to sow maize is used for grain varieties, which clearly shows the table below.

Crop:	**Crop yield (t):**		**Sowing area (ha):**	
Year	**2021**	**2022**	**2021**	**2022**
Maize for silage	28 682 700	26 172 980	691 920	680 070
Maize for grain	7 321 910	8 510 950	998 470	1 181 510[1]

As the table shows, grain maize area is almost two times bigger than the area sown to later become silage.

No matter which type of maize yield is harvested, an appropriate protection, especially in terms of weeds, in the aforementioned crop, is inevitable. Chemical control of weeds is highly important in production of agricultural crops, especially in maize because of its late sowing time and wide row spacing. Most of weeds species, which are present in maize, 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

[1] Data from 2022 for Poland, according to EUROSTAT.

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 maize. Other weeds have very fast growing pace and can outcompete maize almost completely.

Weeds, which were present in field trials of MEZ-HER 100 SC are the known as serious maize competitors. The results are showing that a lot of weeds can be controlled by the product.

Weeds presented in field trials	**Maize Dose rate (L/ha)**
AMARE *Amaranthus retroflexus* Pigweed	1 ms ~~1.5~~
BRSNN *Brassica napus* oilseed rape	1 ms ~~1.5~~
CAPBP *Capsella bursa-pastoris* shepherd's purse	1 ~~1.5~~
CHEAL *Chenopodium album* fat-hen	1 ms ~~1.5~~
ECHCG *Echinochloa crus-galli* Common barnyard grass	1 ms ~~1.5~~
GALAP *Galium aparine* cleavers	1 ~~1.5~~
GASPA *Galinsoga parviflora* gallant soldier	1 ~~1.5~~
MATIN *Tripleurospermum inodorum* False chamomile	1 ~~1.5~~
POLCO *Fallopia convolvulus* wild buckwheat	1 ms ~~1.5~~
STEME *Stellaria media* common chickweed	1 ~~1.5~~
THLAR *Thlaspi arvense* fanweed	1 ~~1.5~~
VIOAR *Viola arvensis* field pansy	1 ~~1.5~~

ms – moderately susceptible
mr –moderately resistant
r - resistant
x – not present

According to Statistics Poland means of production in agriculture in the farming year 2021 (latest year with 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 44875 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**
Maize	X		Mono- and dicotyledonous weeds	X (for PL: AMARE, CHEAL, ECHCG, POLCO)	X (for PL: BRSNW, CAPBP, GALAP, GASPA, MATIN, STEME, THLAR, VIOAR)

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)

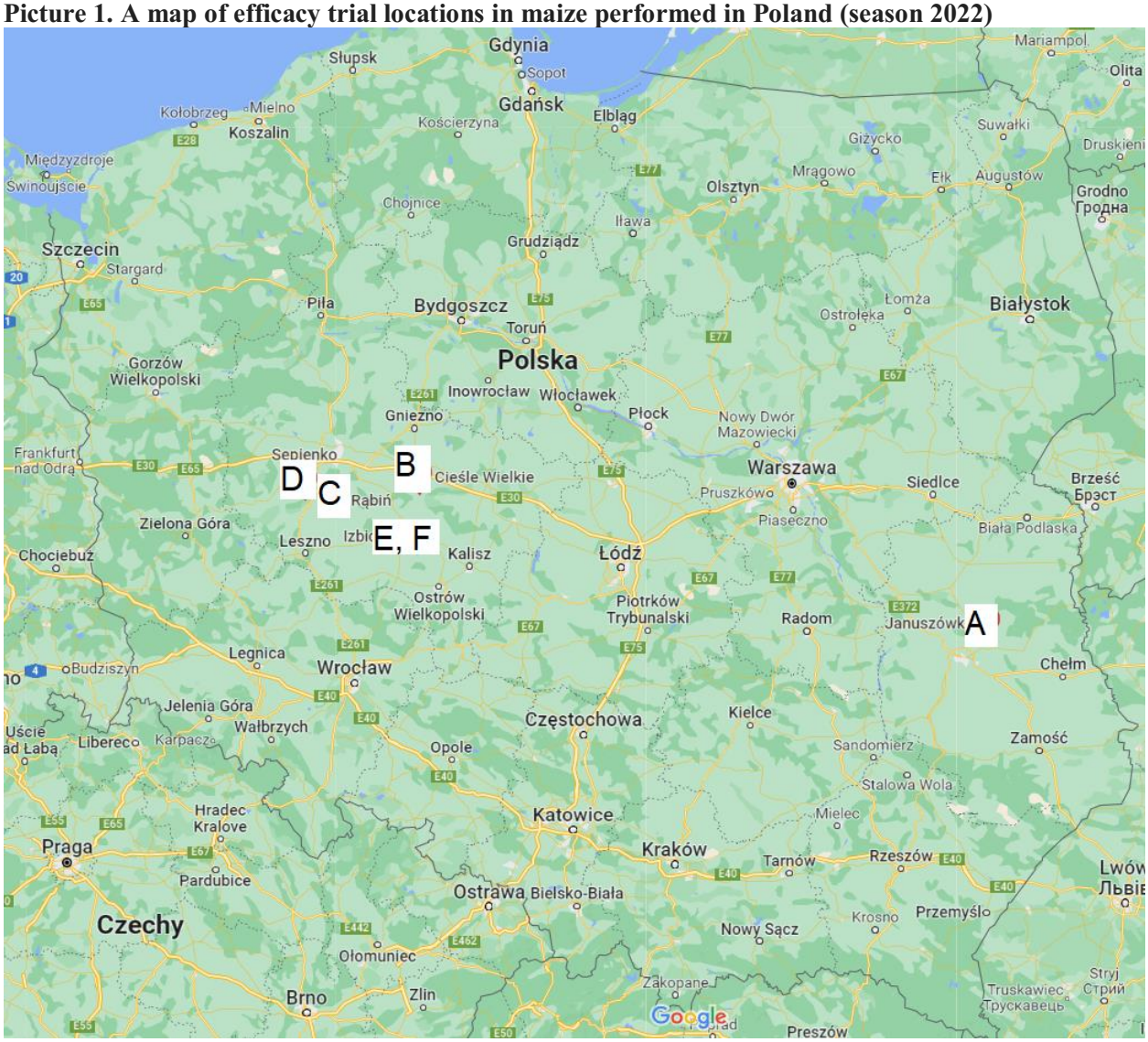
Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials...)

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		
Maize	Dicot and monocot weeds	Poland	2022	MED + E	6 (6)	GEP	-
TOTAL	Dicotyledonous weeds	Poland	2022	MED + E	6 (6)	GEP	-

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

Efficacy trials of MEZ-HER 100 SC herbicide were carried out during one growing season - 2022 in different regions of Poland. Map below presents locations of these trials.

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



From total of six trials, all MEZ-HER 100 SC trails were set in maize during 2022 season. All of them were performed in Poland. Trials were set in two voivodeships: Greater Poland and Lubelskie.

Trials were conducted by Fertico Sp. z o.o. in the locations below:

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2022	PL	181_01_F22_340	Januszówka	RGT Inedixx	Sandy clay	6.3
B	2022	PL	181_01_F22_341	Cieśle Wielkie	ES Gallery	Sandy clay loam	6.4
C	2022	PL	181_01_F22_343	Rąbiń	DKC3201	Silty sand	6.3
D	2022	PL	181_01_F22_344	Sepienko	Hulk	Sand	5.8
E	2022	PL	181_01_F22_345	Izbiczno	Kwinns	Sandy clay loam	6.3
F	2022	PL	181_01_F22_346	Izbiczno	RGT Muxxeal	Sandy clay	6.1

All of the abovementioned trials were conducted in randomized complete block design in four replications. Primary weed infestation levels assessments were done at the same time when application of the MEZ-HER 100 SC was done, during crop BBCH 14 and 15.
First assessments after application we performed up to 2 weeks after treatment.
Second assessments were done 3-4 weeks after treatment.
Abovementioned assessments were done according to the EPPO 1/50 (3) guideline "Weeds in maize".
Additional, third assessment, was done 44-63 days after the application of the product. This assesment is not listed in the guideline 1/50, however due to the weather conditions in Poland during growing season 2022 (periods of temperatures lower than the annual average in May/June, which caused the products working in slightly slower pace) 3rd assessment was necessary to fully assess the product efficacy. Regarding the meteo situation during growing season 2023 A3 assessment was considered for the summaries prepared in purpose of this report.

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 sub-stance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treat-ment)	Remark(4)
					Type(2)	Concentra-tion of a.s.			
Maize	Maisot 100 SC	PL	R-206/2019	mesotri-one;	SC	100 g/L;	0.75-1.5 L/ha	1.5 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 (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

Comments for ZRMS:

This document presented the information related to the efficacy of the plant protection product – Mecorn 100 SC (product code: MEZ-HER 100 SC). Product will be used as a herbicide against weeds in maize at BBCH 14-15. Mecorn 100 SC is a suspension concentrate (SC) containing 100 g/L of mesotrione.

