FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: JME-HER 12 OD

Product name: -

Chemical active substance:

Iodosulfuron-methyl-sodium, 2 g/L
Mesosulfuron-methyl, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: December 2023, revision: April 2024

MS Finalisation date: 25/04/2025

Version history

When	What
January 2024	Dossier sent for evaluation
04.2024	Update of dRR on evaluator's request
July 2024	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after 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:	Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. The parts of the text amended or added by the zRMS evaluator are highlighted in grey and the parts struck off are ~~visibly marked with the grey font.~~

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

Abstract

zRMS to provide main conclusions on each use. Indicate whether the overall assessment was performed according to the uniform principles. Overall summaries are not necessary here, as they will be provided at the end of each chapter of the dRR. The text of the abstract should complete the table below, by briefly explaining the reasons of the conclusions proposed (data missing, restrictions proposed, warnings...). For uses for which the proposed conclusion is “acceptable”, the text can be “zRMS considers that the data provided support the following uses: ...

dRR point 3.1	ZRMS conclusion
The overall assessment was performed according to the uniform principles. ZRMS considers that the data provided support the following uses: 1, 2, 3 presented in the GAP table. During the evaluation the unprotected efficacy data performed for Atlantis 12 OD was also used for JME-HER 12 OD. For both products the lower efficacy than at the national label classification of the reference product ATLANTIS 12OD was observed. It is proposed to conditionally accept weeds susceptibility classification presented on the label of reference product Atlantis 12 OD for the JME-HER 12 OD. To determine the confirmation of the efficacy of the JME-HER 12 OD in the scope of weed classification indicated on the Atlantis 12 OD label, it is suggested to submit additionally 2-3 trials each on the indicated weed species: - APESV, BRSNW, CAPBP, CHEAL, MATIN, ANTAR, STEME, THLAR, SINAR, MYOAR at the dose 0,45 l/ha; - AVEFA, BROSE, ALOMY at the dose 0,9 l/ha.	

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Winter wheat	F	Susceptible weeds (0,45-0,6l/ha): Field chamomile (*Anthemis arvensis*) ANTAR Wind grass (*Apera spica-venti*) APESV Oilseed rape (*Brassica napus*) BRSNN Shepherd's purse (*Capsella bursa-pastoris*) CAPBP Fat-hen (*Chenopodum album*) CHEAL Wild mustard (*Sinapis arvensis*) SINAR Common chickweed (*Stellaria media*) STEME Fanweed (*Thlaspi arvense*) THLAR Horse daisy (*Tripleurospermum inodorum*) MATIN Forget-me-not (*Myosotis arvensis*) MYOAR Susceptible weeds (0.9-1.2 L/ha): Common wild oat (*Avena fatua)* AVEFA Cheat grass (*Bromus secalinus*) BROSE Black twitch (*Alopecurus myosuroides*) ALOMY Moderately susceptible weeds: Field pansy (*Viola arvensis*) VIOAR Common poppy (*Papaver rhoeas*) PAPRH Speedwells (*Veronica Sp.)* 1VERG	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1		a) 0,45 - 1.2 l/ha b) 0,45 - 1.2 l/ha	a) 2.4 iodosulfuron 12 mesosulfuron - 0.9 iodosulfuron 4.5 mesosulfuron b) same as a)	200-300	not relevant		
2	Poland	Winter triticale												

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use -No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				Resistant weeds: Cleavers (*Galium aparine*) GALAP Knotgrasses (*Polygonum/Fallopia Sp.)* 1FOPG										
~~3~~	~~Poland~~	~~Winter wheat~~	F	Susceptible weeds (0.45-0.6 L/ha): Field chamomile (*Anthemis arvensis*) ANTAR Wind grass (*Apera spica-venti*) APESV Oilseed rape (*Brassica napus*) BRSNN Shepherd's purse (*Capsella bursa-pastoris*) CAPBP Fat-hen (*Chenopodium album*) CHEAL Wild mustard (*Sinapis arvensis*) SINAR Common chickweed (*Stellaria media*) STEME Fanweed (*Thlaspi arvense*) THLAR Horse daisy (*Tripleurospermum inodorum*) MATIN Forget-me-not (*Myosotis arvensis*) MYOAR	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	–	~~a~~) 0.45 L/ha b) 0.45 L/ha	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	not relevant		
~~4~~	~~Poland~~	~~Winter triticale~~												

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
~~5~~ 3	Poland	Rye		~~Moderately susceptible weeds:~~ ~~Field pansy (*Viola arvensis*) VIOAR~~ ~~Common poppy (*Papaver rhoeas*) PAPRH~~ ~~Speedwells (*Veronica Sp.*) 1VERG~~ ~~Resistant weeds:~~ ~~Cleavers (*Galium aparine*) GALAP~~ ~~Knotgrasses (*Polygonum/Fallopia Sp.*) 1FOPG~~ ~~Moderately susceptible (MS) at the dose rate 0,45 l/ha: SINAR~~										

* 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 JME-HER 12 OD according to Article 33 based on Article 34 of Regulation 1107/2009. JME-HER 12 OD is an oil dispersion (OD) formula, containing 2 g/L of iodosulfuron-methyl-sodium and 10 g/L of mesosulfuron-methyl to be used as a herbicide to protect cereals. This is a core dossier in order to allow the approval of product JME-HER 12 OD in Poland (zRMS).
The reference product to the product under the code JME-HER 12 OD is Atlantis 12 OD, that has been first registered in Poland according to authorisation Minister of Agricultural and Rural Development No. 98/2009 of August, 14th 2009 which means, that data protection, for the data presented by Atlantis 12 OD authorisation holder, for purposes of registration, has been expired.
According to the current Polish registration requirements, performing 1-2 trials for use is sufficient for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009.
In respect to the above and taking into account Polish requirements applicant provides five efficacy bridging trials to confirm that herbicidal properties of JME-HER 12 OD are comparable to properties of Atlantis 12 OD in protection of cereals against weeds.

Description of active substances

The active substances of the herbicide JME-HER 12 OD is iodosulfuron-methyl-sodium and mesosulfuron-methyl, 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

Iodosulfuron-methyl-sodium is a broad spectrum, post-emergence herbicide used throughout the world for treating wheat and other cereals. It is classified as an imidazolinone herbicide. Iodosulfuron-methyl-sodium inhibits the acetohydroxy acid synthase (AHAS) enzyme which is responsible for the synthesis of the branched chain amino acids valine, leucine, and isoleucine. When applied, Iodosulfuron-methyl-sodium halts weed growth which eventually kills the weed or causes the weed to die due to its incapability to compete with surrounding vegetation.

Metsulfuron-methyl is a residual sulfonylurea herbicide that kills broadleaf weeds and some annual grasses. It is a systemic compound with foliar and soil activity, that inhibits cell division in shoots and roots.

Iodosulfuron-methyl-sodium and mesosulfuron-methyl belongs to inhibitors of acetolactate synthase group of herbicides and belongs to HRAC group 2 (legacy B group).

Table 3.2-1: Details of the active substances

Active substance	Iodosulfuron-methyl-sodium	Mesosulfuron-methyl
Concentration	2 g/L	10 g/L
Chemical group	Sulfonylurea	Sulfonylurea
Mode of action	Acetolactate synthase inibition (ALS)	Acetolactate synthase inibition (ALS)
Biological action	Post-emergence herbicide	Post-emergence herbicide

Description of the plant protection product

JME-HER 12 OD is an oil dispersion (OD) containing 2 g/L iodosulfuron-methyl-sodium and 10 g/L mesosulfuron-methyl active substances.

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

Uses		Mem-ber State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	**Target(s)**			
Winter wheat, Winter triticale,	Field chamomile (*Anthemis arvensis*) ANTAR, Black twitch (*Alopecurus myosuroides*) ALOMY, Silky apera (*Apera spica*-venti) APESV, Common wild oat (*Avena fatua*) AVEFA, Cheat grass (*Bromus secalinus*) BROSE, Oilseed rape (*Brassica napus*) BRSNN, Shepherd's purse (*Capsella bursa*-pastoris) CAPBP, Fat-hen (*Chenopodium album*) CHEAL, Cleavers (*Galium aparine*) GALAP, False chamomile (*Tripleurospermum indorum*) MATIN, Forget-me-not (*Myosotis arvensis*) MYOAR, Common poppy (*Papaver rhoeas*) PAPRH, Wild mustard (*Sinapis arvensis*) SINAR, Common chickweed (*Stellaria media*) STEME, Fanweed (*Thlaspi arvense*) THLAR, Field pansy (*Viola arvensis*) VIOAR, Speedwells (*Veronica Sp.)* 1VERG, Knotgrasses (*Polygonum/Fallopia Sp.)* 1FOPG	PL	0.45 - 1 L/ha	-
Winter wheat, Winter triticale, Rye	Field chamomile (*Anthemis arvensis*) ANTAR, Silky apera (*Apera spica*-venti) APESV, Oilseed rape (*Brassica napus*) BRSNN, Shepherd's purse (*Capsella bursa*-pastoris) CAPBP, Fat-hen (*Chenopodium album*) CHEAL, Cleavers (*Galium aparine*) GALAP, False chamomile (*Tripleurospermum indorum*) MATIN, Forget-me-not (*Myosotis arvensis*) MYOAR, Common poppy (*Papaver rhoeas*) PAPRH, Wild mustard (*Sinapis arvensis*) SINAR, Common chickweed (*Stellaria media*) STEME, Fanweed (*Thlaspi arvense*) THLAR, Field pansy (*Viola arvensis*) VIOAR, Speedwells (*Veronica Sp.)* 1VERG, Knotgrasses (*Polygonum/Fallopia Sp.)* 1FOPG	PL	0.45 L/ha	-

