FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 4300 A

Product name(s): Mesotrione MIGHTY

Chemical active substance: Mesotrione 100 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem

Submission date: December/2018

MS Finalisation date: 04/06/2024

Version history

When	What
02/2020	Dossier sent for evaluation
06/2020	zRMS finalised evaluation
November 2023	Applicant updated document for the dose of 1.0 l/ha due to risk is ecotoxicology section
December 2023	Applicant updated document
January 2024	Applicant updated document
April 2024	zRMS updated comments following change in GAP
June 2024	Final version prepared by zRMS after the second 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)

Comments of zRMS:	Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out..

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

Abstract

This document is prepared for Mighty, post-emergence herbicide effective on weeds in maize. Mighty is a new herbicide containing 100 g of mesotrione per litre and is formulated as a Suspension Concentrate (SC).

The applicant has submitted this zonal application in order to authorise this product in Central EU zone of EU.

The zRMS considers that the data provided by the applicant support the use of Mighty to control broad-leaved and grass weeds in maize. This product is to be applied at a 1.5 L/ha, once per season.

The assessment was performed according to the uniform principles.

Applicant requested for modification in dose to 1,0 l/ha due to risk in ecotoxicology section. The dossier was evaluated for a dose of 1,0 l/ha.
The plant protection product Mesotrione MIGHTY applied at a 1,0 L/ha, once per season is recommended to be approved to use according to the table of intended uses for Mesotrione MIGHTY (Table 3.1- 1). The evaluation was carried out in accordance with the Uniform Principles.

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: develop-mental 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	CEU	**Maize**	F	Broadleaved- and grass weeds	Foliar Spray	BBCH 10-14	a) 1 b) 1	n.r.	a) 1.0 b) 1.0	a) 0.100 b) 0.100	200-600	NA	(*) Weeds at early stages	PL A The Maritime and SE EPPO climate zones

* 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

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product MIGHTY (MIGHTY (MESOTRIONE 10% SC)) containing the active substance mesotrione, which was included into Annex I of Council Directive 91/414/EEC.

The SANCO report for mesotrione (SANCO/1416/2001-final) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 April 2005 shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of mesotrione relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	**KCP 6.0/001 Biological Assessment Dossier MIGHTY (MESOTRIONE 10% SC) , Central**

Description of active substance mesotrione

Mesotrione was first introduced in 2001. It belongs to the chemical group of Triketones. Mesotrione is a new callistemone herbicide that inhibits the HPPD enzyme (p-hydroxyphenylpyruvate dioxygenase), a component of the biochemical pathway that converts tyrosine to plastoquinone and α-tocopherol (Lee et al. 1998; Cornes 2005). Following treatment in sensitive plants, carotenoid biosynthesis is disrupted in the chlorophyll pathway, resulting in a bleaching effect (Wichert et al., 1999). Carotenoid pigments protect chlorophyll from decomposing in sunlight. Injured weeds appear white to translucent rather than chlorotic (yellow).

Mesotrione is a member of the benzoylcyclo-hexane-1,3-dione family of herbicides, which are chemically derived from a natural phytotoxin obtained from the *Callistemon citrinus* (Curtis) Skeels plants.

Today, mesotrione is registered and commercialised in several formulations around the world.

Table 3.2-1: Current approvals of mesotrione in the EU Central zone as well as connected EPPO zones where trials were conducted

Country	Product	Active ingredient	Approval number
Austria	Callisto	Mesotrione 100 g/L SC	2726
Belgium	Callisto	Mesotrione 100 g/L SC	9308P/B
Czech Rep.	Callisto	Mesotrione 100 g/L SC	4514-0
Germany	Callisto	Mesotrione 100 g/L SC	024660-00
Greece	Callisto	Mesotrione 100 g/L SC	7732
Hungary	Callisto 4 SC	Mesotrione 40 g/L SC	04.2/660-2/2016
Italy	Callisto	Mesotrione 100 g/L SC	011253
Latvia	Starship	Mesotrione 100 g/L SC	0520
Lithuania	Starship	Mesotrione 100 g/L SC	AS2-19H2016
Poland	Callisto 100 SC	Mesotrione 100 g/L SC	R-25/2009

Country	Product	Active ingredient	Approval number
Portugal	Callisto	Mesotrione 100 g/L SC	0021
Romania	Callisto 480 SC	Mesotrione 480 g/L SC	2156/11.10.2002
Slovakia	Callisto 100 SC	Mesotrione 100 g/L SC	07-11-0872
Spain	Callisto	Mesotrione 100 g/L SC	22.313
UK	Callisto	Mesotrione 100 g/L SC	12323

Mode of action

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 (WSSA group 27) herbicide.

Table 3.2-2: Details of the formulation and the active substance

Proposed trade name	MIGHTY (MESOTRIONE 10% SC)
A.S. content:	Mesotrione 100 g/L
Formulation type:	SC
Synonyms:	-
Active substance	**Mesotrione**
IUPAC name:	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
Chemical group:	Triketone
Mode of action:	Inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase.
Plant translocation:	Absorbed by foliage and root and distributed throughout the plant by both xylem and phloem
Biological action:	Selective

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Description of the plant protection product

MIGHTY (MIGHTY (MESOTRIONE 10% SC)) is a suspension concentrate (SC) formulation containing 100 g/L mesotrione for use in maize crops.

According to the GAP, the proposed application rate of MIGHTY (MIGHTY (MESOTRIONE 10% SC)) is 1.0 Liter per hectare (L/ha) in maize crops, with one post-emergence application per season. This will deliver 100 g mesotrione per hectare. In the treated crops, the test product was tested against equivalent dose rates (1.5 and 3.0 L/ha) of the mesotrione reference product currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for mesotrione for the control of grass- and broadleaved weeds in maize.