Mesotrione is a selective herbicide commonly used to control broadleaf weeds and certain grasses in various crops such as maize, soybeans, turfgrass, and ornamental plants. Mesotrione inhibits the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD), which is essential for chlorophyll biosynthesis in plants. The disruption of chlorophyll production leads to bleaching and death of susceptible weeds. Mesotrione is selective, meaning it primarily targets broadleaf weeds while having minimal impact on grass species like corn and turfgrass when used according to label instructions. The selectivity allows for effective weeds control without significant damage to the desired crop.

Mesotrione can have residual activity in the soil, which may affect subsequent crops if they are sensitive

to the herbicide. Farmers need to consider crop rotation restrictions and planting intervals to avoid injury to succeeding crops. Mesotrione is typically applied as a pre-emergence or post-emergence herbicide, depending on the target weeds and the crop being grown. It is available in various formulations, including liquid sprays and granules, for application by ground or aerial equipment. Like other herbicides, repeated use of mesotrione can lead to the development of herbicide-resistant weed populations. To mitigate the risk, it is important for farmers to rotate herbicides with different modes of action and incorporate cultural practices like crop rotation and weed scouting. When used according to label instructions, mesotrione is considered to have low toxicity to mammals and aquatic organisms. However, it can be harmful to non-target plants if applied incorrectly or if drift occurs.

Using mesotrione in maize offers several advantages. Mesotrione is effective against a wide range of broadleaf weeds commonly found in maize fields, including species like pigweed and ragweed. It is a broad spectrum activity helps ensure comprehensive weed control, reducing competition for water, nutrients and sunlight, which can lead to improve maize yields. Mesotrione can be applied both pre- and post-emergence, providing flexibility in weed management strategies. Mesotrione exhibits selective herbicidal activity, meaning it primarily targets broadleaf weeds while having minimal impact on maize crops when applied correctly. This selectivity allows for effective weed control without causing significant injury of yield loss in maize crops. When used according to label instructions, mesotrione is considered safe for maize crops. It does not typically cause phytotoxicity or significant crop injury when applied correctly.

Also, some disadvantages of mesotrione should been presented. Factors such as application rate, timing, weather conditions, and maize growth stage can influence the risk of crop injury and must be carefully managed to minimize adverse effects. Overreliance on mesotrione without proper resistance management practices may lead to the emergence of weed species that are no longer effectively controlled by the herbicide, necessitating alternative weed control strategies. While mesotrione is considered to have low toxicity to mammals and aquatic organisms when used according to label instructions, it can still pose risks to non-target organisms and ecosystems if misused or if drift occurs. Environmental considerations, including runoff, leaching and impact on beneficial organisms, must be taken into account to minimize potential adverse effects on the environment.

While mesotrione offers effective weed control in maize, growers should weight these potential disadvantages and advantages alongside its benefits and consider integrated weed management approaches to optimize weed control while minimizing risks and maximizing sustainability.

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

All necessary information's about tested and evaluated PPP, active substance, studied weed species, reference product, etc. are correctly presented un this dRR by Applicant.

In Poland, 58 PPPs with mesotrione as an active compound are registered and commonly used in Poland on the basis on the Ministry Register of Plant Protection Products, dated 30.04.2024.

Poland is a ZRMs. No cMS was reported by Applicant. The PPP – Mecorn 100 SC (product code: MEZ-HER 100 SC) by Pestila Spółka z ograniczoną odpowiedzialnością has not been previously evaluated in any country according to Uniform Principles.

3.2.1 Preliminary tests (KCP 6.1)

No results of the preliminary range-finding tests are presented since no screening trials were carried out. However, the active substances of MEZ-HER 100 SC, mesotrione has been commonly used in agricultural practice for many years.

Comments for ZRMS:

Mesotrione was first introduced as a herbicide in the early 2000s. It was discovered and developed by

Syngenta and was initially marketed under the brand name Callisto. Mesotrione received regulatory approval for use in various crops, including corn, turfgrass and certain vegetables, and has been used in agriculture since then.

In Poland, 58 PPPs with mesotrione as an active compound are registered and commonly used in Poland on the basis on the Ministry Register of Plant Protection Products, dated 30.04.2024. So, the active substance of Mecorn 100 SC (product code: MEZ-HER 100 SC) – mesotrione is registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. ZRMs agree with Applicant that no primary and screening tests are required.

3.2.2 Minimum effective dose tests (KCP 6.2)

Minimum effective dose tests were not carried out. However, several doses of MEZ-HER 100 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.

Maize and dicotyledonous weeds

6 field trials were established to present the control of the mono and dicotyledonous weeds in maize. MEZ-HER 100 SC was tested in rates from 0.6 L/ha to 1.5 L/ha (60-150 g/ha of mesotrione) in order to determine the minimum effective dose in ~~cereals~~ maize for the control of mono and dicotyledonous weeds. The rates reflect the proposed label rates, 60% ~~and 80%~~ of the lowest recommended rate, which in this case was 0.6 L/ha ~~and 1 L/ha,~~ of MEZ-HER 100 SC, in accordance with the EPPO standard PP 1/225 (2) '*Minimum effective dose'*.
When used at the BBCH 14-15, the 0.6 L/ha dose of MEZ-HER 100 SC provided inferior control when compared to ~~0.8~~ 1-1.5 L/ha of MEZ-HER 100 SC in 6 trials out of 6 trials. Recommended dose for use in line to GAP table and label project is dose 1.0 L/ha.

Table 3.2-7: Minimum effective dose. Efficacy of MEZ-HER 100 SC at proposed label rates, at 60% ~~and 80%~~ of the lowest recommended dose rate at crop BBCH 14-15 against mono and dicotyledonous weeds in maize.

Grouping *	Number of trials	Infestation of the untreated control (unit)		% control with MEZ-HER 100 SC					
				0.6 L/ha (60% of the lowest recommended rate)		1 L/ha (~~The lowest~~ recommended rate)		1.5 L/ha (~~Full~~ higher rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
AMARE	2	6.88	5.75-8	73.13	53.75-92.5	83	72.25-93.75	90.38	86.25-94.5
BRSNW	2	5.75	5.5-6	75.63	67.5-83.75	80	71.25-88.75	91.88	86.25-97.5
CAPBP	2	5.75	5.5-6	70.63	70-71.25	85.75	85.5-86	92.5	92.5-92.5
CHEAL	6	7.83	5.5-10.25	69.17	47.5-91.25	84.58	75.75-96	93.63	87.75-98.75
ECHCG	6	5.83	5-6.5	71.46	48.75-82.5	84.38	72.5-92.5	91.67	85-97.5
GALAP	2	6.38	5.75-7	77.5	76.25-78.75	85	81.25-88.75	94.38	91.25-97.5
GASPA	1	8.75	8.75-8.75	72.5	72.5-72.5	85.25	85.25-85.25	91	91-91
MATIN	1	5	5-5	90	90-90	93.75	93.75	94.75	94.75-94.75
POLCO	3	7.5	5.25-9.25	61.67	47.5-76.25	77.08	65-88.75	92.33	85-97.5
STEME	2	7.25	6.75-7.75	72.5	72.5-72.5	87.13	86.75-87.5	95.63	93.75-97.5
THLAR	4	6.25	5-7.25	70.31	60-82.5	85.38	75.75-93.75	94.13	92.25-96.5

Grouping *	Number of trials	Infestation of the untreated control (unit)		% control with MEZ-HER 100 SC					
				0.6 L/ha (60% of the lowest recommended rate)		1 L/ha (The lowest recommended rate)		1.5 L/ha (Full higher rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
VIOAR	4	5.5	5-6	74.06	63.75-83.75	85.31	77.5-93.75	92.44	88.25-97.5

Summary and conclusions on the minimum effective dose

According to the presented results, 1-~~1.5~~ L/ha dosage of MEZ-HER 100 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 maize, for which activity of MEZ-HER 100 SC is claimed.

As a result, the proposed rate of 1 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 for ZRMS:

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose (s). For example, 60-80% of the recommended dose should be used during field trials, to that which would be recommended. It is utilized to achieve the desired effect. During efficacy field tests Applicant used different doses of Mecorn 100 SC. So, separated MED dose were not presented in the documentation. However, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line to EPPO 1/225 (2).

Efficacy was tested under a range of environmental conditions to full challenge the product. All trials were carried out only in one EPPO zone in Poland in one growing season. Following doses were studied during trials: 0.6 L/ha (0.6N); 1 L/ha (N recommended) and 1.5 L/ha. All trials were characterized by acceptable level of infestation.