The applicant carried out 5 efficacy trials on winter wheat, winter triticale, winter rye. 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*
ANTAR	***Anthemis arvensis***	**Field chamomile**
ALOMY	*Alopecurus myosuroides*	Black twitch
APESV	***Apera spica-venti***	**Silky apera**
AVEFA	*Avena fatua*	Common wild oat
BROSE	*Bromus secalinus*	Cheat grass
BRSNN	***Brassica napus***	**Oilseed rape**
CAPBP	***Capsella bursa-pastoris***	**Shepherd's purse**
CENCY	***Centaurea cyanus***	**Cornflower**
CHEAL	***Chenopodium album***	**Fat-hen**
GALAP	***Galium aparine***	**Cleavers**
MATIN	***Tripleurospermum inodorum***	**False chamomile**
MYOAR	*Myosotis arvensis*	Forget-me-not
POAAN	***Poa annua***	**Pathgrass**
PAPRH	***Papaver rhoeas***	**Common poppy**
PAPRS	***Papaver rhoeas subsp. strigosum***	**Common poppy**
SINAR	***Sinapsis arvensis***	**Kedlock**
STEME	***Stellaria media***	**Common chickweed**
THLAR	***Thlaspi arvense***	**Fanweed**
VIOAR	***Viola arvensis***	**Field pansy**
VICVP	***Vicia villosa subsp. ambigua***	**Downy vetch**
1FOPG	*Polygonum/Fallopia Sp.*	Speedwells
1VERG	*Veronica Sp*	Knotgrasses

* 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).

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

Total arable land area reached 8 700 000 ha

Crop:	Crop yield (t):	Sowing area (ha):
Wheat	13 400 000	2 500 000
Rye	2 300 000	700 000
Triticale	5 500 000	1 200 000

The above presented numbers show that sown area of winter wheat, barley, rye and triticale in total exceeded 3.77 mln ha in 2022. Comparing to the year 2021: winter wheat area increased by 7%, rye area sown

decreased by 13% and winter triticale decreased by 3%.

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

Weeds, which were present in field trials of JME-HER 12 OD are the known as serious cereals competitors. The results are showing that a lot of weeds can be controlled by the product.

Weeds presented in field trials	**Cereals** **Dose rate (L/ha)**
ANTAR *Anthemis arvensis* field chamomile	0.6-1.2
APESV *Apera spica-venti* silky apera	0.45-1.2
BRSNN *Brassica napus* oilseed rape	0.6-1,2
CAPBP *Capsella bursa-pastoris* shepherd's purse	0.6-1.2
CENCY *Centaurea cyanus* cornflower	0.45
CHEAL *Chenopodium album* fat-hen	0.45-1.2
GALAP *Galium aparine* cleavers	0.6-1.2
MATIN *Tripleurospermum inodorum* False chamomile	0.6-1.2
PAPRH *Papaver rhoeas* common poppy	0.6-1.2
PAPRS *Papaver rhoeas subsp. strigosum* common poppy	0.45
POAAN *Poa annua* pathgrass	0.45
SINAR *Sinapsis arvensis* kedlock	0.45
STEME *Stellaria media* common chickweed	0.45-1.2
THLAR *Thlaspi arvense* fanweed	0.6-1.2
VICVP *Vicia villosa subsp. ambigua* downy vetch	0.45
VIOAR *Viola arvensis* field pansy	0.45-1.2

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 sulfonylurea herbicides data available) such as herbicides, were commonly used in Poland. Sales of plant protection products (in commodity mass) such as herbicides, haulm destructors and moss killers aimed 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
Winter wheat, Winter triticale, Winter rye	X		Mono- and dicotyle-donous weeds	X	

Compliance with the Uniform Principles

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

Information on trials submitted (3.1 Efficacy data)

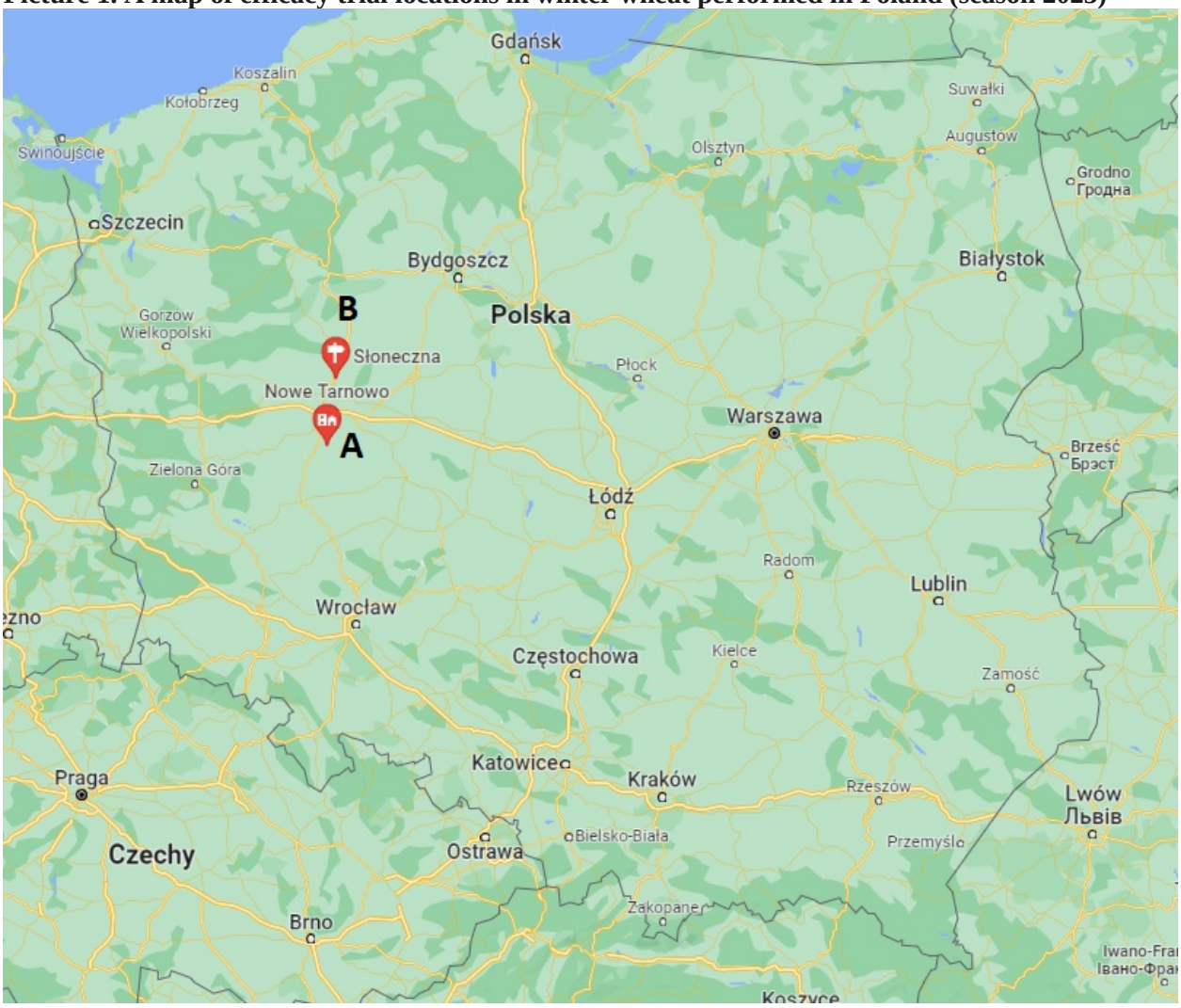
Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials...)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)	GEP, non-GEP, official***	Comments (any other relevant information)
					North-East zone		
Winter wheat	Dicot and monocot weeds	Poland	2023	E	2 (2)	GEP	-
Winter triticale	Dicot and monocot weeds	Poland	2023	E	1 (1)	GEP	-
Rye	Dicot and monocot weeds	Poland	2023	E	2 (2)	GEP	-
TOTAL	Dicot and monocot weeds	Poland	2023	E	5 (5)	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 JME-HER 12 OD herbicide were carried out during one growing season - 2023 in different regions of Poland. Map below presents locations of these trials.