Table 3.2-3: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Maize	Annual grasses and Broadleaved weeds	CEU	1.0 L/ha	BBCH 10-14

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

Description of the target pests

All the listed weeds are present throughout or in parts of the Central zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
GGGGG		Grass weeds
AVEFA	*Avena fatua*	Wild oat
DIGSA	*Digitaria sanguinalis*	Hairy crabgrass
DIGSS	*Digitaria* species	Crabgrass
ECHCG	*Echinochloa crus-galli*	Common barnyard grass
ECHSS	*Echinochloa* spp.	Barnyard grass
LOLPE	*Lolium perenne*	Perennial ryegrass
PASDS	*Paspalum distichum*	Knotgrass
POAAN	*Poa annua*	Annual bluegrass
SETPF	*Setaria pallidefusca*	Yellow foxtail
SETVE	*Setaria verticillata*	Bristly foxtail
SETVI	*Setaria viridis*	Green foxtail
SETSS	*Setaria* spp.	Foxtail
BBBBB		Broadleaved weeds
ADSSP	*Adenostoma sparsifolium*	Redshank chamise
AMADE	*Amaranthus deflexus*	Large-fruit amaranth
AMAHH	*Amaranthus hybridus*	Green amaranth
AMARE	*Amaranthus retroflexus*	Common amaranth
AMASS	*Amaranthus* spp.	Amaranth
CAGSE	*Calystegia sepium*	Great bindweed
CAPBP	*Capsella bursa-pastoris*	Shepherd's purse
CHEAL	*Chenopodium album*	Common lambsquarters
DATST	*Datura stramonium*	Common thorn apple
FUMOF	*Fumaria officinalis*	Common fumitory

EPPO code	Scientific name	Common name
GALAP	*Galium aparine*	Cleavers
LAMAM	*Lamium amplexicaule*	Henbit deadnettle
LAMPU	*Lamium purpureum*	Purple deadnettle
LAPCO	*Lapsana communis*	Nipplewort
MATCH	*Matricaria chamomilla*	Scented mayweed
MATIN	*Tripleurospermum inodorum*	Scentless mayweed
POLCO	*Fallopia convolvulus*	Black bindweed
POLLA	*Persicaria lapathifolia*	Pale persicaria
POLPE	*Persicaria maculosa*	Redshank
POLPI	*Polygonum persicarioides*	n.a.
POROL	*Portulaca oleracea*	Common purslane
SENVU	*Senecio vulgaris*	Common groundsel
SOLNI	*Solanum nigrum*	Black nightshade
STEME	*Stellaria media*	Common chickweed
THLAR	*Thlaspi arvense*	Field pennycress
VERAG	*Veronica agrestis*	Field speedwell
VERAR	*Veronica arvensis*	Corn speedwell
VIOAR	*Viola arvensis*	Field pansy

Table 3.2-5: 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	CEU	-	Annual grasses and broadleaved weeds	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Germany, UK, France, Poland, Latvia, Lithuania, Romania, Bulgaria, Spain and Italy in 2015. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application, 23 efficacy trials were conducted in the Maritime (4), the North-east (14), the South-east (1) and the Mediterranean (4) EPPO zone.

Table 3.2-6: Presentation of efficacy 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)
					EPPO zone					
					MAR	MED	S-E	N-E		
Maize (Spring appl., post-emergence)	Grasses and broadleaved weeds	Germany	2015	E + MED	2 (2)	-	-	-	GEP	
		UK	2015	E + MED	1 (1)	-	-	-	GEP	
		France	2015	E + MED	1 (1)	1 (1)	-	-	GEP	
		Poland	2015	E + MED	-	-	-	8 (8)	GEP	
		Latvia	2015	E + MED	-	-	-	3 (3)	GEP	
		Lithuania	2015	E + MED	-	-	-	3 (3)	GEP	
		Romania	2015	E + MED	-	-	1 (1)	-	GEP	
		Italy	2015	E + MED	-	2 (2)	-	-	GEP	
		Spain	2015	E + MED	-	1 (1)	-	-	GEP	
		Total, maize – spring appl.			4 (4)	4 (4)	1 (1)	14 (14)	-	

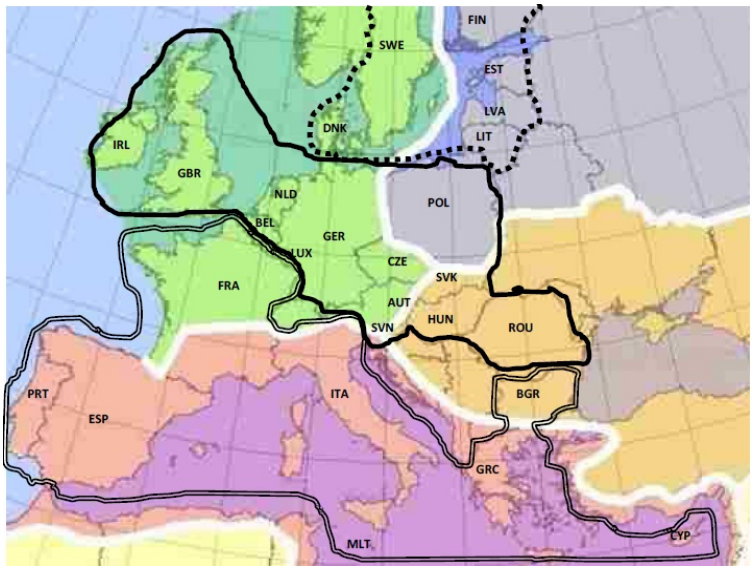
Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country[1].

The UK, Germany and N-France are located in the Maritime EPPO zone; Poland, Latvia and Lithuania are located in the North-east EPPO zone; Bulgaria and Romania are located in the South-east EPPO zone; and Spain, Italy and S-France are located in the Mediterranean EPPO zone (Figure 3.2-1).

[1] Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



This document is prepared to support the submission of MIGHTY (MIGHTY (MESOTRIONE 10% SC)) throughout the Central Registration zone, therefore data from the Maritime, the North-east as well as the South-East EPPO zones are included. Data obtained in the Mediterranean EPPO zone has also been added as supporting information, however the data from each climatic zone is summarised separately.

Agronomic conditions

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between UK, Germany, France, Poland, Latvia, Lithuania, Bulgaria, Romania, Italy and Spain. The same mesotrione containing herbicides are already registered and used in all countries to control the same key grass- and broadleaved weed species. In each country these are used at similar application timings when the weeds and crops are at similar growth stages.

(i) *Weed physiology*

Broadleaved weeds, like velvet leaf (*Abuthilon* spp.), common lambsquarters (*Chenopodium album*), pigweeds (*Amaranthus* spp.), sunflower (*Helianthus annuus*) and nightshades (*Solanum nigrum*) as well as grass weeds, like crabgrass (*Digitaria* spp.), barnyard grass (*Echinochloa* spp.) and foxtail grasses (*Setaria* spp.), are all controlled by MIGHTY (MIGHTY (MESOTRIONE 10% SC)) and are all key weeds throughout Central Europe. In each country these weeds are very common and can cause large reductions in yield.

Currently, there are no reported cases of weed resistance to mesotrione reported from within the EU (Heap, 2016), therefore when treating the same weeds at the same application timing no difference in level of control should be observed between countries. Therefore, the efficacy results from one country should be valid in another country.