Results for MED (Minimum Effective Dose):

Weed species	No. trials	Infestation	Eff. at dose 0.6 L/ha	Eff. at dose 1.0 L/ha	Eff. at dose 1.5 L/ha
AMARE	2	6.9	73.1	83.0	90.4
BRSNW	2	5.8	75.7	80.0	91.9
CAPBP	2	5.8	70.6	85.8	92.5
CHEAL	6	7.8	69.2	84.6	93.7
ECHCG	6	5.8	71.5	84.4	91.7
GALAP	2	6.4	77.5	85.0	94.4
GASPA	1	8.8	72.5	85.3	91.0
MATIN	1	5.0	90.0	93.8	94.8
POLCO	3	7.5	61.7	77.1	92.3
STEME	2	7.3	72.5	87.1	95.6
THLAR	4	6.3	70.3	85.4	94.1
VIOAR	4	5.5	74.1	85.3	92.4

S 85-100% **MS** 70-84.9% **MT** 60-69.9% **T** < 60%

On the basis on obtained results it has been noted that:

- ✓ ***for dose 0.6 L/ha*** – 2 weeds were classified as a moderately tolerant (CHEAL, POLCO), 9 weeds as moderately susceptible (AMARE, BRSNW, CAPBP, ECHCG, GALAP, GASPA, STEME,

THLAR, VIOAR) and one weed was characterized by susceptible (MATIN), Lack of weeds tolerant against Mecorn 100 SC.

- ✓ ***for dose 1.0 L/ha –*** lack of weeds tolerant and moderately tolerant. 5 weeds were characterized by moderately susceptible (AMARE, BRSNW, CHEAL ECHCG, POLCO) and 7 weeds as a susceptible (CAPBP, GALAP, GASPA, MATIN, STEME, THLAR, VIOAR).
- ✓ ***for dose 1.5 L/ha –*** all studied weeds were characterized as a susceptible (AMARE, BRSNW, VAPBP, CHEAL, ECHCG, GALAP, GASPA, MATIN, POLCO, STEME, THLAR, VIOAR).

In the opinion of ZRMS, on the basis on results presented above it can be concluded that dose 1.5 L/ha was characterized by the best efficacy. However, dose 1.0 L/ha was also characterized by good level of efficacy. So, in the opinion of ZRMs **dose 1.0 L/ha can be recommended for use in line to proposal of Applicant in GAP and label project and submitted documentation.**

3.2.3 Efficacy tests (KCP 6.2)

A total of 6 trials were carried out in year 2022 to evaluate the efficacy of MEZ-HER 100 SC for the control of weeds in maize, and compare it to the standard (Maisot 100 SC) in two different regions of Poland, which were different 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 litres of working solution per hectare. All trials were conducted in compliance with GEP principles and following appropriate EPPO guidelines: EPPO PP 1/50 (3), EPPO PP 1/135 (4), EPPO PP 1/152 (4), EPPO PP 1/181 (4). Also EPPO PP 1/225 (2) guideline was considered when choosing MEZ-HER 100 SC doses for efficacy trials.

As a reference product for MEZ-HER 100 SC in efficacy and selectivity trials, applicant used Maisot 100 SC not Callisto 100 SC, since Calisto has been unavailable on the market in 2022 season.
According to the EPPO guideline PP 1/307(2), describes conditions for a bridging studies *"it is recognized that sometimes the original authorized formulation may no longer be commercially available and so direct comparisons in trials are not possible. In such cases, a bridging approach to another authorized product containing the same active substance may still be possible, but the extent of required data is likely to be more than that needed where direct comparisons are available. This approach is dependent on comparisons across a broad and representative range of uses and demonstrating that the proposed formulation performs as expected for such a product type on the basis of existing knowledge on the formulated active substance".*
Maisot 100 SC contains the same of amount of mesotrione active substance as Callisto 100 SC as well as is also registered for using in maize against several weeds.
Since the efficacy and selectivity trials have been performed on the different than reference plant protection product applicant provides an increased number of studies, as follows:

- 6 efficacy trials (1-2 studies are required according to the Polish guidelines for registration in art. 33 based on 34);
- 5 selectivity trials (not required for the registration according to the Polish guidelines for registration in art. 33 based on 34).

The results of these trials are presented in the Table 3.2 18. Besides of results of trials on MEZ-HER 100 SC and Maisot 100 SC (as a reference product) the Table 3.2 18. contains the results of efficacy trials of Callisto 100 SC, described in the Registration Report of Callisto 100 SC of 17th December 2008.

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 1/50 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	21 m²
	Number of replications	4

Crop	Trials per crop	Maize (6)
	Varieties per crop	Maize: DKC3201, ES Gallery, Hulk, Kwinns, RGT Inedixx, RGT Muxxeal
	Sowing period	Maize: 05.10.2019 – 13.11.2019; 22.09.2020-07.11.2020
Application	Crop stage (BBCH)* at application	Maize: BBCH 14-15
	Timing Pest stage at application (1)	AMARE 13-14 BRSNW 12-13 CAPBP 12 CHEAL 12-15 ECHCG 13-14 GALAP 12-15 GASPA 14 MATIN 14 POLCO 12-15 STEME 13-14 THLAR 12-13 VIOAR 23-14
	Number of applications Intervals between applications	1 N/A
	Spray volumes	200 L/ha
Assessment	Assessment types	weeds infestation level (no/m^2)
	Assessment dates	0 DA-A, 14 DA-A, 28-30 DA-A, 34-63 DA-A
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	1. Sandy clay, pH 6.1 – 6.3 2. Sandy clay loam, pH 6.3 – 6.4 3. Silty sand, pH 6.3 4. Sand, pH 5.8
	e.g. Natural / artificial innocula-tion…	Natural
	e.g. Field / Greenhouse...	Field

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

Table 3.2-18: Efficacy of active substance components in MEZ-HER 100 SC trials in Maize

Grouping *	Number of trials	Infestation of the untreated control (number of plants)		**MEZ-HER 100 SC** mesotrione 60 g/ha		**MEZ-HER 100 SC** mesotrione 100 g/ha		**MEZ-HER 100 SC** mesotrione 150 g/ha		**Maisot 100 SC** mesotrione 150 g/ha		**Callisto 100 SC**[2] mesotrione 100 g/ha		**Callisto 100 SC**[2] mesotrione 150 g/ha		No of trials where MEZ-HER 100 SC at full recommended dose is >, <, = compared to standard(s)**
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	Plants/m²	Plants/m²	%	%	%	%	%	%	%	%	%	%	%	%	[-]
AMARE	2	6.88	5.75-8	73.13	53.75-92.5	83	72.25-93.75	90.38	86.25-94.5	90.38	86-95.75	97.2	92-100	99.9	99-100	1 trial > 1 trial <
ANTAR[1]	-	-	-	-	-	-	-	-	-	-	-	98.3	95-100	100	100-100	-
BRSNN	2	5.75	5.5-6	75.63	67.5-83.75	80	71.25-88.75	91.88	86.25-97.5	92.5	87.5-97.5	-	-	-	-	1 trial < 1 trial =
CAPBP	2	5.75	5.5-6	70.63	70-71.25	85.75	85.5-86	92.5	92.5-92.5	92.38	92.25-92.5	100	100-100	100	100-100	1 trial > 1 trial =
CHEAL	6	7.83	5.5-10.25	69.17	47.5-91.25	84.58	75.75-96	93.63	87.75-98.75	93.96	87.5-98.75	100	100-100	100	100-100	3 trials > 1 trial < 2 trials =
ECHCG	6	5.83	5-6.5	71.46	48.75-82.5	84.38	72.5-92.5	91.67	85-97.5	92.63	85-98.75	95.8	95-100	99.3	97-100	1 trial > 3 trials < 2 trials =
FUMOF[1]	-	-	-	-	-	-	-	-	-	-	-	80	40-100	91.7	75-100	-
GALAP	2	6.38	5.75-7	77.5	76.25-78.75	85	81.25-88.75	94.38	91.25-97.5	95	92.5-97.5	96	95-100	97.5	90-100	1 trial < 1 trial =
GASPA	1	8.75	8.75-8.75	72.5	72.5-72.5	85.25	85.25-85.25	91	91-91	91	91-91	100	100-100	100	100-100	1 trial =
LAMPU[1]	-	-	-	-	-	-	-	-	-	-	-	100	100-100	100	100-100	-
MATIN	1	5	5-4	90	90-90	93.75	93.75	94.75	94.75-94.75	97	97-97	-	-	-		1 trial <
POLCO	3	7.5	5.25-9.25	61.67	47.5-76.25	77.08	65-88.75	92.33	85-97.5	90.83	86.25-98.75	100	100-100	100	100-100	1 trial > 2 trials <
STEME	2	7.25	6.75-7.75	72.5	72.5-72.5	87.13	86.75-87.5	95.63	93.75-97.5	97.25	94.5-100	100	100-100	100	100-100	2 trial <
THLAR	4	6.25	5-7.25	70.31	60-82.5	85.38	75.75-93.75	94.13	92.25-96.5	94.38	92.5-96.25	100	100-100	100	100-100	2 trials > 2 trials <
VIOAR	4	5.5	5-6	74.06	63.75-83.75	85.31	77.5-93.75	92.44	88.25-97.5	93.63	87.5-98.75	98.3	95-100	99.2	95-100	1 trial > 2 trials < 1 trial =

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

** Optional
[1],[2] Efficacy results from Polish Callisto 100 SC registration report from 2008

According to statistical analysis, data assessed in trials demonstrated that the efficacy of MEZ-HER 100 SC in control of weeds in maize at the rate of 1.5 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of reference product – Maisot 100 SC – used in rate of 1.5 L/ha. Additionally in the cells where background is in grey colour, results for Callisto 100 SC are shown. They come from the Polish registration report for this product, from 2008, to which the applicant gained access through the application to the Ministry of Agriculture and Rural Development to be provided with the Callisto 100 SC registration report and data for which data protection have expired. This information was used to develop the trials layout and to compare the obtained results with Callisto 100 SC. Instead of Callisto 100 SC the applicant had to use different reference product - Maisot 100 SC, which has similar, if not the same, formulation and same amount of the active substance. Callisto 100 SC samples for the purposes of efficacy field trials were impossible to get in 2022, hence why Maisot 100 SC was used instead.