Picture 1. A map of efficacy trial locations in winter wheat performed in Poland (season 2023)

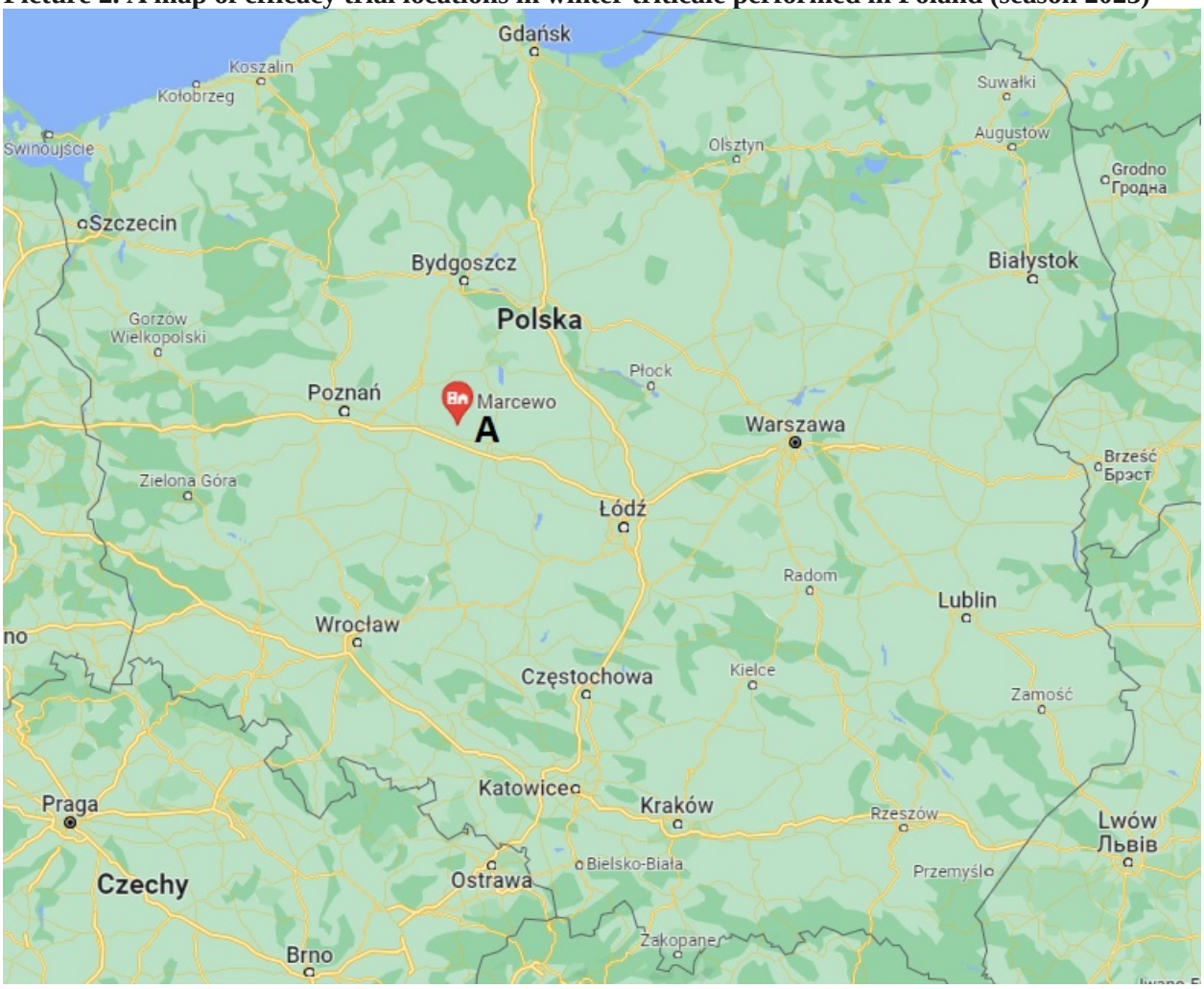


From total of five trials, two JME-HER 12 OD trails were set in winter wheat during 2023 season. All of them were performed in Poland. Trials were set in one voivodeship - Greater Poland.

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

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2023	PL	32_01_F23_059	Tarnowo Nowe	Julius	Clayly sand	6.9
B	2023	PL	32_02_F23_060	Słoneczna, Chludowo	Julius	Sandy silit	6.7

Picture 2. A map of efficacy trial locations in winter triticale performed in Poland (season 2023)

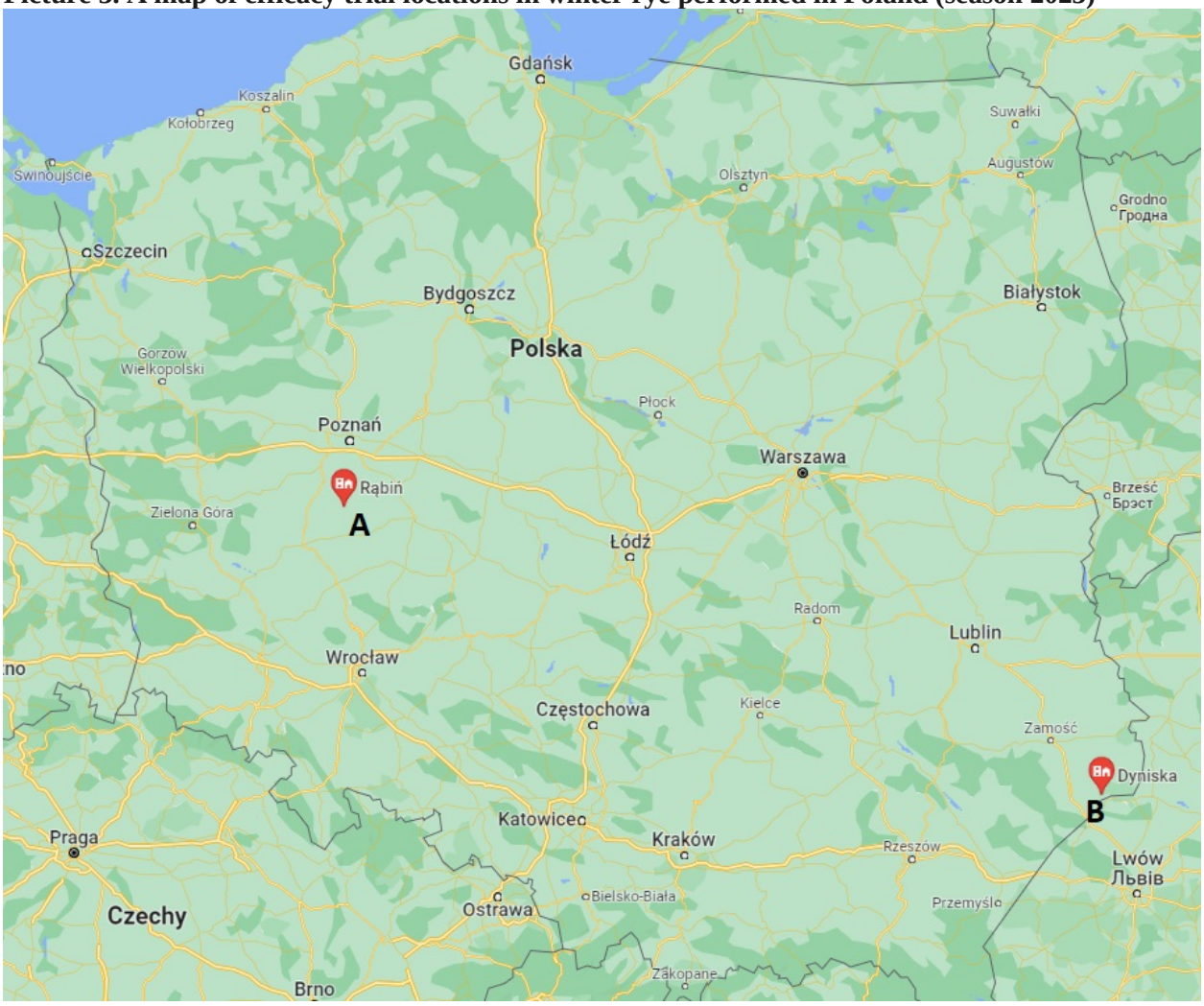


From total of five trials, one JME-HER 12 OD trail was set in winter triticale during 2023 season. It was performed in Poland. Trial was set in one voivodeship: Greater Poland.

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

	Year	Coun-try	Trial ID	Location	Variety	Soil type	pH
A	2023	PL	33_01_F23_061	Marcewo	Grenado	Sandy clay loam	6.4

Picture 3. A map of efficacy trial locations in winter rye performed in Poland (season 2023)



From total of five trials, two JME-HER 12 OD trails were set in winter rye during 2023 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	2023	PL	34_01_F23_062	Rąbiń	KWS Dolaro	Sand	5.8
B	2023	PL	34_02_F23_063	Dyniska	Bojko	Clayey sand	5.9

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 JME-HER 12 OD was done, during crop BBCH 29 and 34.
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 1/93(3) guideline “Weeds in cereals”.
Additional, third assessment, was done 41-50 days after the application of the product. This assessment is optional in the guideline 1/93(3), 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.

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.			
Winter wheat, Winter triticale,	Atlantis 12 OD	PL	R - 3/2023b	iodosulfu-ron-me-thyl-so-dium; mesosulfu-ron-methyl	OD	2 g/L; 10 g/L	0.45-1.2 L/ha	0.45-1.2 L/ha	1. application per season; 200 L/ha of spray volume; foliar spray
Winter rye	Atlantis 12 OD	PL	R - 3/2023b	iodosulfu-ron-me-thyl-so-dium; mesosulfu-ron-methyl	OD	2 g/L; 10 g/L	0.45 L/ha	0.45 L/ha	1. application per season; 200 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.).