(ii) *Site selection*

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each weed species the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high weed densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted.

(iii) *Agronomic practices*

Agronomic practices for growing maize are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. Maize crops are sown in the spring and levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries the crop safety of MIGHTY (MIGHTY (MESOTRIONE 10% SC)) has been tested on a wide range of varieties in both the selectivity and efficacy trial. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for maize production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

Mesotrione is a foliar acting herbicide with some soil activity. In each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

On the basis that the above factors do not influence the overall performance of MIGHTY (MESOTRIONE 10% SC) , it is the applicant's contention that data from Germany, UK, France, Poland, Romania and Bulgaria is equally valid in demonstrating the products performance throughout the Central EU zone and the data from the Mediterranean zone is valid as supporting data.

Efficacy and crop safety trials were carried out with MIGHTY (MESOTRIONE 10% SC) in comparison to the Syngenta reference mesotrione 100 g/L product (Callisto 100 SC) in Germany, UK, France, Poland, Latvia, Lithuania, Romania, Italy and Spain. All trials were carried out on maize.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates [L/ha]	Indication	Country	N° of trials
Callisto 100 SC	SC	100 g/L mesotrione	1.0	Control of grasses and broad-leaved weeds	DE UK FR PL LV LT RO ES IT	2 1 2 8 3 3 1 1 2

Comments of zRMS:	**Evaluation, summary and conclusion by zRMS:**
	Europe is divided into four climatic zones, according to EPPO standard PP 1/241. The United Kingdoom, Germany and N-France are located in the Maritime zone; Poland, Latvia and Lithuania are located in the North-East zone; Bulgaria and Romania are located in the South-East EPPO zone; and Spain, Italy and

	S-France are located in the Mediterranean zone. Conditions of the different crops and agronomy (cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between UK, Germany, France, Poland, Latvia, Lithuania, Bulgaria, Romania, Italy and Spain. The same mesotrione containing herbicides are already registered and used in all countries to control the same key grass- and broadleaved weed species. In each country these are used at similar application timings when the weeds and crops are at similar growth stages. No differences were found in the level of control between the different countries where the trials were carried out. zRMS agrees with the Applicant.

3.2.1 Preliminary tests (KCP 6.1)

The activity of mesotrione is well known, as it has been marketed since 2001 by e.g. Syngenta to control mono- and dicotyledonous weeds in maize and other crops. Based on the knowledge about the active substance (+15 years) and the experiences with using mesotrione in the label claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Evaluation, summary and conclusion by zRMS:

The applicant has not submitted new tests.
zRMS agrees. New tests are not necessary.

3.2.2 Minimum effective dose tests (KCP 6.2)

To determine the minimum effective dose rate, nineteen trials conducted in maize, i.e. four trials from the Maritime zone, fourteen trials from the North-east zone and one trial from the South-east zone have been included in this section. To give additional support to the minimum effective dose rate, the data obtained from four trials conducted in maize in the Mediterranean EPPO zone have also been included. Data from the Mediterranean trials has been added as the same weed species that are affecting maize crops in the South zone may affect the maize cultivation in the Central zone as well. Therefore, to demonstrate the wide range of control obtained with mesotrione, the Mediterranean data has been added to the current evaluation. Data from each zone has been summarized separately.

In the twenty-three trials, the level of control obtained by MIGHTY (MESOTRIONE 10% SC) was assessed on mono- and dicotyledonous weeds present in the trials.

Control of annual grasses and broadleaved weeds in Maize

Twenty-three field trials were established in order to determine the minimum effective dose for the control of annual grasses and broadleaved weeds in maize. MIGHTY (MESOTRIONE 10% SC) was tested at 0.75 L/ha, 1.0 L/ha and 1.5 L/ha (75 g/ha mesotrione, 100 g/ha mesotrione and 150 g/ha mesotrione) in maize for the control of annual grass weeds. The rates reflect the proposed label rate, 75% and 150% of the full recommended rate of MIGHTY (MESOTRIONE 10% SC) , in accordance with the EPPO standard PP 1/225 '*Minimum effective dose'* and the EU Central zone efficacy requirements.

Annual grass weeds

The results obtained with MIGHTY (MESOTRIONE 10% SC) applied in the spring on maize, when evaluating the control of annual grasses are presented in Table 3.2-8, Table 3.2-9, Table 3.2-10 and Table 3.2-11 for results obtained in the Maritime EPPO zone (four trials), the North-east EPPO zone (14 trials), the South-east EPPO zone (one trial) and the Mediterranean EPPO zone (four trials), respectively.

Table 3.2-8: Minimum effective dose – Maritime zone: Efficacy of MIGHTY (MESOTRIONE 10% SC) at 75% and 150% of proposed label rate on annual grass weeds at four to nine weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max) 0.75 L/ha	1.0 L/ha	1.5 L/ha
Grass weeds						
ECHCG	3	07-12	12.8 (5-28.3)	90.6 (85.4-100)	81.2 (52.9-99.4)	94.4 (90.6-100)
LOLPE	1	40	6.8	35	28.8	51.3

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max)		
				0.75 L/ha	1.0 L/ha	1.5 L/ha
PASDS	1	33	80.3	72.5	72.5	76.3
POAAN	1	40	19.3	42.5	57.5	60.0
GGGGG	4	07-40	-	81.9 (60-100)	77.4 (47.5-99.4)	86.9 (62.5-100)
Mean, Monocot assessments	10	07-40	24.1 (5-80.3)	74.9 (35-100)	71.2 (28.8-99.4)	81.8 (51.3-100)

Table 6.1.2-9: Maritime zone: Statically analysis of Minimum effective dose between doses 0.75 L/ha and 1.0 L/ha.