Taking into account the results presented above, a comparison was made over across a broad and representative range of uses and it was demonstrated that the proposed formula performs as expected for such a product type on the basis of existing knowledge on the formulated active substance.

Minor use

Not relevant.

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

Not relevant.

Summary and conclusion

6 trials total were conducted to confirm efficacy of MEZ-HER 100 SC in control of dicotyledonous and monocotyledonous weeds in ~~winter cereals~~ maize. MEZ-HER 100 SC showed its effectiveness in control of weed species listed below, in maize at the proposed label rates:

1 L/ha –
Susceptible weeds:
~~Pigweed *Amaranthus retroflexus*;~~
~~Field chamomile *Anthemis arvensis*;~~
Shepherd's purse *Capsella bursa-pastoris*;
~~Fat-hen *Chenopodium album*;~~
~~Common barnyard grass *Echinochloa crus-galli*;~~
Cleavers *Galium aparine*;
~~Gallant soldier *Galinsoga parviflora*;~~
~~Purple deadnettle *Lamium purpureum*;~~
~~Wild buckwheat *Fallopia convolvulus*;~~
Common chickweed *Stellaria media*;
Fanweed *Thlaspi arvense*;
Field pansy *Viola arvensis*

Moderately susceptible weeds:
~~Common fumitory *Fumaria officinalis*~~
Brassica napus oilseed rape
Fat-hen *Chenopodium album*;
Common barnyard grass *Echinochloa crus-galli*;

Comments for ZRMS:

All details about efficacy methodology used during efficacy trials (in total 6) were presented above by Applicant. Submitted reports were from field trials carried out on maize in PL (N-E). Trials 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.

Applicant properly presented efficacy trials. Only trials with greater than 4-5 weeds/m^2 should be taken for assessment. According to EPPO 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. Therefore, based on knowledge of major/minor status of weeds, weeds with insufficient results should be excluded. In Poland, 58 PPPs with mesotrione are registered and commonly used for protect crops against weeds. So, in line to Polish rules for major weeds – at least 4 trials are required and for minor – at least 2.

Applicant would like to register Mecorn 100 SC in line to Article 33 and 34 with using unprotected data of Callisto 100 SC. In line to Polish rules, Applicant should present bridging trials in which Callisto as a st. ref. product and tested product – Mecorn 100 SC should be tested at the same time in the same field trial. However, in submitted trials other PPP as a st. reference product was used (Maisot 100 SC not

Callisto 100 SC). So, registration in line to Article 34 is not possible now. Only conditionally registration could be considered as a dRR was submitted by Applicant before 1st January 2024 within 2 years after registration for submitting full package of bridging trials. However, ZRMs proposed registration of tested product – Mecorn 100 SC only in line to Article 33 on the basis on 6 trials submitted. ZRMs accepted conducting trials only in one growing season as many PPPs with mesotrione are registered and used in PL for protect maize against weeds. Applicant presented eff. results from Callisto in the table Table 3.2 18. However, those results are from unprotected dRR from 2008 not from filed trials submitted for assessing now. As, no valid bridging trials were presented, ZRMs not assessed results from Callisto and not consider in evaluation of Mecorn 100 SC. The applicant explained that they did not conduct research on Callisto 100 SC because it was unavailable in 2022. However, according to information on the manufacturer's website and in the registry of plant protection products, Callisto 100 SC is permitted until 2033, and its sales deadline is set for 2034. Also, the list of plant protection products authorized for sale and use in 2022 in Poland included Callisto 100 SC (code: II.83 for herbicides).

Applicant submitted enough number of trials for Mecorn 100 SC (6) for registration inline to Article 33. Accepted weed species for PL should be presented to following scale of sensitivity:

- S (susceptible) >85%
- MS (moderately susceptible) 70-85%
- MT (moderately tolerant) 60-70%
- T (tolerant) < 60%

All studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by Chief inspector of Plant health and Seed Inspection and are officially GEP recognized.

All trials had 4 replicates, a randomised block design and a valid plot size (21m^2) was used. Water volumes of 200 L/ha were tested, which not encompasses the full range proposed in the GAP table (200-300 L/ha). In the opinion of ZRMs recommended water volume can be 200-300 L/ha as in line to protection programs for mesotrione and in line to registered uses of st. ref. product used during trials (Maisot 100 SC). Application window BBCH 14-15 is in line to submitted documentation and trials.

In all trials Maisot 100 SC as a st. reference product was used at dose 1.5 L/ha. Tested product – Mecorn 100 SC is recommended by Applicant for use at dose 1.0 L/ha (in line to submitted GAP and label project), so Maisot 100 SC should be tested at dose 1.5 L/ha (its registration is for 0.75-1.5 L/ha). However, ZRMs accepted submitted documentation as valid for the assessment of Mecorn 100 SC.

Below. ZRMs presented results for noted efficacy during trials.

Weed	Number of trials	Level of infefstation (no/m^2)	Mean eff at 1.0 L/ha	Mean eff. at dose 1.5 L/ha	st. ref. product (Maisot 100 SC) at dose 1.5 L/ha
AMARE	2	6.9	83.0	90.4	90.4
BRSNW	2	5.8	80.0	91.9	92.5
CAPBP	2	5.8	85.8	92.5	92.4
CHEAL	6	7.8	84.6	93.7	94.0
ECHCG	6	5.8	84.4	91.7	92.6
GALAP	2	6.4	85.0	94.4	95.0
GASPA	1	8.8	85.3	91.0	91.0
MATIN	1	5.0	93.8	94.8	97.0
POLCO	3	7.5	77.1	92.3	90.8
STEME	2	7.3	87.1	95.6	97.3
THLAR	4	6.3	85.4	94.1	94.4
VIOAR	4	5.5	85.3	92.4	93.6

All trials were characterized by sufficient level of infestation.

Weeds represented only by one trial should be excluded from the assessment. Excluded weed species due to very limited number of trials (only one) are: GASPA and MATIN. Also AMARE and POLCO should be excluded due to not sufficient number of trials for major weeds in maize (at least 4 trials are required).

BRSNW, CAPBP, GALAP, STEME, THLAR and VIOAR can be accepted as a minor weeds and CHEAL, ECHCG as a major weeds in maize. The most effective and mostly comparable to st. ref. product was dose 1.5 L/ha of Mecorn 100 SC. However, also dose 1.0 L/ha is efficacy against weeds so it

can be recommended in line to GAP table and label project.

Accepted list of weed species and their sensitivity for Polish label against recommended dose (1.0 L/ha) of Mecorn 100 SC:

- ✓ *moderately susceptible weeds*: BRSNW, CHEAL, ECHCG
- ✓ *susceptible weeds*: CAPBP, GALAP, STEME, THLAR, VIOAR.

Mecorn 100 SC can be registered for use on maize cultivated on grain, bioethanol and silage. Varieties for grain, silage and bioethanol were tested during trials.

ZRMs do not agree with Applicant that data from Maisot 100 SC can be used for registration under Article 34 in exchange for Callisto 100 SC whose data have expired). The licence holder of Maisot 100 SC is Albaugh TKI d.o.o, for Callisto 100 SC – Syngenta Polska Sp. z o.o. Maisot 100 SC was registered in 2019 and its data are still protected. Also, Applicant did not present any results for comparable of phys.-chemical comparison of the two measures (Maisot 100 SC and Mecorn 100 SC, only assessment against Mecorn 100 SC and Callisto 100 SC was made). The Applicant's statement that both agents are comparable, i.e. Maisot100 SC and Callisto 100 SC, only on the basis of the content of the active substance and their label is not sufficient. What is important, Maisot 100 SC is registered for use at dose 0.75-1.5 L/ha, whilst Callisto 100 SC – 1.0-1.5 L/ha. Sensitivity of weeds from Maisot 100 SC label is presented only for dose 0.75 and 1.5 L/ha. It is not possible to compare its effectiveness for Callisto 100 SC or Mecorn 100 SC used at dose 1.0 L/ha (lack of such data). So, in the opinion of ZRMs without submitting by Applicant the comparable of phys.-chemical comparison of the two measures (Maisot 100 SC and Mecorn 100 SC) and consent of the Maisot 100 SC authorisation holder to the use of its data is not possible. Also, the both products Maisot 100 SC and Mecorn 100 SC should be used at the same dose. Whilst during trials Mecorn was studied at dose 1.0 and 1.5 L/ha and Maisot 100 SC only at dose 1.5 L/ha.