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 JME-HER 12 OD, iodosulfuron-methyl-sodium and mesosulfuron-methyl has been commonly used in agricultural practice for many years.

3.2.2 Minimum effective dose tests (KCP 6.2)

Minimum effective dose tests were not carried out.

3.2.3 Efficacy tests (KCP 6.2)

A total of 5 trials were carried out in year 2023 to evaluate the efficacy of JME-HER 12 OD for the control of weeds in cereals, and compare it to the standard (Atlantis 12 OD) 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 1/93 (3), EPPO PP 1/135 (4), EPPO PP 1/152 (4), EPPO PP 1/181 (4).

Table 3.2-10: Details on methodology of efficacy trials in winter wheat

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/93 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	15-21 m²
	Number of replications	4
Crop	Trials per crop	Winter wheat (2)
	Varieties per crop	Julius
	Sowing period	29.09.2022 – 14.10.2022
Application	Crop stage (BBCH)* at application	BBCH 29-32
	Timing Pest stage at application (1)	ANTAR 14 APESV 12-14 BRSNN 16 CHEAL 24 GALAP 18 MATIN 16 PAPRH 15 STEME 18 VIOAR 18
	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, 14-16 DA-A, 28-29 DA-A, 41-50 DA-A,
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	1. Clayey sand, pH 6.9 2. Sandy silit, pH 6.7
	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

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

Table 3.2-11: Details on methodology of efficacy trials in winter triticale

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/93 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	21 m²
	Number of replications	4
Crop	Trials per crop	Winter triticale (1)
	Varieties per crop	Grenado
	Sowing period	28.09.2022
Application	Crop stage (BBCH)* at application	BBCH 30
	Timing Pest stage at application (1)	ANTAR 14 APESV 15 CAPBP 14 STEME 16 THLAR 14 VIOAR 18
	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 DA-A, 45 DA-A, 50 DA-A
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	1. Sandy clay loam, pH 6.4
	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

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

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

Guidelines	General guidelines	EPPO PP 1/135 (4), 1/152 (4), 1/181 (4),
	Specific guidelines	EPPO PP 1/93 (3)
Experimental design	Plot design	Randomized Complete Block RCBD
	Plot size	15 m²
	Number of replications	4
Crop	Trials per crop	Rye (2)
	Varieties per crop	KWS Dolaro, Bojko
	Sowing period	21.09.2022 – 24.09.2012
Application	Crop stage (BBCH)* at application	BBCH 30-34
	Timing Pest stage at application (1)	APESV 14 CENCY 13 CHEAL 12 PAPRS 18 POAAN 13 STEME 14-15 VICVP 17 VIOAR 12
	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 DA-A, 41-45 DA-A, 47 DA-A
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	1. Sand, pH 5.8 2. Clayey sand, pH 5.9
	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

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

Table 3.2-18: Efficacy of active substance components in JME-HER 12 OD trials in winter wheat and winter triticale

Grouping *	Number of trials	Infestation of the untreated control (number of plants)		% control								No of trials where JME-HER 12 OD at full recommended dose is >, <, = compared to standard(s)**
				JME-HER 12 OD iodosulfuron-methyl-sodium 1.2 g/ha, mesosulfuron-methyl 6 g/ha		**JME-HER 12 OD** iodosulfuron-methyl-sodium 2.4 g/ha, mesosulfuron-methyl 12 g/ha		**Atlantis 12 OD** iodosulfuron-methyl-sodium 1.2 g/ha, mesosulfuron-methyl 6 g/ha		**Atlantis 12 OD** iodosulfuron-methyl-sodium 2.4 g/ha, mesosulfuron-methyl 12 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	Plants/m²	Plants/m²	%	%	%	%	%	%	%	%	[-]
ANTAR	2	5.5	5-6	70.6	62.5-78.8	90.6	82.5-98.8	71.3	63.8-78.8	91.9	83.8-100	2 trial <
APESV	3	6	5-7	75.4	62.5-87.5	89.6	82.5-96.3	75.8	63.8-87.5	89.6	82.5-97.5	1 trial > 1 trial = 1 trial <
BRSNN	1	5	5-5	52.5	52.5-52.5	72.5	72.5-72.5	52.5	52.5-52.5	72.5	72.5-72.5	1 trial =
CAPBP	1	6	6-6	71.3	71.3-71.3	97.5	97.5-97.5	73.8	73.8-73.8	100	100-100	1 trial <
CHEAL	1	6	6-6	73.8	73.8-73.8	81.3	81.3-81.3	73.8	73.8-73.8	82.5	82.5-82.5	1 trial <
GALAP	1	6	6-6	72.5	72.5-72.5	83.8	83.8-83.8	72.5	72.5-72.5	83.8	83.8-83.8	1 trial =
MATIN	1	5	5-5	87.5	87.5-87.5	96.3	96.3-96.3	87.5	87.5-87.5	97.5	97.5-97.5	1 trial <
PAPRH	1	6	6-6	76.3	76.3-76.3	85	85-85	78.8	78.8-78.8	90	90-90	1 trial <
STEME	2	6	6-6	82.5	77.5-87.5	98.1	96.3-100	83.8	78.8-88.8	99.4	98.8-100	1 trial = 1 trial <
THLAR	1	6	6-6	76.3	76.3-76.3	97.5	97.5-97.5	77.5	77.5-77.5	98.9	98.8-98.8	1 trial <
VIOAR	1	6	6-6	78.8	78.8-78.8	86.3	86.3-86.3	78.8	78.8-78.8	88.8	88.8-88.8	1 trial <

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

** Optional

Table 3.2-19: Efficacy of active substance components in JME-HER 12 OD trials in winter rye ~~wheat and winter triticale~~

Grouping *	Number of trials	Infestation of the untreated control (number of plants)		% control								No of trials where JME-HER 12 OD at full recommended dose is >, <, = compared to standard(s)**
				JME-HER 12 OD iodosulfuron-methyl-sodium 0.54 g/ha, 2.7 mesosulfuron-methyl g/ha		**JME-HER 12 OD** iodosulfuron-methyl-sodium 0.72 g/ha, mesosulfuron-methyl 3.6 g/ha		**JME-HER 12 OD** iodosulfuron-methyl-sodium 0.9 g/ha, mesosulfuron-methyl 4.5 g/ha		**Atlantis 12 OD** iodosulfuron-methyl-sodium 0.9 g/ha, mesosulfuron-methyl 4.5 g/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
	[-]	Plants/m²	Plants/m²	%	%	%	%	%	%	%	%	[-]
APESV	2	7.4	6.8-8	58.8	52.5-65	67	57.5-76.5	81.6	73.8-89.5	82.8	75-90.5	2 trial <
CENCY	1	5.8	5.8-5.8	45	45-45	55	55-55	71.5	71.5-71.5	71	71-71	1 trial >
CHEAL	1	7	7-7	63	63-63	75	75-75	88	88-88	89	89-89	1 trial <
PAPRS	1	6	6-6	46.3	46.3-46.3	47.5	47.5-47.5	63.8	63.8-63.8	63.8	63.8-63.8	1 trial =
POAAN	1	5	5-5	63.5	63.5-63.5	73	73-73	91	91-91	90.5	90.5-90.5	1 trial >
SINAR	1	5	5-5	52.5	52.5-52.5	53.8	53.8-53.8	82.5	82.5-82.5	82.5	82.5-82.5	1 trial =
STEME	2	7.5	7-8	59.6	46.3-73	66	47.5-84.5	79.1	63.8-94.5	78.4	63.8-93	1 trial > 1 trial =
VICVP	1	10	10-10	63.8	63.8-63.8	62.5	62.5-62.5	73.8	73.8-73.8	73.8	73.8-73.8	1 trial =
VIOAR	1	7.3	7.3-7.3	23.5	23.5-23.5	33	33-33	43	43-43	44.5	44.5-44.5	1 trial <

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

** Optional

According to statistical analysis, data assessed in trials demonstrated that the efficacy of JME-HER 12 OD in control of weeds in winter wheat and winter triticale at the rate of 1.2 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of reference product – Atlantis 12 OD – used in rate of 1.2 L/ha. In control of weeds in winter rye at the rate of 0.45 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of reference product – Atlantis 12 OD – used in rate of 0.45 L/ha. More efficacy results for Atlantis 12 OD are shown in the Polish registration report for this product, to which the applicant gained access through the application to the Ministry of Agriculture and Rural Development to be provided with the Atlantis 12 OD registration report and data for which data protection have expired.

Minor use

Not relevant.

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

5 trials total were conducted to confirm efficacy of JME-HER 12 OD in control of dicotyledonous and monocotyledonous weeds in winter cereals. The selectivity trials for JME-HER 12 OD haven't been provide by the applicant, since they are not required for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. Taking into account Polish requirements applicant provides five efficacy bridging trials to confirm that herbicidal properties of JME-HER 12 OD are comparable to properties of Atlantis 12 OD in protection of cereals against weeds. Since the compositions of JME-HER 12 OD and Atlantis 12 OD are comparable, it has been assumed that the properties of both product on yield will be comparable.