EPPO Code	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max)		No. of trials where MIGHTY (MESOTRIONE 10% SC) at 0.75 L/ha is >, < or =, compared to the 1.0 L/ha = : ± 5% control			Overall
			0.75 L/ha	1.0 L/ha	>	=	<	
ECHCG	3	12.8 (5-28.3)	90.6 (85.4-100)	81.2 (52.9-99.4)		2	1	=
LOLPE	1	6.8	35	28.8		1		
PASDS	1	80.3	72.5	72.5		1		
POAAN	1	19.3	42.5	57.5		1		
GGGGG	4	-	81.9 (60-100)	77.4 (47.5-99.4)		4		
Mean, monocot assessments	10	24.1 (5-80.3)	74.9 (35-100)	71.2 (28.8-99.4)		9	1	=

Table 3.2-10: Minimum effective dose – North-east zone: Efficacy of MIGHTY (MESO-TRIONE 10% SC) at 75% and 150% of proposed label rate on annual grass weeds at three to ten weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max)		
				0.75 L/ha	1.0 L/ha	1.5 L/ha
Grass weeds						
AVEFA	2	11-22	15.8 (11.7-19.8)	2.5 (0-5)	2.5 (0-5)	2.5 (0.0-5.0)
ECHCG	12	10-14	46.9 (7-229.7)	54.7 (0-93.5)	61.5 (5-97.8)	68.0 (7.5-100)
POAAN	1	10-11	15	92.8	94.5	96.8
SETPF	1	10-13	6	60	76.3	77.3
GGGGG	1	12	5	80	95	100.0
Mean, Monocot assessments	17	10-22	36.5 (5-229.7)	52.6 (0-93.5)	59.4 (0-97.8)	64.4 (0.0-100)

Table 6.1.2-11: North-east zone: Statically analysis of Minimum effective dose between doses 0.75 L/ha and 1.0 L/ha.

EPPO Code	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max)		No. of trials where MIGHTY (MESOTRIONE 10% SC) at 0.75 L/ha is >, < or =, compared to the 1.0 L/ha = : ± 5% control			Overall
			0.75 L/ha	1.0 L/ha	>	=	<	
AVEFA	2	15.8 (11.7-19.8)	2.5 (0-5)	2.5 (0-5)		2		=
ECHCG	~~128~~	46.9 (7-229.7)	54.7 (0-93.5)	61.5 (5-97.8)		3	5	<
POAAN	1	15	92.8	94.5		1		=
SETPF	1	6	60	76.3			1	<
GGGGG	1	5	80	95			1	<
Mean, monocot assessments	~~173~~	36.5 (5-229.7)	52.6 (0-93.5)	59.4 (0-97.8)		~~76~~	7	=, <

Table 3.2-12: Minimum effective dose – South-east zone: Efficacy of MIGHTY (MESOTRIONE 10% SC) at 75% and 150% of proposed label rate on annual grass weeds at four weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max) 0.75 L/ha	1.0 L/ha	1.5 L/ha
Grass weeds						
SETVI	1	10	32.5	71	85	96.0

Table 6.1.2-13: South-east zone: Statically analysis of Minimum effective dose between doses 0.75 L/ha and 1.0 L/ha.

EPPO Code	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 0.75 L/ha	1.0 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 0.75 L/ha is >, < or =, compared to the 1.0 L/ha = : ± 5% control >	=	<	Overall
SETVI	1	32.5	71	85			1	<
Mean, monocot assessments							1	<

Table 3.2-14: Minimum effective dose – Mediterranean zone: Efficacy of MIGHTY (MESOTRIONE 10% SC) at 75% and 150% of proposed label rate on annual grass weeds at three to nine weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max) 0.75 L/ha	1.0 L/ha	1.5 L/ha
Grass weeds						
DIGSA	3	12-15	43.3 (27.5-64.5)	77.5 (60.1-95)	81.9 (71.8-92.8)	89.2 (82.6-95.0)
ECHSS	3	12-13	40.3 (25.5-61)	68.8 (50-93.9)	77.7 (52.5-93.9)	87.1 (72.5-95.0)
SETVE	2	13-14	34.5 (30-39)	67.5 (41.2-93.8)	83.8 (75.1-92.5)	89.7 (84.3-95.0)
GGGGG	2	12	12	54.6 (37.5-71.8)	57.5 (32.5-82.6)	76.0 (66.3-85.7)
Mean, Monocot assessments	10	12-15	36.9 (12-64.5)	68.3 (37.5-95)	76.2 (32.5-93.9)	86.0 (66.3-95.0)

At the timing of the assessments, the dose of 1.0 L/ha of MIGHTY (MESOTRIONE 10% SC) provided a superior control to the dose of 0.75 L/ha of MIGHTY (MESOTRIONE 10% SC) in the majority of the trials conducted in the Maritime, the North-east, the South-east and the Mediterranean EPPO zone. A clear dose rate effect was observed, with statistical differences (where a statistical analysis is available) in 11 of 38 assessments compared to the lower dose rates of 0.75 L/ha.

For MIGHTY (MESOTRIONE 10% SC) to consistently achieve satisfactory control against the annual grass weeds claimed in the GAP, MIGHTY (MESOTRIONE 10% SC) has to be applied at 1.0 L/ha on weeds in maize that are not on too advanced growth stages.

Broadleaved weeds

The results obtained with MIGHTY (MESOTRIONE 10% SC) applied in the spring on maize, when evaluating the control of broadleaved weeds are presented in Table 3.2-12, Table 3.2-13, Table 3.2-14 and Table 3.2-15 for results obtained in the Maritime EPPO zone (four trials), the North-east EPPO zone (14 trials), the South-east EPPO zone (one trial) and the Mediterranean EPPO zone (four trials), respectively.

Table 3.2-15: Minimum effective dose – Maritime zone: Efficacy of MIGHTY (MESOTRIONE 10% SC) at 75% and 150% of proposed label rate on broadleaved weeds at two to nine weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max) 0.75 L/ha	1.0 L/ha	1.5 L/ha
Broadleaved weeds						
ADSSP	1	35	8.5	95	95	95.0
AMARE	1	07	5	100	100	100.0
CHEAL	4	12-35	30.1 (5.3-75)	98.1 (95-100)	98.8 (95-100)	98.4 (93.8-100)
FUMOF	1	30	7.8	87.5	85	90.0
MATCH	1	12	4.8	100	100	100
POLCO	2	13-14	7.5 (6-9)	86.7 (84.7-88.8)	94.4 (88.8-100)	93.7 (92.5-94.9)
SOLNI	2	12-30	14.5 (13-16)	97.5 (95-100)	96.9 (93.8-100)	97.5 (95.0-100)
STEME	1	12	5.5	100	100	100
BBBBB	4	07-35	-	95.1 (90-100)	96.9 (90-100)	96.9 (90.0-100)
Mean, Monocot assessments	17	07-35	15.1 (5-75)	95.5 (84.7-100)	96.8 (85-100)	97.0 (90-100)

Table 6.1.2-16: Maritime zone: Statically analysis of Minimum effective dose between doses 0.75 L/ha and 1.0 L/ha.