If the Applicant has a comparison of the compositions of Maisot 100 SC and Mecorn 100 SC (optimally) or Callisto 100 SC and Maisot 100 SC (optionally) and the consent of the Maisot 100 SC authorisation holder to use its data, then registration will be possible on the basis of the use of bridging studies of Maisot 100 SC, as requested by the applicant at the time of comment. Also, both products (Maisot 100 SC and Mecorn 100 SC should be used during trials at the same dose). Without mentioned above, only registration in line to Article 33 is possible with treated Maisot 100 SC as a st. ref. product, which was already done during this assessment.

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 MEZ-HER 100 SC - mesotrione is by inhibition of the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme in target plants, is classified in Group 27. Aforementioned enzyme is necessary in the process of biosynthesis of alpha-tocopherol and plastoquinone (which is made from tyrosine) – substances essential for carotenoid production in the plants. When carotenoid synthesis in the chlorophyll pathway is disrupted, which causes degradation of chlorophyll. This causes bleaching effect to happen, which later leads to plant death.
No cases of resistant weeds were discovered in Europe so far. Three species which have developed resistance to mesotrione were discovered worldwide: *Raphanus raphanistrum* (in Australia, first resistant biotype discovered in 2015), *Amaranthus tuberculatus* (first discovered in 2009 in USA), *Amaranthus palmeri* (also discovered in USA, in year 2009). These species are uncommon in Europe, thus in the applicant opinion occurrence of weed species with resistance to mesotrione is low. In Europe maize is grown on a lower scale than in the USA, considering this, along with the fact that North American farmers have different approach to cultivation (GMO varieties, different chemicals available etc), bigger threat in case of herbicide resistant weeds in Europe are ALS inhibitors, sulfonylourea group herbicides to be precise. These herbicides were and still are main weapon in the arsenals of European farmers to fight with the weeds

in maize. The better the availability of herbicides that belong to groups other than ALS inhibitors, the lower the risk of resistance occurrence, and providing farmers with more products to be used in maize, would help them to rotate the herbicides more.

Comments for ZRMS:

Resistance to mesotrione, like with many herbicides can develop in weed populations over time due to repeated use of the herbicide. When weeds are exposed to the same herbicide over and over again, the ones that have genetic variations that make them less susceptible to the herbicide survive and reproduce, passing on their resistant traits to their offspring.

There have been documented cases of weed populations developing resistance to mesotrione, particularly in species such as waterhemp and palmer amaranth. To manage resistance, integrated weed management strategies are recommended, which may include rotating herbicides with different modes of action, using cultural practices to reduce weed pressure, and employing non-chemical methods such as crop rotation and mechanical weed control. Additionally, utilizing herbicide mixtures or tank-mixing mesotrione with other effective herbicides can help delay the development of resistance.

Mesotrione is a callistemone herbicide that inhibits the HPDD enzyme and introduces a new naturally selective tool into weed management programmes for use in maize.

Mesotrione provides control of the major broad-leaved weeds, and it can be used in integrated weed-management programmes depending on the grower's preferred weed control strategy. At post-emergence rates of 150 a.s./ha or less, mesotrione provides naturally selective control of key species that may show triazine resistance (TR), ex. CHEAL AMARE, SOLNI, as well as species of weed that show resistance to acetolactase synthase (ALS) inhibitors, eg. *Amaranthus* sp.

Mecorn 100 SC (product code: MEZ-HER 100 SC) containing mesotrione (100 g/L), a potent bleaching herbicide that belonging to triketone herbicide family (HRAC Group 2). Mecorn 100 SC is a post-emergence herbicide used to control weeds in maize crops.

The following table show that current worldwide resistance weeds specifically to the herbicide mesotrione (according to http://www.weedscience.org);

#	Year	Species	Country	MOAs	Actives	Situations
1	2015	*Raphanus raphanistrum*	Australia (Western Australia)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Phytoene Desaturase inhibitors HRAC Group 12 (Legacy F1), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	chlorsulfuron, atrazine, diflufenican, fluridone, isoxaflutole, 2,4-D, mesotrione, tembotrione	Wheat
2	2020	*Raphanus raphanistrum*	Australia (Western Australia)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	metsulfuron-methyl, dicamba, 2,4-D, mesotrione, pyrasulfotole, topramezone	Wheat
3	2021	*Amaranthus tuberculatus (=A. rudis)*	Canada (Ontario)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, atrazine, metribuzin, lactofen, glyphosate, mesotrione	Corn (maize), Soybean, Dry, bean, edible

4	2009	*Amaranthus tuberculatus (=A. rudis)*	United States (Illinois)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, chlorimuron-ethyl, atrazine, mesotrione, tembotrione, topramezone	Seed corn
5	2016	*Amaranthus tuberculatus (=A. rudis)*	United States (Illinois)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, chlorimuron-ethyl, atrazine, fomesafen, lactofen, acifluorfen, dicamba, 2,4-D, mesotrione, tembotrione, topramezone	Corn (maize), Soybean
6	2009	*Amaranthus tuberculatus (=A. rudis)*	United States (Iowa)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	thifensulfuron-methyl, rimsulfuron, atrazine, mesotrione, tembotrione, topramezone	Seed corn
7	2011	*Amaranthus tuberculatus (=A. rudis)*	United States (Iowa)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazamethabenz-methyl, thifensulfuron-methyl, chlorimuron-ethyl, atrazine, isoxaflutole, glyphosate, mesotrione	Corn (maize), Soybean
8	2022	*Amaranthus palmeri*	United States (Iowa)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, atrazine, glyphosate, mesotrione	Corn (maize), Soybean
9	2009	*Amaranthus palmeri*	United States (Kansas)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	thifensulfuron-methyl, atrazine, mesotrione, pyrasulfotole, tembotrione, topramezone	Corn (maize), Sorghum
10	2015	*Amaranthus palmeri*	United States (Kansas)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	chlorsulfuron, atrazine, glyphosate, 2,4-D, mesotrione	Sorghum
11	2021	*Amaranthus palmeri*	United States (Kansas)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Histidine	imazethapyr, thifensulfuron-methyl, chlorsulfuron, atrazine, metribuzin, bromoxynil, fomesafen, lactofen, glyphosate, imazamox, mesotrione, pyrasulfotole, tembotrione	Sorghum

				215 Binders HRAC Group 6 (Legacy C3), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)		
12	2011	*Amaranthus tuberculatus (=A. rudis)*	United States (Nebraska)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	mesotrione, tembotrione, topramezone	Corn (maize)
13	2011	*Amaranthus palmeri*	United States (Nebraska)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	mesotrione, tembotrione, topramezone	Corn (maize)
14	2014	*Amaranthus palmeri*	United States (Nebraska)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	atrazine, mesotrione, tembotrione, topramezone	Corn (maize)
15	2016	*Amaranthus palmeri*	United States (North Carolina)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	mesotrione	Corn (maize)
16	2020	*Amaranthus tuberculatus (=A. rudis)*	United States (North Carolina)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, atrazine, fomesafen, glyphosate, mesotrione	Soybean
17	2022	*Amaranthus retroflexus*	United States (North Carolina)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E)	imazamethabenz-methyl, thifensulfuron-methyl, fomesafen, lactofen, mesotrione	Soybean

17 cases of resistance against mesotrione were recorded in two weed species (both, *Amaranthus* sp. and *Raphanus raphanistrum*). All cases were reported in USA, Canada and Australia. No case reported in Europe yet. The active substance is therefore classified as having a low inherent risk.

Mesotrione acts by the inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase which in turn inhibits carotenoid biosynthesis. Due to its primary target site and its chemical family, in the HRAC mode of action classification, it is classified as group F2 herbicide (4-hydroxyphenyl-pyruvate-dioxygenase (4-HPPD) inhibition). In the WSSA resistance classification system, the callistemones are classified as group 27.

The mechanism for resistance in the two weed species is currently unknown. Based on the HRAC resistance classification, cross resistance should be expected to be likely between mesotrione and other HRAC group F2 herbicides. Thus, the analysis of the risk for the development of weed resistance to mesotrione is made under the assumption that cross resistance exists between all herbicides classified as HRAC group F2. No cross-resistance was observed between F2 herbicides in the ten cases reported from the US.