Summary and conclusion

5 trials total were conducted to confirm efficacy of JME-HER 12 OD in control of dicotyledonous and monocotyledonous weeds in winter cereals. JME-HER 12 OD showed its effectiveness in control of weed species listed below, in winter wheat, winter triticale and winter rye at the proposed label rates:

0.45-0.6 L/ha –
Susceptible weeds:
Field chamomile *Anthemis arvensis*;
Silky apera *Apera spica-venti*;
Oilseed rape *Brassica napus*;
Shepherd's purse *Capsella bursa-pastoris*;
Fat-hen *Chenopodium album*;
False chamomile *Tripleurospermum indorum*;
Forget-me-not *Myosotis arvensis*;
Wild mustard *Sinapis arvensis*;
Common chickweed *Stellaria media*;
Fanweed *Thlaspi arvense*;

0.9-1.2 L/ha –
Susceptible weeds:
Cheat grass *Bromus secalinus*;
Black twitch *Alopecurus myosuroides*;
Common wild oat *Avena fatua*;

Moderately susceptible weeds:
Common poppy *Papaver rhoeas*;
Field pansy *Viola arvensis;*
Speedwells *Veronica Sp.;*

Resistant weeds:
Cleavers *Galium aparine*;
Knotgrasses *Polygonum/Fallopia Sp.*

dRR point 3.2.3	ZRMS conclusion

Control of dicot and monocot weeds in PL

To support authorization of the product JME-HER 12 OD considering Art. 34 of the Regulation 1107/2009, the applicant submitted 5 trials carried out in winter wheat, winter triticale (1 trial) and rye (2 trials) in 2023, in two regions of Poland against dicot and monocot weeds:

- winter wheat 2 trials, BBCH: 29-32, spray volume 200 l/ha
- winter triticale – 1 trial, BBCH: 30, spray volume 200 l/ha
- rye - 2 trials, BBCH 30-34, spray volume 200 l/ha

The reference product for which the applicant refers to unprotected data is Atlantis 12 OD.

Efficacy trials were carried out by organizations that are officially recognized as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013. All trials have been conducted according to GEP.
The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:
1. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
2. PP 1/135 (4) Phytotoxicity assessment
3. PP 1/152 (4) Design and analysis of efficacy evaluation trials
4. PP 1/93 (3) Weeds in cereals
Trials were of randomized block design with a minimum of four replicates.

Weed species are classified as:

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

The tested product and the reference product were applied at dose rates 0.45; 0.6; 1.2 l/ha. JME-HER 12 OD product was also tested at two lower rates: 0,36 l/ha and 0,27 l/ha. The two dose rates are not place on the label of the reference product and results for these two doses were not taken into account during evaluation.

In all bridging trials, the efficacy of the product tested was comparable to the reference product Atlantis 12 OD when applied at dose rates 0.45; 0.6; 1.2 l/ha. Nevertheless, both products (JME-HER 12 OD and the reference product) showed lower efficacy against most tested weed species in bridging trials compared to weeds susceptibility classification presented on the label currently authorised reference product Atlantis 12 OD. The noticed decrease in efficacy may indicate potential resistance to the active substances.
For both products the lower efficacy than at the national label classification of the reference product ATLANTIS 12OD was observed:
- at the dose rate 0,45 l/ha, against the following weed species: APESV, STEME, SINAR
- at the dose rate 0,6 l/ha, against the following weed species: ANTAR, APESV, BRSNW, CAPBP, CHEAL, STEME, THLAR.
What is more following weed species, recognised susceptible on the reference product label were not tested in bringing trials:
- at the dose 0,45 l/ha: ANTAR, BRSNW, CAPBP, MATIN, THLAR, MYOAR.
- at the dose 0,9 l/ha: AVEFA, BROSE, ALOMY
Taking into consideration the fact that for majority of weed species one efficacy result each was presented it may not be sufficient to conclude about efficacy of both products in above clarified situation.

Therefore it is proposed to conditionally accept weeds susceptibility classification presented on the label of reference product Atlantis 12 OD for the JME-HER 12 OD.
To determine the confirmation of the efficacy of the JME-HER 12 OD in the scope of weed classification indicated on the Atlantis 12 OD label, it is suggested to submit additionally 2-3 trials each on the indicated weed species:

- APESV, BRSNW, CAPBP, CHEAL, MATIN, ANTAR, STEME, THLAR, SINAR, MYOAR at the dose 0,45 l/ha;
- AVEFA, BROSE, ALOMY at the dose 0,9 l/ha.

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

According to the HRAC code list active substances of JME-HER 12 OD - iodosulfuron-methyl-sodium and mesosulfuron-methyl, both are an ALS-inhibiting herbicide (Chemical Family: Sulfonylurea) classified in Group 2. ALS is a key enzyme re-sponsible for biosynthesis of amino acids such as valine, leucine and isoleucine. Susceptible weeds ex-posed to iodosulfuron-methyl-sodium and mesosulfuron-methyl show various injuries as: inhibition of plant growth, shortening of internodes, purplish foliage, and shortening of lateral roots, resulting in plant death, caused by deficiency in branched-chain amino acids.
ALS-inhibiting herbicides are used in all major agronomic crops and have been widely adopted due to their low dose rates and high efficacy against a broad spectrum of weeds, relatively low mammalian toxicity, mild toxicological profile, and excellent crop selectivity. However, the widespread use of ALS-inhibiting herbicides led to rapid selection of many resistant weed populations. ALS-resistant weeds represent the fastest-growing group of herbicide-resistant weeds worldwide.

Mode of Action

Iodosulfuron-methyl-sodium and mesosulfuron-methyl belong to the chemical group of the sulfonylurea herbicides (SUs). The two herbicides inhibit the acetolactate synthase enzyme (ALS) and as a result both prevent the formation of branched chain amino acids (leucine, isoleucine and valine). Branched-chain amino acids, like valine, leucine and isoleucine are required components of the growth processes. By blocking ALS and preventing branched-chain amino acid production, sulfonylurea herbicides rapidly inhibit cell division at the root and shoot tips. After application of the product, sensitive grasses and broad-leaved weeds do not develop any significant further growth - therefore weed competition stops - and they die three to six weeks later. According to the Herbicide Resistance Action Committee (HRAC), iodosulfuron-methyl-sodium and mesosulfuron-methyl are classified as Group B herbicides. This chemical group contains five different chemical subgroups, which differentiate in patterns of resistance development and cross-resistance patterns.

Mechanism of Resistance

The major resistance mechanisms reported in literature for ALS inhibiting herbicides are due to target site mutations and herbicide metabolism. Taking in account target site resistance mechanism to ALS, 18 amino acid residues are involved in herbicide binding (McCourt et al., 2006), structurally different ALS herbicides orientate differently in the herbicide binding domain, with partial overlap. Thus, a particular amino acid substitution within the herbicide binding domain can confer resistance to some but not to all ALS herbicides (Powles and Yu, 2010). Metabolic resistance is less predictable and therefore the cross-resistance patterns vary more among different resistant weeds (Delye et al., 2013).
Fitness cost is associated to the some of the amino acid substitution involved in target site resistance (Vila-Aiub et al., 2009b). Iodosulfuron-methyl-sodium and mesosulfuron-methyl can be affected by target site and metabolic resistance mechanisms.

Cross Resistance

Cross-resistance among ALS inhibitors and to different mode of action is quite common worldwide.

Evidence of Resistance, Sensitivity Data and Resistance Risk

ALS inhibitors have selected more resistant weeds than any other herbicide group mainly because of three reasons: there are many ALS inhibitor herbicides (over 55 actives in 5 chemical classes, twice as many as any other herbicide group), they are used extensively for more than 30 years and they are used on a greater area annually than any other herbicide group. Moreover, ALS inhibitors exert a strong selection pressure because they have very high activity on sensitive biotypes and they also have soil residual activity (Heap, 2014). There are now 160 weed species that have evolved resistance to the diverse ALS inhibitors, 98 cases involving iodosulfuron-methyl-sodium and 73 cases regarding mesosulfuron-methyl (Heap, 2019). Due to long use of ALS inhibitors in Europe and therefore the long exposure of key weeds to these herbicides, data on initial sensitivity are not available. The information available on the diffusion of resistance among ALS-inhibiting herbicides leads to suggest a high inherent risk.

JME-HER 12 OD is a mixture of two compounds with the same mode of action. The resistance risk and resistance dynamics in weeds are determined by a range of factors, which will be described in the following sections as far as they are relevant and known. It is of considerable importance to resistance evolution whether a target organism already has evolved a resistance mechanism against the new compound mode of action or not. The presence of cross-resistance to other compounds or mode of action groups has also to be taken into account.

Depending on the weed phonological stage, JME-HER 12 OD is a powerful herbicide to give effective control in winter and spring cereals to a wide range of broadleaves and grasses. No sensitivity data are available for JME-HER 12 OD. Field efficacy data demonstrate the efficacy of the product under near-practical conditions and the field data will be considered a measure of sensitivity for future reference (Anonymous, 2015).
From the field trials results presented in the biological dossier, JME-HER 12 OD provide a high efficacy on all the major dicotyledonous weeds and grasses found in cereals.

The information available on the diffusion of resistance among the two herbicides alone and the cross-resistance pattern lead to suggest a high inherent risk but a reasonable practical risk of selecting resistant biotypes when the product is used following the good agronomic practices.