EPPO Code	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 0.75 L/ha	1.0 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 0.75 L/ha is >, < or =, compared to the 1.0 L/ha = : ± 5% control >	=	<	Overall
ADSSP	1	8.5	95	95		1		=
AMARE	1	5	100	100		1		=
CHEAL	4	30.1 (5.3-75)	98.1 (95-100)	98.8 (95-100)		4		=
FUMOF	1	7.8	87.5	85		1		=
MATCH	1	4.8	100	100		1		=
POLCO	2	7.5 (6-9)	86.7 (84.7-88.8)	94.4 (88.8-100)		2		=
SOLNI	2	14.5 (13-16)	97.5 (95-100)	96.9 (93.8-100)		2		=
STEME	1	5.5	100	100		1		=
BBBBB	4	-	95.1 (90-100)	96.9 (90-100)		4		=
Mean, monocot assessments	17	15.1 (5-75)	95.5 (84.7-100)	96.8 (85-100)		=		=

Table 3.2-17: Minimum effective dose – North-east zone: Efficacy of MIGHTY (MESOTRIONE 10% SC) at 75% and 150% of proposed label rate on broadleaved weeds at two to ten weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max) 0.75 L/ha	1.0 L/ha	1.5 L/ha
Broadleaved weeds						
AMARE	4	10-13	8.5 (5.8-13)	78.8 (61.3-100)	91.7 (82.5-100)	98.4 (93.8-100)
CAPBP	4	10-18	10.6 (7.3-18)	94.1 (78.3-100)	98.8 (97-100)	99.3 (99.0-100)
CHEAL	13	10-39	66.5 (6-266)	90.9 (48.8-100)	96.8 (86.8-100)	98.1 (94.3-100)
GALAP	1	12	6	90	96	99.0
LAMAM	1	12	6	100	100	100.0
LAMPU	3	10-13	15.7 (7-26.3)	92.3 (79-99.3)	99.7 (99.3-100)	100 (100-100)
LAPCO	1	12-14	9	98	96	100
MATIN	4	10-14	15.6 (5-42.5)	75.3 (28.8-92.8)	79.9 (35-97.5)	84.0 (41.3-99.5)
POLCO	4	10-13	15.7 (7-24)	65.6 (18.8-85)	71.0 (35-88)	80.8 (45.0-96.0)
POLLA	1	11-15	10.7	18.8	35	91.8
POLPE	2	10-11	8.8 (5-12.5)	79.6 (61.3-98)	85.6 (71.3-100)	98.4 (96.8-100)
SOLNI	1	10-13	6	80.3	98	100
STEME	4	10-12	9.4 (5-15)	79.2 (35.5-100)	84.8 (45-100)	99.3 (98.8-100)
THLAR	1	n.r.	5	100	100	100.0
VERAG	1	11-12	26	71.3	72.5	86.0
VERAR	1	12	20	93	93	100.0
VIOAR	7	10-14	16.3 (7-52)	77.7 (42.5-100)	87.0 (51.3-100)	91.4 (65.0-100)

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max) 0.75 L/ha	1.0 L/ha	1.5 L/ha
BBBBB	1	12	30	99	100	100
Mean, Monocot assessments	54	10-39	25.9 (5-266)	83.0 (18.8-100)	89.5 (35-100)	95.1 (41.3-100)

EPPO Code	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 0.75 L/ha	1.0 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 0.75 L/ha is >, < or =, compared to the 1.0 L/ha = : ± 5% control >	=	<	Overall
AMARE	4	8.5 (5.8-13)	78.8 (61.3-100)	91.7 (82.5-100)		1	2	<
CAPBP	4	10.6 (7.3-18)	94.1 (78.3-100)	98.8 (97-100)			1	<
CHEAL	13	66.5 (6-266)	90.9 (48.8-100)	96.8 (86.8-100)		5	4	=, <
GALAP	1	6	90	96				
LAMAM	1	6	100	100		1		=
LAMPU	3	15.7 (7-26.3)	92.3 (79-99.3)	99.7 (99.3-100)		2	1	=
LAPCO	1	9	98	96				
MATIN	4	15.6 (5-42.5)	75.3 (28.8-92.8)	79.9 (35-97.5)		2	1	=
POLCO	4	15.7 (7-24)	65.6 (18.8-85)	71.0 (35-88)		1	1	=,<
POLLA	1	10.7	18.8	35			1	
POLPE	2	8.8 (5-12.5)	79.6 (61.3-98)	85.6 (71.3-100)		1		=
SOLNI	1	6	80.3	98			1	<
STEME	4	9.4 (5-15)	79.2 (35.5-100)	84.8 (45-100)		2	1	=
THLAR	1	5	100	100				
VERAG	1	26	71.3	72.5				
VERAR	1	20	93	93				
VIOAR	7	16.3 (7-52)	77.7 (42.5-100)	87.0 (51.3-100)		1	4	<
BBBBB	1	30	99	100			1	<
Mean, monocot assessments	54	25.9 (5-266)	83.0 (18.8-100)	89.5 (35-100)		16	18	=, <

Table 3.2-18: Minimum effective dose – South-east zone: Efficacy of MIGHTY (MESO-TRIONE 10% SC) at 75% and 150% of proposed label rate on broadleaved weeds at four weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max) 0.75 L/ha	1.0 L/ha	1.5 L/ha
Broadleaved weeds						
AMARE	1	11	10.5	68	86	96.0
CHEAL	1	12	14.8	73	88	98.0
BBBBB	1	11-12	-	70	86	96.0
Mean, Monocot assessments	3	11-12	12.6 (10.5-14.8)	70.3 (68-73)	86.7 (86-88)	96.7 (96.0-98.0)

Table 6.1.2-19: South-east zone: Statically analysis of Minimum effective dose between doses 0.75 L/ha and 1.0 L/ha.

EPPO Code	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 0.75 L/ha	1.0 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 0.75 L/ha is >, < or =, compared to the 1.0 L/ha = : ± 5% control >	=	<	Overall
AMARE	1	10.5	68	86			1	<
CHEAL	1	14.8	73	88			1	<
BBBBB	1	-	70	86			1	<
Mean, monocot assessments	3	12.6 (10.5-14.8)	70.3 (68-73)	86.7 (86-88)			3	<

Table 3.2-20: Minimum effective dose – Mediterranean zone: Efficacy of MIGHTY (MESOTRIONE 10% SC) at 75% and 150% of proposed label rate on broadleaved weeds at three to nine weeks after application in maize.