The mesotrione resistant *Amaranth* species (*Amaranthus tuberculatus* and *Amaranthus palmeri*) populations in Iowa, Illinois, Kansas and Nebraska (USA) mentioned in section 3.3.4 were reported to be

cross-resistant to ALS inhibitors (HRAC group B/2), Photosystem II inhibitors (HRAC group C1/5), PPO inhibitors (HRAC group E/14), Synthetic Auxins (HRAC group 0/4) and/or EPSP synthase inhibitors (HRAC group G/9).

Mesotrione have been used as straight products as well as in mixtures for many years. Without any precautions, the resistance risk is unacceptable. However, taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)) should be the followed in the weed management strategy. Uses of mixtures with herbicides with different modes of action and weed spectrum is re-commended, to obtain a high degree of weed control and get rid of eventually resistant weeds in the field and prevent resistance build up.

Follow the label recommendations regarding application rate (max. 1 application per year), growth stage, doses etc.

Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broadleaved weeds.

Mesotrione is a widely used post-emergence herbicide for maize. The toxicity of mesotrione to maize (especially sweet corn) has been widely reported, and some sweet corn varieties are highly sensitive to mesotrione, which affects subsequent plant growth periods. However, the molecular mechanisms responsible for the differences in susceptibility to mesotrione are not known.

3.4 Adverse effects on treated crops (KCP 6.4)

The applicant carried out:
-5 selectivity trials in maize.

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)
Maize	Poland	S	~~11~~ 5	2022	GEP	
		S + Y	5			
		S + Y + Q	5			
TOTAL	-	S	~~11~~ **5**	-	-	
		S + Y	**5**			
		S + Y + Q	**5**			

According to the GAP table

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

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

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

Trial number	Crop(s)	Reference standards	Country(ies) where the product is registered[1]	Authorization number	Active substance(s) (a.s)	Formulation		Registered application rate[3]	Application rate in trials (per treatment)	Remark[4]
						Type[2]	Concentration of a.s.			
III 6.2.1/01 (S-M-PL-2022-) III 6.2.1/02 (S-M-PL-2022-) III 6.2.1/03 (S-M-PL-2022-) III 6.2.1/04 (S-M-PL-2022-) III 6.2.1/05 (S-M-PL-2022-)	Maize	Maisot 100 SC	Poland	R-113/2022b	Mesotrione	SC	300 g/L (mesotrione)	0.75-1.5 L/ha	1.5-3 L/ ha	-

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

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Table 3.4-3: Phytotoxicity of product to maize

Number of trials with…		Selectivity trials (5 trials)				Efficacy trials (6 trials)	
		Test product		Standard 1		Test product	Standard 1
		1.5N (1.5 L/ha)	~~≥~~ 3 N ~~(or other)~~ (3 L/ha)	N (1.5 L/ha)	2N (~~or other~~ 3 L/ha)	N (1.0 L/ha)	N (1.5 L/ha)
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	5	5	5	6	6
	>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%	5	5	5	5	6	6
	>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 selectivity trials were carried out on maize in Poland, in year 2022 on a range of commercially grown varieties: Volodia, DKC3787, SY Kardona, DKC3201, RGT MUXXEAL. Trials were conducted in two regions of Poland: Greater Poland and Lubelskie.
No phytotoxicity symptoms caused by 1.5N nor ~~≥~~ 3N dose of MEZ-HER 100 SC at the proposed dose rate of ~~1.5~~ 1 L/ha, were observed in any of the performed selectivity trials. Also in the efficacy trials no phytotoxicity was observed in each of tested rates.

Comments for ZRMS:

In the evaluation process the fact that the active compound – mesotrione is used in many plant protection products and have been commonly used in crop protection for many years were taken into consideration by ZRMs.

The Applicant submitted in total 5 selectivity trials carried out in Poland (N-E) in one growing season. The selectivity evaluation of the herbicide is to be performed in line to listed below EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction. Phytotoxicity assessment was carried out with the use of different cultivars (commonly grown varieties). Dosage N was not studied as Applicant would like to register product for use at dose 1.0 L/ha. Only dose 1.5N (1.5 L/ha) and 3N (3 L/ha) was studied during trials. St. ref. product (Maisot 100 SC) was studied at dose 1.5 L/ha and 3.0 L/ha. Experimental details and assessments methods were in line to EPPO standards. Detailed information's were presented by Applicant in the tables above.

Registration of Mecorn 100 SC cannot be done in line to Article 34, because in trials Callisto 100 SC which data are unprotected was not studied and compared to tested Mecorn 100 SC. As a st. ref. product Applicant used different product – Maisot 100 SC so registration could be only in line to Article 33 as a sufficient number of selectivity trials for Mecorn 100 SC was studied.

In the opinion of ZRMs, submitted documentation is sufficient. Studied only higher doses than included in GAP and label project is acceptable by ZRMs as a worse scenario. No phytotoxicity symptoms caused by 1.5 L/ha nor 3.0 L/ha dose of MEZ-HER 100 SC were observed in any of the performed selectivity trials. Also in the efficacy trials no phytotoxicity was observed in each of tested rates.

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

Table 3.4-4: Relationship between MEZ-HER 100 SC rate and yield (green maize) fresh

3 trials were carried out on green maize in Poland, in 2022, on a range of commercially grown silage maize varieties. Both yield of fresh mass and dry mass were analysed. Table below shows the results for fresh weight of mass harvested.

Test report	Variety	Yield in the untreated control Absolute figures (unit)	Yield at 1N and 1.5N as % of untreated		Yield at 2N and 3N ~~(or other)~~ rate as % of untreated	
			Test product (1.5 L/ha)	Standard 1 (1.5 L/ha)	Test product (3.0 L/ha)	Standard 1 (3.0 L/ha)
III 6.2.1/01 (S-M-PL-2022-182_02_F22_347) Maize	Volodia	43.88 t/ha	43.43 t/ha 99%	43.61 t/ha 99.4%	44.94 t/ha 102.5%	43.26 t/ha 98.6%
III 6.2.1/03 (S-M-PL-2022-182_02_F22_349) Maize	SY Kardona	54.89 t/ha	54.69 t/ha 99.6%	55.24 t/ha 100.7%	55 t/ha 100.2%	55.24 t/ha 100.6%
III 6.2.1/05 (S-M-PL-2022-182_02_F22_351) Maize	RGT Muxxeal	52.35 t/ha	51.82 t/ha 99.2%	52.36 t/ha 100.1%	52.23 t/ha 99.9%	51.37 t/ha 98.2%

Table 3.4-5: Relationship between MEZ-HER 100 SC rate and yield (green maize) dry mass

3 trials were carried out on green maize in Poland, in 2022, on a range of commercially grown silage maize varieties. Both yield of fresh mass and dry mass were analysed. Table below shows the results for dry mass results of the yield harvested.

Test report	Variety		Yield at 1N and 1.5N as % of untreated	Yield at 2N and 3N ~~(or other)~~ rate as % of untreated

		Yield in the untreated control Absolute figures (unit)	Test product (1.5 L/ha)	Standard 1 (1.5 L/ha)	Test product (3.0 L/ha)	Standard 1 (3.0 L/ha)
III 6.2.1/01 (S-M-PL-2022-182_02_F22_347) Maize	Volodia	14.23 t/ha	13.79 t/ha 97.1%	13.79 t/ha 97.2%	14.71 t/ha 103.8	14.1 t/ha 99.1%
III 6.2.1/03 (S-M-PL-2022-182_02_F22_349) Maize	SY Kardona	19.49 t/ha	19.52 t/ha 100.2%	19.85 t/ha 101.9%	19.52 t/ha 100.2	19.57 t/ha 100.5%
III 6.2.1/05 (S-M-PL-2022-182_02_F22_351) Maize	RGT Muxxeal	18.31 t/ha	18.29 t/ha 100.1%	18.3 t/ha 100%	18.27 t/ha 99.9	17.8 t/ha 97.3%

Table 3.4-6: Relationship between MEZ-HER 100 SC rate and yield (grain maize)

2 trials were carried out on grain maize in Poland, in 2022, on a range of commercially grown grain maize varieties. Grain yield of was analysed. Table below shows the results of grain yield.