Acceptability of the Resistance Risk

The resistance risk analysis takes in account the inherent risk of selecting resistant weeds to the product under unrestricted conditions as well as the effect of appropriate measures to be implemented to mitigate the resistance risk (based on EPPO Standard PP 1/213(4) 'Resistance Risk Analysis'; Anonymous, 2015). When the product is used following the label indications (i.e. one application per year) and rotated with herbicides having different modes, the selection pressure exerted by JME-HER 12 OD will be extremely reduced. Based on these assumptions and according to the section 5.2 of the EPPO Standard PP 1/213(4) 'Resistance Risk Analysis' (Anonymous, 2015), the magnitude of the risk of resistance is considered acceptable when the product is used following the label indications.

Resistance Management Strategy and Use Pattern

In terms of resistance management it is advisable to diversify the tactics and the herbicides used for controlling weeds. Depending on the population size, resistance to an herbicide naturally occurs in few rare individuals within a weed population. Nevertheless, in terms of probability it is unlikely to find an individual plant that can survive two or more herbicides belonging to different mode of action. Therefore, to decrease the risk of selecting resistant weeds, the application of an additional herbicide belonging to a different mode of action and having high efficacy on the species to be controlled is recommendable. In this context the use of JME-HER 12 OD is supported considering the product already registered in winter and spring cereals.

Since the inherent resistance risk of JME-HER 12 OD can be considered high, it is recommended to use the product in alternation or in combinations with compounds having a different mode of action. To avoid the selection of resistance it is recommended to perform one application JME-HER 12 OD at the recommended dose(s) per season.

Communication and Implementation of the Management Strategy

The anti-resistance strategy for the product JME HER 12 OD will be communicated to the advisory and at farmer's level essentially on the label. In addition, leaflets and brochures that describe the product properties in a detailed manner contain the essential anti-resistance strategy points.[1]

dRR point 3.3	ZRMS conclusion

According to https://www.weedscience.com/Home.aspx, 60 resistant strains of various weed species have been reported so far in Europe (table below). Both substances are high risk substances for the development of resistance among target organisms. The label of the product should contain recommendations of HRAC resistance management strategy should prevent from development resistance to the herbicide.

Year	Species	Country	Actives	Situations
2019	*Apera spica-venti*	Belgium	iodosulfuron-methyl-Na, foramsulfuron, mesosulfuron-methyl	Wheat
2005	*Apera spica-venti*	Czech Republic	sulfosulfuron, chlorsulfuron, isoproturon, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Cereals, Winter wheat
1991	*Stellaria media*	Denmark	chlorsulfuron, tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Spring Barley, Wheat
2001	*Alopecurus myosuroides*	Denmark	clodinafop-propargyl, fenoxaprop-ethyl, cycloxydim, flupyrsulfuron-methyl-Na, pendimethalin, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Winter wheat
2003	*Papaver rhoeas*	Denmark	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Wheat
2010	*Lolium perenne ssp. multiflorum*	Denmark	clodinafop-propargyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Winter wheat
2010	*Tripleurospermum perforatum (=T. inodorum)*	Denmark	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Spring Barley, Winter wheat

[1] Draft Registration Report, Part B, Section 3, Efficacy Data and Information, „iodosulfuron-methyl-sodium + mesosulfuron methyl (2+10)", Anonymus, 12.2019, Revision 03.2020.

2011	*Apera spica-venti*	Denmark	sulfosulfuron, iodosulfuron-methyl-Na	Winter wheat
2016	*Lolium perenne*	Denmark	clodinafop-propargyl, iodosulfuron-methyl-Na	Wheat
2016	*Apera spica-venti*	Denmark	fenoxaprop-ethyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Wheat
2003	*Alopecurus myosuroides*	France	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, sethoxydim, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2003	*Lolium perenne ssp. multiflorum*	France	haloxyfop-methyl, clodinafop-propargyl, diclofop-methyl, sethoxydim, flupyrsulfuron-methyl-Na, iodosulfuron-methyl-Na, mesosulfuron-methyl, propoxycarbazone-Na	Wheat
2006	*Apera spica-venti*	France	iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Wheat
2006	*Avena sterilis*	France	metsulfuron-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Wheat
2006	*Avena fatua*	France	metsulfuron-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Wheat
2006	*Alopecurus myosuroides*	France	imazamethabenz-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2006	*Lolium rigidum*	France	flupyrsulfuron-methyl-Na, iodosulfuron-methyl-Na, mesosulfuron-methyl, propoxycarbazone-Na	Wheat
2007	*Papaver rhoeas*	France	metsulfuron-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2009	*Bromus sterilis*	France	iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam, propoxycarbazone-Na	Wheat
2009	*Senecio vulgaris*	France	tribenuron-methyl, prosulfuron, metsulfuron-methyl, flazasulfuron, imazamox, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, thiencarbazone-methyl	Grapes, Wheat
2012	*Poa trivialis*	France	iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2012	*Stellaria media*	France	thifensulfuron-methyl, metsulfuron-methyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2015	*Poa annua*	France	iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2016	*Papaver rhoeas*	France	metsulfuron-methyl, MCPA, 2,4-D, iodosulfuron-methyl-Na, mesosulfuron-methyl, aminopyralid	Cereals
2016	*Conyza sumatrensis*	France	flazasulfuron, iodosulfuron-methyl-Na, mesosulfuron-methyl, penoxsulam	Grapes
2016	*Conyza sumatrensis*	France	flazasulfuron, glyphosate, iodosulfuron-methyl-Na, mesosulfuron-methyl, penoxsulam	Grapes
2005	*Apera spica-venti*	Germany	sulfosulfuron, chlorsulfuron, flupyrsulfuron-methyl-Na, sulfometuron-methyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Wheat
2007	*Alopecurus myosuroides*	Germany	fenoxaprop-ethyl, isoproturon, chlorotoluron, flufenacet, mesosulfuron-methyl, pinoxaden	Wheat
2008	*Lolium perenne*	Germany	iodosulfuron-methyl-Na, pinoxaden, pyroxsulam	Wheat

2009	*Apera spica-venti*	Germany	fenoxaprop-ethyl, sulfosulfuron, isoproturon, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden, pyroxsulam	Spring Barley, Winter wheat
2009	*Alopecurus myosuroides*	Germany	fenoxaprop-ethyl, cycloxydim, flupyrsulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Cereals
2009	*Avena fatua*	Germany	fenoxaprop-ethyl, cycloxydim, flupyrsulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Sugar beets
2011	*Stellaria media*	Germany	thifensulfuron-methyl, amidosulfuron, triflusulfuron-methyl, tribenuron-methyl, nicosulfuron, imazamox, florasulam, iodosulfuron-methyl-Na, tritosulfuron, mesosulfuron-methyl, pyroxsulam	Spring Barley, Wheat, Rapeseed
2002	*Papaver rhoeas*	Greece	2,4-D, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2021	*Poa annua*	Ireland	propaquizafop, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden, pyroxsulam	Wheat
2021	*Alopecurus myosuroides*	Ireland	propaquizafop, cycloxydim, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2021	*Lolium perenne ssp. multiflorum*	Ireland	propaquizafop, cycloxydim, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Wheat
1998	*Papaver rhoeas*	Italy	tribenuron-methyl, 2,4-D, iodosulfuron-methyl-Na	Wheat
1998	*Papaver rhoeas*	Italy	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Durum wheat
2002	*Lolium perenne ssp. multiflorum*	Italy	clodinafop-propargyl, diclofop-methyl, sethoxydim, tralkoxydim, cycloxydim, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Durum wheat
2004	*Avena sterilis*	Italy	clodinafop-propargyl, cycloxydim, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Durum wheat
2005	*Lolium perenne ssp. multiflorum*	Italy	iodosulfuron-methyl-Na, mesosulfuron-methyl	Durum wheat
2006	*Sinapis arvensis*	Italy	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Durum wheat
2007	*Avena sterilis*	Italy	iodosulfuron-methyl-Na, mesosulfuron-methyl	Durum wheat
2012	*Lolium perenne ssp. multiflorum*	Italy	glyphosate, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
2015	*Apera spica-venti*	Latvia	iodosulfuron-methyl-Na	Wheat, Winter wheat
2013	*Apera spica-venti*	Lithuania	iodosulfuron-methyl-Na	Winter wheat
2005	*Apera spica-venti*	Poland	sulfosulfuron, chlorsulfuron, iodosulfuron-methyl-Na, procarbazone-Na	Winter wheat
2010	*Alopecurus myosuroides*	Poland	iodosulfuron-methyl-Na, mesosulfuron-methyl	Winter wheat
2011	*Avena fatua*	Poland	sulfometuron-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl, propoxycarbazone-Na	Spring Barley, Spring wheat

2011	*Avena fatua*	Poland	fenoxaprop-ethyl, metsulfuron-methyl, sulfometuron-methyl, iodosulfuron-methyl-Na, pinoxaden, propoxycarbazone-Na	Spring Barley, Spring wheat
2012	*Alopecurus myosuroides*	Poland	fenoxaprop-ethyl, sulfometuron-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Winter wheat
2007	*Sinapis alba*	Spain	tribenuron-methyl, iodosulfuron-methyl-Na	Winter wheat
2011	*Sinapis arvensis*	Spain	tribenuron-methyl, iodosulfuron-methyl-Na	Cereals
2015	*Alopecurus myosuroides*	Spain	clodinafop-propargyl, cloransulam-methyl, isoproturon, chlorotoluron, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Wheat, Canola, Peas, Winter barley, Faba beans
2018	*Rapistrum rugosum*	Spain	tribenuron-methyl, iodosulfuron-methyl-Na	Winter wheat, Winter barley
2010	*Apera spica-venti*	Sweden	sulfosulfuron, iodosulfuron-methyl-Na, pyroxsulam	Winter wheat
2011	*Papaver rhoeas*	Sweden	amidosulfuron, iodosulfuron-methyl-Na, propoxycarbazone-Na	Winter wheat
2014	*Alopecurus myosuroides*	Sweden	fenoxaprop-ethyl, cycloxydim, flupyrsulfuron-methyl-Na, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Spring wheat, Winter wheat, Winter barley

3.4 Adverse effects on treated crops (KCP 6.4)

The selectivity trials for JME-HER 12 OD haven't been provide by the applicant, since they are not required for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. Taking into account Polish requirements applicant provides five efficacy bridging trials to confirm that herbicidal properties of JME-HER 12 OD are comparable to proper-ties of Atlantis 12 OD in protection of cereals against weeds. Since the compositions of JME-HER 12 OD and Atlantis 12 OD are comparable, it has been assumed that the properties of both product on yield will be comparable.