EPPO Code	No. of trials	Weed Growth stage at application [BBCH]	Ground cover (No./m²)	Efficacy obtained with Mesotrione 10% SC at: Mean (min-max)		
				0.75 L/ha	1.0 L/ha	1.5 L/ha
Broadleaved weeds						
AMADE	1	16	27.3	95	94.2	95.0
AMAHH	1	14	65.5	78.8	86.3	96.3
CAGSE	1	11	36.3	71.3	83.8	91.3
CHEAL	3	11-16	35.9 (10.5-67)	89.2 (73.8-100)	92.3 (85-98.8)	97.5 (95.0-100)
DATST	1	11	10.3	100	99.9	100.0
LAMPU	1	12	35.5	76.3	83.8	98.8
POLPI	1	18	24.3	87.5	92.5	93.8
POROL	2	12-18	44.3 (20.3-68.3)	20.6 (12.5-28.8)	17.9 (15.8-20)	23.4 (16.8-30.0)
SENVU	1	13	59.5	77.5	86.3	98.8
SOLNI	3	12-15	22.3 (19-24.5)	95.0 (90-100)	95.8 (92.5-100)	98.3 (95.0-100)
VERAR	1	12	53.3	87.2	92.3	100
BBBBB	2	12	15	89.4 (78.8-00)	95.6 (92.5-98.8)	100 (100-100)
Mean, Monocot assessments	18	11-18	34.7 (10.3-68.3)	80.3 (12.5-100)	83.9 (15.8-100)	89.3 (16.8-100)

At the timing of the assessments, the dose of 1.0 L/ha of MIGHTY (MESOTRIONE 10% SC) provided a superior control to the dose of 0.75 L/ha of MIGHTY (MESOTRIONE 10% SC) and equal control of the 1.5 L/ha dose in the majority of the trials conducted in the Maritime, the North-east, the South-east and the Mediterranean EPPO zone. A clear dose rate effect was observed, with statistical differences (where a statistical analysis is available) in 32 out of 92 assessments compared to the lower dose rates of 0.75 L/ha. No dose rate effect was observed, with statistical differences only in 31 out of 92 assessments compared to the higher dose rates of 1.5 L/ha.

For MIGHTY (MESOTRIONE 10% SC) to consistently achieve satisfactory control against the broad-leaved weeds claimed in the GAP, MIGHTY (MESOTRIONE 10% SC) has to be applied at 1.0 L/ha on weeds in maize that are not on too advanced growth stages.

Summary and conclusions on the minimum effective dose

MIGHTY (MESOTRIONE 10% SC) applied at 1.0 L/ha in maize to control annual grasses and broad-leaved weeds achieved good to excellent control of all target weeds. As grasses and broadleaved weeds often occur as a complex of several weed species with different susceptibility towards mesotrione, one application of MIGHTY (MESOTRIONE 10% SC) at the recommended rate should be used to efficiently control all weeds claimed on the label.

This document clearly demonstrates that the efficacy and crop safety of MIGHTY (MESOTRIONE 10% SC) is equivalent to that of the standard mesotrione reference product to which it was compared. The applicant therefore wishes to cite the original registrant's data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Evaluation, summary and conclusion by zRMS:

Mighty was tested in 23 efficacy trials at rates: 0.75 L/ha, 1.0 L/ha and 1.5 L/ha (75 g/ha mesotrione, 100 g/ha mesotrione and 150 g/ha mesotrione). The trials were carried out in the different EPPO zones: Maritime zone (4), the North-East zone (14), the South-East zone (1) and in the Mediterranean EPPO zone (4). Data from the Mediterranean trials has been added as the same weed species that are affecting maize crops in the South zone may affect the maize cultivation in the Central zone as well.

In all trials, the dose of 1.5 L/ha of Mighty provided a superior control to the dose of 0.75 L/ha and 1.0 L/ha of Mighty in the Maritime, the North-East, the South-East and the Mediterranean EPPO zones in maize for the control broadleaved and grass weeds.

Based on the above data, the dose of 1.5 L/ha of Mighty is considered as the minimum effective dose.

Applicant requested for modification in dose to 1,0 l/ha due to risk in ecotoxicology section. The following is an opinion for a dose of 1,0 l/ha.

comments of zRMS: dRR point 3.2.2	**Minimum effective dose tests** The claimed dose rate is 1,0 l/ha for. **<u>Maritime EPPO climate zone</u>** The dose justification of Mesotrione 10% SC has been supported by data from 4 efficacy trials on maize against grass weeds and broadleaved weeds weeds for which efficacy of Mesotrione 10% SC is claimed. Efficacy of the claimed dose rate 1,0 l/ha was compared with the reduced dose rate of 0,75 /ha. In the trials presented, no difference was observed between the two doses. The product at 1,0 l/ha performed better than 0,75 l/ha in only one trial, against ECHCG. **<u>NE EPPO climate zone</u>** The dose justification of Mesotrione 10% SC has been supported by data from 14 efficacy trials on maize against grass weeds and broadleaved weeds weeds for which efficacy of Mesotrione 10% SC is claimed. Efficacy of the claimed dose rate 1,0 l/ha was compared with the reduced dose rate of 0,75 /ha. In the NE EPPO climatic zone efficacy trials Mesotrione 10% SC at the dose rate of 1,0 l/ha showed higher level of efficacy than the reduced dose rate 0,75 l/ha in half presented trials. 1,0 l/ha dose rate of Mesotrione 10% SC can be considered the minimum effective dose rate. **<u>SE EPPO climate zone</u>** The dose justification of Mesotrione 10% SC has been supported by data from 1 efficacy trial on maize against three weed species for which efficacy of Mesotrione 10% SC is claimed. Efficacy of the claimed dose rate 1,0 l/ha was compared with the reduced dose rate of 0,75 /ha. Presented data are limited, but in the trials dose rate of 1,0 l/ha showed higher level of efficacy than the reduced dose rate 0,75 l/ha. The ZRMS proposes to consider data from other climate zones. **Comment of SI:** Only one trial for S-E EPPO zone is not acceptable. The minimum number of trials is 6.

3.2.3 Efficacy tests (KCP 6.2)

Data from nineteen efficacy trials conducted in the Maritime EPPO zone (4; i.e. N-France (1), Germany (2) and the United Kingdom (1)), the North-east EPPO zone (14; i.e. Poland (8), Latvia (3) and Lithuania (3)) and the South-east EPPO zone (1; Romania) and additionally, four efficacy trials conducted in the Mediterranean EPPO zone (4; Italy (2), S-France (1) and Spain (1)) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. Data from each zone has been summarized separately.

In the efficacy trials, the performance of MIGHTY (MESOTRIONE 10% SC) was measured against a commercial standard formulation of mesotrione. The mesotrione standard used was Callisto 100 SC (registered by Syngenta). The trials were carried out on maize for grain and forage.

In the twenty-three trials, the level of control obtained by MIGHTY (MESOTRIONE 10% SC) was assessed on mono- and dicotyledonous weeds present in the trials.