Test report	Variety	Yield in the untreated control Absolute figures (unit)	Yield at 1N and 1.5N as % of untreated		Yield at 2N and 3N ~~(or other)~~ rate as % of untreated	
			Test product (1.5 L/ha)	Standard 1 (1.5 L/ha)	Test product (3.0 L/ha)	Standard 1 (3.0 L/ha)
III 6.2.1/02 (S-M-PL-2022-182_02_F22_348) Maize	DKC3787	10.9 t/ha	11.12 t/ha 102%	11.38 t/ha 104.4%	10.98 t/ha 100.7%	10.66 t/ha 97.8%
III 6.2.1/04 (S-M-PL-2022-182_02_F22_350) Maize	DKC3201	8.27 t/ha	8.28 t/ha 100.1%	8.22 t/ha 99.4%	8.22 t/ha 99.4%	8.29 t/ha 100.2%

Test report	Variety	Quality trait in the untreated control Absolute figures (unit)			Quality traits at 1N and 1.5 absolute figures and % of untreated						Quality traits at 2N and 3N absolute figures and % of untreated					
					Test product (1.5 L/ha)			Standard 1 (1.5 L/ha)			Test product (3.0 L/ha)			Standard 1 (3.0 L/ha)		
		Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)
III 6.2.1/02 (S-M-PL-2022-182_02_F22_348) Maize	DKC3787	28.8	266.65	72.43	29.5	268.35	72.3	29.7	266.75	72.35	29.7	267.58	72.43	29.6	267.83	72.28
III 6.2.1/04 (S-M-PL-2022-182_02_F22_350) Maize	DKC3201	27.45	280.35	69.68	27.8	279.05	70.8	27.73	281.45	71.18	27.8	275.05	71.03	28.08	273.03	71.15

In none of the efficacy and selectivity trials performed by the applicant, phytotoxicity have occurred. In selectivity trials, according to the statistical analysis, MEZ-HER 100 SC treatments did not have any negative impact on yield and its quality, when both 1.5N (1.5 L/ha) and ~~2~~ 3 N (3 L/ha) rates were used.

Comments for ZRMS:

ZRMs agree with Applicant. No negative relationship between MEZ-HER 100 SC rate and yield were noted during selectivity trials.

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

5 selectivity studies conducted in 2022 season in Poland, on green and grain maize varieties revealed that the product MEZ-HER 100 SC had no negative impact on quality of plants. Application of MEZ-HER 100 SC in a dose of 1.5 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 all of the efficacy the trials (6 trials total) no phytotoxic effect (changes in growth, plant height, tillering, dates of succeeding growth stages, thinning out of plants, discolorations, necroses, deformations) of MEZ-HER 100 SC, was recorded.

Comments for ZRMS:

Test report	Variety	Quality trait in the untreated control Absolute figures (unit)			Quality traits at 1N and 1.5 absolute figures and % of untreated						Quality traits at 2N and 3N absolute figures and % of untreated					
					Test product (1.5 L/ha)			Standard 1 (1.5 L/ha)			Test product (3.0 L/ha)			Standard 1 (3.0 L/ha)		
		Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)	Moisture (%)	TGW (g)	Hectolitre weight (kg)
III 6.2.1/02 (S-M-PL-2022-182_02_F22_348) Maize	DKC3787	28.8	266.65	72.43	29.5	268.35	72.3	29.7	266.75	72.35	29.7	267.58	72.43	29.6	267.83	72.28
III 6.2.1/04 (S-M-PL-2022-182_02_F22_350) Maize	DKC3201	27.45	280.35	69.68	27.8	279.05	70.8	27.73	281.45	71.18	27.8	275.05	71.03	28.08	273.03	71.15

Submitted trials are sufficient. Impact of Mecorn 100 SC (product code: MEZ-HER 100 SC) on the yield was evaluated during selectivity trials. Summary of the data on yield can be found in tables above. The evaluation was carried out in line to EPPO standards. No significant differences occurred. There were no statistically significant difference between the treatment objects and untreated samples. In selectivity trials, according to the statistical analysis, MEZ-HER 100 SC treatments did not have any negative impact on yield and its quality, when both 1.5 L/ha and 3 L/ha rates were used. So, **it can be concluded that no negative effect of yield is expected for recommended dose of 1.0 L/ha of Mecorn 100 SC**.

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 MEZ-HER 100 SC no processing trials were performed. There is no indication from agricultural practice that herbicides with the active substance mesotrione have affected the processing of harvested maize grains in the past. Furthermore, the test product is intended for application in BBCH 14-15 of maize, not close to harvest or after harvest.

Comments for ZRMS:

The effect of mesotrione on transformation processes in maize primarily involves its action as a herbicide. Mesotrione inhibits the enzyme HPDD, which plays a crucial role in the synthesis of carotenoid pigments in plants. The inhibition leads to the accumulation of toxic intermediates, resulting in bleaching and necrosis of plant tissues.

In terms of transformation processes in maize, mesotrione can affect various aspects of plant growth and

development. These effects may include:

- ✓ *Photosynthesis*: As mesotrione disrupts carotenoid synthesis, it can impair photosynthetic efficiency in maize plants, leading to reduced growth and yield. This inhibition can lead to the bleaching of plant tissues due to the accumulation of toxic intermediates, reducing chlorophyll levels and impairing photosynthesis.
- ✓ *Stress response*: maize plants treated with mesotrione may activate stress response pathways to cope with the herbicidal effects. This can influence the expression of genes involved in stress signalling and defence mechanisms. The herbicide's mode of action disrupts normal metabolic processes, weakling the plant's ability to respond effectively to external challenges. But, by controlling weeds, mesotrione can help minimize the spread of pests and diseases, reducing stress on maize crops and promoting healthier plant growth. Effective weed control with mesotrione can result in cleaner maize fields with fewer weed seeds contaminating harvested grain. This can improve the quality of maize grain and reduce post-harvest losses associated with weed infestations.
- ✓ *Hormonal regulation*: mesotrione exposure can alter the balance of plant hormones, such as auxins and cytokines, which play key roles in growth regulation and development. Disruption of hormonal pathways can impact various transformation processes, including cell division, elongation, and differentiation. These alternations may disrupt normal growth and development, leading to phenotypic abnormalities and reduced crop quality.
- ✓ *Metabolic processes*: mesotrione induced stress can affect metabolic pathways in maize leading to changes in the synthesis and accumulation of secondary metabolites, including phytoalexins and antioxidants. These alternations can impact on the plant defence mechanism and overall physiological responses.

The effect of mesotrione on transformation processes in maize is complex and multifaceted, involving interactions with various physiological and molecular pathways. Understanding these effects is essential for optimizing treatments and mitigating potential risks to maize production and crop performance.

While mesotrione's primary function is weed control, its indirect positive impacts on transformation processes in maize highlight its role in promoting more sustainable and efficient agricultural practices. However, it's essential to use herbicide responsibly and in conjunction with integrated weed management strategies to maximize their benefits while minimizing potential negative effects on the environment and human health.

Considering that product is applied at early stage of the crop and maize is not a typical crop used for subsequent processing, it could be agreed that no negative impact on processing is expected. The latest time of application for Mecorn 100 SC is crop growth stage BBCH 15. Since application of Mecorn 100 SC is made at an early stage in the crop's development there is no risk that the actives would be translocated to the grain. Also, the germination of maize seeds will be not negatively affected by the application of Mecorn 100 SCC, in the opinion of ZRMs.

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

2 studies conducted in 2022 season in Poland on grain maize varieties, revealed no negative impact of MEZ-HER 100 SC on propagation material – maize seeds.

Summary and conclusion

No adverse effects on treated plants such as phytotoxicity symptoms, negative impact on yield quality/ quantity and transformation processes were observed in efficacy and selectivity trials of MEZ-HER 100 SC.

Comments for ZRMS:

Mesotrione, primarily utilized as a herbicide, does not have direct positive effects on the propagating purposes of maize. Instead, its impact is primarily negative due to its herbicidal action, which targets broadleaf weeds.

Mesotrione targets weeds that compete with maize for resources such as nutrients, water and sunlight. While this is beneficial for maize growth, it does not directly impact maize propagation itself. Mesotrione can persist in the soil and may impact soil microbial communities, which play a crucial role in nutrient cycling and soil fertility. Disruption of these microbial communities could indirectly affect maize propagation by altering soil health and nutrient availability. Mesotrione, like other herbicides, can have environmental impacts if not used responsibly. Runoff of leaching of mesotrione into water bodies can harm aquatic ecosystems and potentially affects the availability of water resources for irrigation, which can indirectly impact maize propagation.

Mesotrione can indirectly benefit maize propagation by controlling weeds and reducing competition. It is essential to use mesotrione responsibly and in accordance with best management practices to minimize potential adverse impacts on maize propagation and overall agricultural sustainability.

The active substance – mesotrione is commonly used for many years in many countries. No adverse effects on parts of plant used for propagating purposes were reported. No adverse effect on the yield and its quality and no phytotoxicity symptoms were recorded in the field trials. Also, no information is available pointing to presence of any limitations to using of mesotrione in seed crops of maize. In the opinion of ZRMs, the product – Mecorn 100 SC (product code: MEZ-HER 1000 SC) may be used on maize.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

MEZ-HER 100 SC (containing mesotrione) is not harmful for succeeding plants since its active substance decomposes relatively quick (According to PPDB by University of Hertfordshire[2], DT_{90} values from field tests are in range between 36 and 78 days). Consequently, the product decomposes within the growing season without making any damage to succeeding plants. It is concluded that after the appropriate application of MEZ-HER 100 SC in maize, all the possible following crops can be grown when usual crop rotation and seedbed preparation is used.