Analysis the obtained results, it can be concluded that Atlantis 12 OD used in the dose range from 0.45 L/ha to 2.4 L/ha is safe for the tested winter wheat varieties, and the phytotoxicity symptoms that occur are transient and usually occurred when the highest doses were used or in unfavourable weather conditions. The tested plant protection product did not cause significant differences between control objects (without protection) and objects where the comparison plant protection product was used.
In the case of winter triticale and rye, no adverse effects were noted on any of the tested varieties, regardless of the dose used.[2]

[2] Instytut Ochrony Roślin-Państwowy Instytut Badawczy, „Ocena skuteczności działania środka ochrony roślin Atlantis 12 OD", Anonymus, 2008, (translated into English).

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Table 3.4-1: Phytotoxicity of product to cereals

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

In the efficacy trials no phytotoxicity was observed in each of tested rates.
The selectivity trials for JME-HER 12 OD haven't been provide by the applicant, since they are not required for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. Taking into account Polish requirements applicant provides five efficacy bridging trials to confirm that herbicidal properties of JME-HER 12 OD are comparable to properties of Atlantis 12 OD in protection of cereals against weeds. Since the compositions of JME-HER 12 OD and Atlantis 12 OD are comparable, it has been assumed that the properties of both product on phytotoxicity to host crop will be comparable.

The following winter wheat varieties treated with recommended doses of 0.45 L/ha and 0.6 L/ha and double doses of 0.9 and 1.2 L/ha were evaluated in the trials: Tonacja, Mikon, Mewa, Zyta (two locations), Korweta (two locations), Turnia, Kobra. In the case of assessing the phytotoxicity of the recommended dose of 1.2 L/ha and a double dose of 2.4 1/ha, the reactions of the following winter wheat varieties were tested: Symfonia, Tonacja (two locations), Kobra, Kris.

For assessing the selectivity of winter triticale to the plant protection product used at the recommended dose of 0.6 L/ha and a double dose of 1.2 L/ha, the following varieties were used: Prado, Bogo (2 locations), Magnat, Fidelio. The Bogo variety was used to test the selectivity of winter triticale to the highest recommended dose, i.e. 1.2 L/ha and a double dose of 2.4 L/ha.

To assess the sensitivity of rye to Atlantis 12 OD applied at a dose of 0.6 L/ha and at a double dose of 1.2 L/ha, the following varieties were used: Dańkowskie Złote, Marder, Nawid, Skat.

The tests were carried out in accordance with the EPPO guidelines for assessing the effectiveness of plant protection products, i.e. standard PP1/135(2) - Phytotoxicity assessment. The control object were mechanically weeded plots, while the reference plant protection product and the tested substances were used in recommended doses and doses doubled in relation to the recommended doses.

In winter wheat plants treated with doses of 0.45 L/ha and 0.6 1/ha and double doses of 0.9 L/ha and 1.2 L/ha, no damage was observed, except for the Mikon variety tested by SGGW Warsaw, where on the sprayed plots with reference doses, 2% of changes were observed, and in plots sprayed with double doses, 5% of changes were observed, the changes disappeared 2 weeks after the treatment. The adverse effect of the plant protection product on the crop could be caused by the weather conditions that prevailed in the spring in Chylice, where the experiment was conducted - a long winter and a cold spring. The use of Atlantis 12 OD at the recommended doses, i.e. 0.45 1/ha and 0.6 L/ha, did not result in a reduction in yield and yield parameters in any of the tested winter wheat varieties. The use of double doses, i.e. 0.9 L/ha and 1.2 L/ha, resulted in a yield reduction: Mewa variety by 4-6%, Zyta 0 variety by 1-5%, Korweta. The use of

Atlantis 12 OD at the recommended dose of 1 1/ha and at a double dose of 2.4 L/ha did not cause damage to winter wheat plants, except for the Kobra variety, which reacted with transient chlorosis and growth inhibition to the double dose - 1.4% changes. The dose of 1 1/ha and the double dose of 2.4 L/ha had no effect on the yield and its parameters in the tested winter wheat varieties, except for the Kobra variety, in which the dose of 2.4 L/ha resulted in a significant decrease in the thousand-grain weight and density. grain, but did not affect the yield.

In winter triticale, the recommended dose of 0.6 L/ha and a double dose of Atlantis 12 OD did not have a phytotoxic effect on the crop and did not have a significant impact on the yield and yield parameters of the following varieties: Prado, Bogo, Magnat and Fidelio. The winter triticale variety Bogo (IOR Winna Góra) did not react negatively to the applied doses of 1.2 L/ha and 2.4 1/ha.

In the rye varieties Dańkowskie Złote, Marder, Nawid and Skat, Atlantis 12 OD applied at the recommended dose of 0.6 L/ha and a double dose did not have a negative effect on the crop and the yield, and even in the Nawid variety tested in the IOR (Winna Góra) at Using a double dose, the yield was significantly higher than in the control plant.

Atlantis 12 OD - selectivity, list of tests performed in the years 2004-2005

Lp.	Autor	Rok	Nr sprawozdania	Lokalizacja	Gatunek zboża	GEP	Uznano
1.	dr J.Grabiński, dr P. Nieróbca, dr E. Szeleźniak – IUNG Puławy	2004	23/2004	RZD Osiny	pszenica ozima	Tak	Tak
				RZD Osiny	pszenica ozima	Tak	Tak
2.	dr Z. Łęgowiak - SGGW	2004	2/2004	Chylice	pszenica ozima	Tak	Tak
			3/2004	Chylice	pszenica ozima	Tak	Tak
3.	dr K. Domaradzki + zespół – IUNG Wrocław	2004	2004	Karczyce	pszenica ozima	Tak	Tak
				Karczyce	pszenica ozima	Tak	Tak
				Wojsław	pszenica ozima	Tak	Tak
				Wojsław	pszenica ozima	Tak	Tak
				Lubcz	pszenica ozima	Tak	Tak
				Lubcz	pszenica ozima	Tak	Tak
				Laskowice	pszenica ozima	Tak	Tak
				Laskowice	pszenica ozima	Tak	Tak
				Turów	pszenica ozima	Tak	Tak
				Turów	pszenica ozima	Tak	Tak
4.	prof K. Adamczewski, mgr S. Jakubiak – IOR Poznań	2004	51/2004	Winna Góra	pszenica ozima	Tak	Tak
				Łyski	pszenica ozima	Tak	Tak
				3Piotrkowiczki	pszenica ozima	Tak	Tak
			49/2004	1. Zakrzewo	pszenżyto ozime	Tak	Tak
			43/2004	Winna Góra	pszenica ozima	Tak	Tak
				Łyski	pszenica ozima	Tak	Tak
				Piotrkowiczki	pszenica ozima	Tak	Tak
5.	dr K. Domaradzki, dr M. Kucharski – IUNG Wrocław	2005	13/2005	Mojęcice 2	pszenica ozima	Tak	Tak
				Lubcz	pszenica ozima	Tak	Tak
			14/2005	Laskowice	pszenica ozima	Tak	Tak/Nie
				Laskowice 2	pszenica ozima	Tak	Tak/Nie
				Mojęcice 2	pszenica ozima	Tak	Tak/Nie
6.	dr T. Praczyk – IOR Poznań	2005	462/2005	Rogoź	pszenica ozima	Tak	Tak
			478/2005	Rogoź	pszenica ozima	Tak	Tak
			481/2005	Psary	pszenica ozima	Tak	Tak