Considering raised arguments and the fact that the literature does not say anything about the adverse impact on succeeding crops after application of herbicides containing this active substance, no specific plant-back restrictions related to MEZ-HER 100 SC are required. However, in case of the need to sift the treated plantation (as a result of crop damage by frost, disease or pest), only maize can be grown on the same field. After deep seedbed preparation (by ploughing) also sorghum can be grown on the same field.

Comments for ZRMS:

The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the mesotrione, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops. Therefore, the Applicant should presented the assessment of the possible effects of Mecorn 100 SC on crops grown as rotational or replacement crops following crops treated with that

[2] http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/442.htm

product, prepared in accordance with EPPO Standard Efficacy evaluation of plant protection product.

Effects on succeeding crops (PP 1/207(2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

The half-life (DT_{50}) for mesotrione in soil is short – about 16.4 days. Therefore, the impact on succeeding crops is unlikely to occur. No risk of phytotoxicity for succeeding crops is expected, in the opinion of ZRMs and lack of calculations of TER values submitted by the applicant based on ER_{10} values coming out from "Seedling Emergence and Seedling Growth test" can be accepted.

In the opinion of ZRMs, necessary precautions to prevent the negative impact on succeeding crops should be included in the label claim. Applicant included in the label project of Mecorn 100 SC information's from Callisto 100 SC which data are unprotected. **Detailed assessment of impact on succeeding crops is presented in section B7.** In the opinion of ZRMs those data can be used if both PPPs are comparable and its composition is the same. Also, if Section B7 assessed those data as valid. So, in the opinion of ZRMs following entry can be included in the label of Mecorn 100 SC:

"*In case of the need for early termination of a plantation treated with the agent (due to damage to maize by hail, diseases, pests, or frost), maize or perennial ryegrass can be cultivated in the field. After deep plowing, besides the aforementioned plants, sorghum can also be cultivated.*

After harvesting maize grown under normal vegetative conditions, treated with MECORN 100 SC herbicide no later than July 1st, and after deep plowing, all crops can be sown. In the case of cultivating sensitive plants such as sugar beet, legumes, winter rapeseed, common sunflower, and vegetables, as well as early-sown winter grains, damage may occur.

Under extremely unfavourable conditions (sandy soils, easily drying soils, soils with low pH (<6.0), soils with high organic matter content (>4.0%), low biological activity, exceptionally low temperatures in winter, exceptionally low soil moisture in summer and/or autumn and/or winter, overlap of sprayed surface with the preparation, excessively compacted soil), temporary whitening, growth inhibition, and reduced plant density in sensitive plants (sugar beets, legumes, common sunflowers, and vegetables) may occur. Therefore, cultivating the above-mentioned plants as successor crops is not recommended when the soil pH is significantly below 6.0, or if a prolonged drought period occurred after using the agent in the previous season. Deep plowing after maize cultivation and soil pH above 6.0 significantly reduce the risk of damage to these plants."

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 MEZ-HER 100 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 rules say that to avoids spray drift to adjacent crops the wind speed, the droplet size and positioning of the spray boom have to be taken into account. As MEZ-HER 100 SC is intended for control of mono and dicotyledonous weeds, the product may cause damages on mono (f.e. cereals) and dicotyledonous adjacent crops if it is misused.

Therefore, it is not expected that appropriate applications of MEZ-HER 100 SC will lead to adverse effects on adjacent crops.

Comments for ZRMS:

The impact of an herbicide containing mesotrione on adjacent crops can vary based on several factors, including the sensitivity of the crops, application rates, timing, environmental conditions, and the herbicide formulation. Mesotrione is a selective herbicide commonly used to control weeds in maize.

During application, mesotrione can drift or overspray onto adjacent crops, especially if not applied under

appropriate weather conditions or with proper equipment. Drift can lead to unintended herbicidal effects on sensitive crops, causing symptoms such as leaf discoloration, stunting, or even crop loss. Mesotrione residues in the soil may impose rotation restrictions on adjacent crops, particularly those sensitive to the herbicide or belonging to the same botanical family as the target weeds. Mesotrione applications as part of an integrated weed management strategy may have positive implications for adjacent crops by reducing weed pressure and competition. Effective weed control with mesotrione can improve resource availability for adjacent cops, potentially enhancing their growth and yield.

The impact on other plants including adjacent crops should be presented in line to EPPO 1/256. Applicant did not presented any data. No negative side effects on target or adjacent crops have been reported in the efficacy and selectivity trials or following use of Mecorn 100 SC. In conclusion, as MEZ-HER 100 SC is intended for control of mono and dicotyledonous weeds, the product may cause damages on mono (e.g. cereals) and dicotyledonous adjacent crops if it is misused.

Based on the probabilistic risk assessment, *to protect plants and non-target arthropods from the action of the agent, it is necessary to designate a protective zone with a width of: 20 meters, or 10 meters with simultaneous use of techniques reducing the drift of the working liquid during the treatment by 50%, or1 meter with simultaneous use of techniques reducing the drift of the working liquid during the treatment by 75%.* This impact is assessed by Section of Environmental Fate and/or Ecological section.

The information in this registration report and label warns against overlapping and drift of the spray liquid is sufficient in the opinion of ZRMs.

Tank cleaning

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

Comments for ZRMS:

ZRMs agree with Applicant.

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 MEZ-HER 100 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.

Comments for ZRMS:

Detailed assessment is presented in Ecotoxicology Section. However, in the opinion of ZRMs from Efficacy section – mesotrione can have direct and indirect effects on beneficial and non-target organisms in the environment. Mesotrione can be toxic to non-target organisms if they come into direct contact with the herbicide. This includes beneficial insects such as pollinators and natural enemies of pests. Direct exposure to mesotrione can lead to mortality or sub-lethal effects, such as reduced reproduction or impaired behaviour.

Mesotrione can indirectly affect non-target organisms through the food chain. Mesotrione residues in the

soil can affect soil microbial communities, earthworms, and other soil-dwelling organisms. Runoff or leaching of mesotrione into water bodies can pose risk to aquatic organisms at certain concentrations, potentially leading to acute or chronic effects on aquatic ecosystems. Even sub-lethal doses of mesotrione can have sub-lethal effects on non-target organisms, affecting their behaviour, physiology, and fitness. These effects may not be immediately apparent but can have long-term implications for population dynamics and ecosystem functioning.

It is essential to consider all potential effects when using mesotrione and to implement best management practices to minimize risks to beneficial and non-target organisms in the environment.

Summary and conclusion

Products which are containing mesotrione, have been used for many years, not only Poland but also in other European countries. According to current knowledge, MEZ-HER 100 SC does not pose any unacceptable risk to other plants also there was no adverse impact on beneficial organisms.

3.6 Other/special studies

Not relevant.

Comments for ZRMS:

Statement accepted.

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)
Fertico Sp. z o.o.	Goliany 43 05-620 Błędów	Yes

GŁÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENNICTWA

Tadeusz Kłos

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: jabłoń, grusza, śliwa, wiśnia, czereśnia, 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

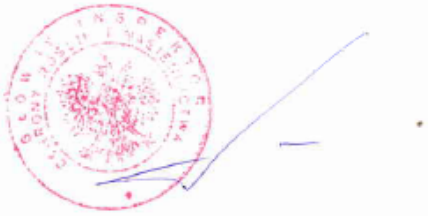
Pismem z dnia 13 kwietnia 2011 r. FERTICO Spółka z o.o. (Goliany 43; 05-620 Błędów), zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Nr 8/2008 z dnia 29 września 2008 r., zmienionej decyzjami

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.



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CERTIFIED TRANSLATION FROM POLISH

[*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] ----------

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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

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	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_340 GEP: Yes Published: No	N	Pestila*
KCP 3.2/02	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_341 GEP: Yes Published: No	N	Pestila*
KCP 3.2/03	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_343 GEP: Yes Published: No	N	Pestila*
KCP 3.2/04	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_344 GEP: Yes Published: No	N	Pestila*

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	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_345 GEP: Yes Published: No	N	Pestila*
KCP 3.2/06	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_346 GEP: Yes Published: No	N	Pestila*
KCP 3.4/01	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_347 GEP: Yes Published: No	N	Pestila*
KCP 3.4/02	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in grain maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_348 GEP: Yes Published: No	N	Pestila*
KCP 3.4/03	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_349 GEP: Yes Published: No	N	Pestila*
KCP 3.4/04	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in grain maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_350 GEP: Yes Published: No	N	Pestila*

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 3.4/05	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_351 GEP: Yes Published: No	N	Pestila*

* Pestila Spółka z ograniczoną odpowiedzialnością

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	Verte-brate 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	Verte-brate study Y/N	Owner