7.	H.Rojek – BCS	2005	H/5/2005	Ostaszewo	pszenica ozima	Tak	Tak
			H/6/2005	Błotnik	pszenica ozima	Tak	Tak
			H/7/2005	Stanowo	pszenica ozima	Tak	Tak
8.	dr K. Domaradzki, dr M. Kucharski – IUNG Wrocław	2007	9/2007	Wojsław	żyto	Tak	Tak
			10/2007	Zagórzyce 1	pszenżyto ozime	Tak	Tak
			11/2007	Zagórzyce 2	pszenżyto ozime	Tak	Tak
			12/2007	Wojsław	żyto	Tak	Tak
			13/2007	Zagórzyce 1	pszenżyto ozime	Tak	Tak
			14/2007	Zagórzyce 2	pszenżyto ozime	Tak	Tak
9.	dr J.Grabiński, dr P. Nieróbca, dr E. Szelężniak – IUNG Puławy	2007		RZD Kępa	żyto	Tak	Tak
					pszenżyto ozime	Tak	Tak
				RZD Kępa	żyto	Tak	Tak
					pszenżyto ozime	Tak	Tak

Analysis the obtained results, it can be concluded that Atlantis 12 OD used in the dose range from 0.45 L/ha to 2.4 L/ha is safe for the tested winter wheat varieties, and the phytotoxicity symptoms that occur are transient and usually occurred when the highest doses were used or in unfavourable weather conditions. The tested plant protection product did not cause significant differences between control objects (without protection) and objects where the comparison plant protection product was used.
In the case of winter triticale and rye, no adverse effects were noted on any of the tested varieties, regardless of the dose used.[3]

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

The selectivity trials for JME-HER 12 OD haven't been provide by the applicant, since they are not required for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. Taking into account Polish requirements applicant provides five efficacy bridging trials to confirm that herbicidal properties of JME-HER 12 OD are comparable to properties of Atlantis 12 OD in protection of cereals against weeds. Since the compositions of JME-HER 12 OD and Atlantis 12 OD are comparable, it has been assumed that the properties of both product on effect on the yield of treated plants or plant product will be comparable.

The use of Atlantis 12 OD at the recommended doses, i.e. 0.45 1/ha and 0.6 L/ha, did not result in a reduction in yield and yield parameters in any of the tested winter wheat varieties. The use of double doses, i.e. 0.9 L/ha and 1.2 L/ha, resulted in a yield reduction: Mewa variety by 4-6%, Zyta 0 variety by 1-5%, Korweta. The use of Atlantis 12 OD at the recommended dose of 1 1/ha and at a double dose of 2.4 L/ha did not cause damage to winter wheat plants, except for the Kobra variety, which reacted with transient chlorosis and growth inhibition to the double dose - 1.4% changes. The dose of 1 1/ha and the double dose of

[3] Instytut Ochrony Roślin-Państwowy Instytut Badawczy, „Ocena skuteczności działania środka ochrony roślin Atlantis 12 OD", Anonymus, 2008, (translated into English).

2.4 L/ha had no effect on the yield and its parameters in the tested winter wheat varieties, except for the Kobra variety, in which the dose of 2.4 L/ha resulted in a significant decrease in the thousand-grain weight and density. grain, but did not affect the yield.

In winter triticale, the recommended dose of 0.6 L/ha and a double dose of Atlantis 12 OD did not have a phytotoxic effect on the crop and did not have a significant impact on the yield and yield parameters of the following varieties: Prado, Bogo, Magnat and Fidelio. The winter triticale variety Bogo (IOR Winna Góra) did not react negatively to the applied doses of 1.2 L/ha and 2.4 1/ha.

In the rye varieties Dańkowskie Złote, Marder, Nawid and Skat, Atlantis 12 OD applied at the recommended dose of 0.6 L/ha and a double dose did not have a negative effect on the crop and the yield, and even in the Nawid variety tested in the IOR (Winna Góra) at Using a double dose, the yield was significantly higher than in the control plant. [4]

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

See point 3.4.2.

dRR point 3.4	ZRMS conclusion
Phytotoxicity of JME-HER 12 OD was tested in all 5 efficacy trials. The maximum tested dose rate was 1,2 l/ha. No phytotoxicity symptoms were observed in the efficacy trials. The point (selectivity data, effect on yield and quality of yield) was also completed based on the unprotected data of the reference product Atlantis 12 OD. The evaluator has no comments.	

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."

JME-HER 12 OD is a formulated product equivalent to registered plant protection product Atlantis 12 OD authorised in EU for long ago, with no negative effects known on transformation processes on the target crops. Additionally, no residues of any of the active ingredients are found at harvest. Therefore, according to EPPO guideline PP 1/243, no further data is deemed to be necessary. A safe use of JME-HER 12 OD can be considered for crops involved on transformation processes.

dRR point 3.4.4	ZRMS conclusion
Data no needed when no residues of any of the active ingredients are found at harvest.	

3.4.5 Impact on treated plants or plant products to be used for

[4] Instytut Ochrony Roślin-Państwowy Instytut Badawczy, „Ocena skuteczności działania środka ochrony roślin Atlantis 12 OD", Anonymus, 2008, (translated into English).

propagation (KCP 6.4.5)

According to EPPO guideline PP 1/135 "Phytotoxicity assessment", trials on plinentants products to be used for propagation would be required in case of post-emergence of the crop when application is made at or after inflorescence initiation e.g. for cereals when the first node is detectable (BBCH 30) or where detectable residues occur in harvested seed.
In 5 efficacy trials of JME-HER 12 OD has shown to be completely similar to the registered plant protection product Atlantis 12 OD authorised for long ago in EU. No negative impact of this equivalent formulation has ever been detected on products to be used for propagation. JME-HER 12 OD, similarly to the references products to which was compared, has shown to be selective to treated crops. Additionally, no residues are detected at harvest. Therefore, no further data is deemed to be necessary. A safe use of JME-HER 12 OD can be considered for plant products to be used for propagation.

dRR point 3.4.5	ZRMS conclusion
Data are not needed because no residues of any of the active ingredients are found at harvest.	

Summary and conclusion

No adverse effects on treated plants such as phytotoxicity symptoms and transformation processes were observed in efficacy trials of JME-HER 12 OD.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

JME-HER 12 OD (containing iodosulfuron-methyl-sodium and mesosulfuron-methyl) is not harmful for succeeding plants since its active substance decomposes relatively quick (According to PPDB by University of Hertfordshire[5], DT_{90} values from field tests are in range between 28 and 257 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 JME-HER 12 OD in cereals, 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 substances, no specific plant-back restrictions related to JME-HER 12 OD 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 cereals can be grown on the same field. After deep seedbed preparation (by ploughing) also sorghum can be grown on the same field.

dRR point 3.5.1	ZRMS conclusion
In the opinion of ZRMS, in case of treated winter wheat, triticale, rye failure (e.g. by hail, disease, pests or frost), only these crops may be sown on the field. After harvesting winter wheat, triticale, rye grown under normal growing conditions, all crops can be cultivated (the product decomposes within the growing season).	

[5] http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/401.htm

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 JME-HER 12 OD, 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 JME-HER 12 OD 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 JME-HER 12 OD will lead to adverse effects on adjacent crops.

dRR point 3.5.2	ZRMS conclusion
At a maximum application rate of 1.2 l/ha: according to the label of the reference product, in order to protect non-target plants, it is necessary to demarcate a buffer zone of: - 5 m or - 1 m and use a drift reduction nozzle of 75%	

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.

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 JME-HER 12 OD on beneficial organisms were observed. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

3.5.4 Compatibility with current management practices including IPM

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

Summary and conclusion

Products which are containing iodosulfuron-methyl-sodium and mesosulfuron-methyl, have been used for many years, not only Poland but also in other European countries. According to current knowledge, JME-HER 12 OD 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.

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

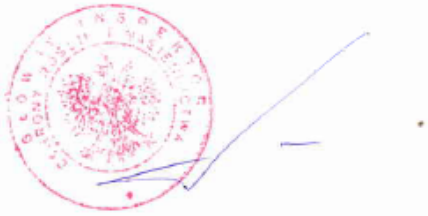
Pismem z dnia 13 kwietnia 2011 r. FERTICO Spółka z o.o. (Goliany 43; 05-620 Błędów), zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Nr 8/2008 z dnia 29 września 2008 r., zmienionej decyzjami

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

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.	2023	Efficacy of JME-HER 12 OD in weed control in winter wheat, Poland 2023 Fertico Sp. z o.o., Poland; Report No.: 32_01_F23_059 GEP: Yes Published: No	N	Pestila*
KCP 3.2/02	Szemendera A.	2023	Efficacy of JME-HER 12 OD in weed control in winter wheat, Poland 2023 Fertico Sp. z o.o., Poland; Report No.: 32_02_F23_060 GEP: Yes Published: No	N	Pestila*
KCP 3.2/03	Szemendera A.	2023	Efficacy of JME-HER 12 OD in weed control in winter triticale, Poland 2023 Fertico Sp. z o.o., Poland; Report No.: 33_01_F23_061 GEP: Yes Published: No	N	Pestila*
KCP 3.2/04	Szemendera A.	2023	Efficacy of JME-HER 12 OD in weed control in winter rye, Poland 2023 Fertico Sp. z o.o., Poland; Report No.: ~~181_01_F22_344~~ 34_01_F23_062 GEP: Yes Published: No	N	Pestila*
KCP 3.2/05	Szemendera A.	2023	Efficacy of JME-HER 12 OD in weed control in winter rye, Poland 2023 Fertico Sp. z o.o., Poland; Report No.: ~~181_01_F22_345~~ 34_02_F23_063 GEP: Yes Published: No	N	Pestila*

* Pestila Spółka z ograniczoną odpowiedzialnością

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