Table 3.2-21: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(3)
	Specific guidelines	EPPO PP 1/50 (3), CEB M046
Experimental design	Plot design	RCBD (23),
	Plot size	12.5-33 m²
	Number of replications	4 (23)
Crop	Trials per crop	Maize, post-emergence application (23)
	Varieties per crop	Maize: Agiraxx, Agromax, Buran, Carella, DKC4795, DKC4814, Farmstar, Fieldstar, Filiax, Glejt, LG30220, LG30260, LG3409, MAS 15P, P 1028-1255, P1817, P7529, Progress, Ravello, Skarb, Zeta
	Sowing period	Maize: April 9th to June 4th
Application	Crop stage (BBCH)* at application	BBCH 10-16
	Timing Pest stage at appl. (1)	BBCH 07-40
	Number of appl. Intervals between appl.	1 (23 trials) n.a.
	Spray volumes	200-400 L/ha
Assessment	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on weed counts (COUPLA) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms.
	Assessment dates	Spring appl.: 15-73 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial innoculation…	Natural
	Field / Greenhouse...	Field

Control of annual grass weeds in Maize

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Maize - Post-emergence BBCH 10-14
Use rate Use frequency Application timing	1.0 L/ha MIGHTY (MESOTRIONE 10% SC) 1x Post-emergence to weeds and crop
Target weeds	Grass weeds, e.g. *Digitaria* spp., *Echinochloa* spp. and *Setaria* spp.

The summary of efficacy results obtained with the application of MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha on grass weeds in maize are listed in Table 3.2-17, Table 3.2-18, Table 3.2-19 and Table 3.2-20 for results from all trials conducted in the Maritime (4), the North-east (14), the South-east (1) and the Mediterranean (4) EPPO zones, respectively. In these trials, the reference product was applied at 1.0 L/ha. The trials were conducted in the United Kingdom (1), Germany (2), N-France (1), Poland (8), Latvia (3), Lithuania (3), Romania (1), Spain (1), Italy (2) and S-France (1).

Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment. The most appropriate timing of assessment to be presented is considered to be the time at two to nine weeks after application, depending on the development of the weed in the respective trial.

When applied at 1.0 L/ha in the Maritime, the North-east, the South-east and the Mediterranean EPPO zones, MIGHTY (MESOTRIONE 10% SC) obtained moderate to excellent levels of control when applied to annual grass weeds. The highest level of control was obtained on the key monocotyledonous weeds, i.e. DIGSS, ECHSS and SETSS, whereas the control obtained against LOLPE and POAAN was more variable. All these grass weeds are commonly found in maize and are known to cause losses in production. In all species evaluated, the effect obtained with MIGHTY (MESOTRIONE 10% SC) was comparable with the effect obtained with the mesotrione reference product applied in the trials.

Table 3.2-22: Maritime zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 28-65 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.5 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
ECHCG	07-12	3	5-28.3	81.2 (52.9-99.4)	94.4 (90.6-100)	84.7 (73.8-98)	1	1	1	=
LOLPE	40	1	6.8	28.8	51.3	45			1	<
PASDS	33	1	80.3	72.5	76.3	80			1	<
POAAN	40	1	19.3	57.5	60	56.3		1		=
GGGGG	07-40	4	-	77.4 (47.5-99.4)	86.9 (62.5-100)	88.3 (62.5-100)		1	3	<
Mean, monocot assessments		10	5-80.3	71.2 (28.8-99.4)	81.8 (51.3-100)	78.9 (45-100)	3	5	2	=

Table 3.2-23: North-east zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 22-73 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.5 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
AVEFA	11-22	1	11.7-19.8	2.5 (0-5)	2.5 (0-5)	2.5 (0-5)		2		=
ECHCG	10-14	12	8-230	61.5 (5.0-97.8)	69.3 (7.5-100)	65.1 (0-100)	2	6	4	=
POAAN	10-11	1	15	94.5	96.8	93.8		1		=
SETPF	10-13	1	6	76.3	77.3	77.5		1		=
GGGGG	12	1	5	95.0	100	100			1	<
Mean, monocot assessments		17	5-230	59.4 (0-97.8)	65.3 (0-100)	62.2 (0-100)	2	10	5	=

Table 3.2-24: South-east zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 28 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with: MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.5 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
SETVI	10	1	32.5	85.0	96	95			1	<

Table 3.2-25: Mediterranean zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 24-64 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with: MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.5 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
DIGSA	12-15	3	27.5-64.5	81.9 (71.8-92.8)	89.2 (82.6-95)	69.8 (58.8-85.7)	2	1		>
ECHSS	12-13	3	25.5-61	77.7 (52.5-93.9)	87.1 (72.5-95)	61.8 (52.5-66.6)	3			>
SETVE	13-14	2	30-59.8	83.8 (75.1-92.5)	90.9 (86.8-95)	58.8 (53.8-63.8)	2			>
GGGGG	12	2	12	57.5 (32.5-82.6)	79.1 (72.5-85.7)	64.1 (42.5-85.7)	1	1		>
Mean, monocot assessments		10	12-64.5	76.2 (32.5-93.9(	86.9 (72.5-95)	64.1 (42.5-85.7)	8	2		>

No differences in the level of weed control or crop safety were seen from the trials conducted in the different EU Member States. In all countries MIGHTY (MESOTRIONE 10% SC) gave good to excellent control of a number of key monocotyledonous weeds found in maize. In all trials, MIGHTY (MESOTRIONE 10% SC) performed similar to the mesotrione reference product.

The proposed label claims of the annual grass weed spectrum controlled after application of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) post-emergence in maize are listed in Table 3.2-25.

Control of broadleaved weeds in Maize

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Maize - Post-emergence BBCH 10-14
Use rate Use frequency Application timing	1.0 L/ha MIGHTY (MESOTRIONE 10% SC) 1x Post-emergence to weeds and crop
Target weeds	Broadleaved weeds, e.g. *Amaranthus* spp., *Capsella bursa-pastoris, Chenopodium album, Datura stramonium, Helianthus annuus, Lamium purupureum, Matricaria* spp., *Polygonum* spp., *Solanum nigrum, Stellaria media* and *Viola arvensis*

The summary of efficacy results obtained with the application of MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha on broadleaved weeds in maize are listed in Table 3.2-21, Table 3.2-22, Table 3.2-23 and Table 3.2-24, for results from all trials conducted in the Maritime (4), the North-east (14), the South-east (1) and the Mediterranean (4) EPPO zones, respectively. In these trials, the reference product was applied at 1.0 L/ha. The trials were conducted in the United Kingdom (1), Germany (2), N-France (1), Poland (8), Latvia (3), Lithuania (3), Romania (1), Spain (1), Italy (2) and S-France (1).

Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment. The most appropriate timing of assessment to be presented is considered to be the time at three to eleven weeks after application, depending on the development of the weed in the respective trial.

When applied at 1.0 L/ha in the Maritime, the North-east, the South-east and the Mediterranean EPPO zones, MIGHTY (MESOTRIONE 10% SC) obtained good to excellent control when applied to dicotyledonous weeds in maize. The highest level of control was obtained on the key dicotyledonous weeds, i.e. AMASS, CAPBP, CHEAL, DATST, LAMPU, MATSS, POLSS, SENVU, SOLNI, STEME and VIOAR, whereas the control obtained against e.g. POROL was more variable. All these broadleaved weeds are commonly found in maize and are known to cause losses in production. In all species evaluated, the effect obtained with MIGHTY (MESOTRIONE 10% SC) was comparable with the effect obtained with the mesotrione reference product applied in the trials.

Table 3.2-26: Maritime zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 15-65 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
ADSSP	35	1	8.5	95.0	95	95		1		=
AMARE	07	1	5	100.0	100	100		1		=
CHEAL	12-35	4	5.3-75	98.8 (95.0-100)	98.4 (93-100)	98.7 (95-100)		4		=
FUMOF	30	1	7.8	85.0	90	87.5		1		=
MATCH	12	1	4.8	100.0	100	100		1		=
POLCO	13-14	2	6-9	94.4 (88.8-100)	93.7 (92-95)	71.1 (47-94.8)	1	1		>
SOLNI	12-30	2	13-16	96.9 (93.8-100)	97.5 (95-100)	97.5 (95-100)		2		=
STEME	12	1	5.5	100	100	100		1		=
BBBBB	07-35	4	-	96.9 (90.0-100)	96.9 (90-100)	94.2 (89.-99.9)	1	3		=
Mean, dicot assessments		17	5-75	96.8 (85.0-100)	97.0 (90-100)	93.6 (47.5-100)	2	15		=

Table 3.2-27: North-east zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 16-73 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	Mesotrione ref. prod. at Mean (min-max) 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
AMARE	10-13	4	5.8-13	91.7 (82.5-100)	98.4 (93.8-100)	96.3 (85-100)		3	1	=
CAPBP	10-18	4	7.3-18	98.8 (97.0-100)	99.3 (99-100)	99.5 (99-100)		4		=
CHEAL	10-39	13	6-266	96.8 (86.8-100)	98.1 (94.3-100)	95.3 (72.5-100)	2	10	1	=
GALAP	12	1	6	96.0	99	100		1		=
LAMAM	12	1	6	100.0	100	100		1		=
LAMPU	10-13	3	7-26.3	99.7 (99.3-100)	100 (-)	99.8 (99.5-100)		3		=
LAPCO	12-14	1	9	96.0	100	100		1		=
MATIN	10-14	4	5-42.5	79.9 (35-97.5)	84.0 (41-99.5)	82.6 (38.8-99)		4		=
POLCO	10-13	4	7-24	71.0 (35.0-88.0)	80.8 (45-96)	74.1 (15-97)	1		3	<

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	1.5 L/ha	Mesotrione ref. prod. at 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
POLLA	11-15	1	10.7	35.0	91.8	15	1			>
POLPE	10-11	2	5-12.5	85.6 (71.3-100)	98.4 (96.8-100)	96.5 (93-100)		2		=
SOLNI	10-13	1	6	98.0	100	100		1		=
STEME	10-12	4	5-15	84.8 (45.0-100	99.3 (98.8-100)	98.3 (94-100)		3	1	=
THLAR	n.r.	1	5	100.0	100	100		1		=
VERAG	11-12	1	26	72.5	86	82.3			1	<
VERAR	12	1	20	93.0	100	100		1		=
VIOAR	10-14	7	7-52	87.0 (51.3-100)	91.8 (65-100)	89.4 (65-100)	1	5	1	=
BBBBB	12	1	30	100	100	100		1		=
Mean, dicot assessments		54	5-266	89.5 (35.0-100)	95.2 (41.3-100)	91.8 (15-100)	5	41	8	=

Table 3.2-28: South-east zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 28 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	1.5 L/ha	Mesotrione ref. prod. at 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
AMARE	11	1	10.5	86.0	96	95		1		=
CHEAL	12	1	14.8	88.0	98	96		1		=
BBBBB	11-12	1	-	86.0	96	96		1		=
Mean, dicot assessments		3	10.5-14.8	86.7 (85.0-88.0)	96.7 (96-98)	95.7 (95-96)	2	16		=

Table 3.2-29: Mediterranean zone: Efficacy of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) and reference product at equivalent dose rate in the efficacy tests 2015 – late spring evaluation, 24-64 DAT.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover (no/m²)	Efficacy obtained with MIGHTY (MESOTRIONE 10% SC) at: Mean (min-max) 1.0 L/ha	1.5 L/ha	Mesotrione ref. prod. at 1.5 L/ha	No. of trials where MIGHTY (MESOTRIONE 10% SC) at 1.0 L/ha is >, < or =, compared to the mesotrione Ref. product at 150 g ai/ha = : ± 5% control >	=	<	Overall
AMADE	16	1	27.3	94.2	95	67.8	1			>
AMAHH	14	1	65.5	86.3	96.3	76.3	1			>
CAGSE	11	1	36.3	83.8	91.3	82.5	1			>
CHEAL	11-16	3	10.5-67	92.3 (85.0-98.8)	97.5 (95-100)	85.9 (66.-100)	1	1	1	=
DATST	11	1	10.3	99.9	100	100		1		=
LAMPU	12	1	35.5	83.8	98.8	52.5	1			>
POLPI	18	1	24.3	92.5	93.8	66.3	1			>
POROL	12-18	2	20.3-68.	17.9 (15.8-20.0)	23.4 (16.8-30)	8.0 (5-11)	2			>
SENVU	13	1	59.5	86.3	98.8	83.8	1			>
SOLNI	12-15	3	19-24.5	95.8 (92.5-100)	98.3 (95-100)	89.5 (68.-100)	1	1	1	=
VERAR	12	1	53.3	92.3	100	100		1		=
BBBBB	12	2	15	95.6 (92.5-98.8)	100 (-)	100 (-)		2		=
Mean, dicot assessments		18	10.3-68	83.9 (15.8-100)	89.3 (16.8-100)	76.2 (5-100)	10	6	2	>

No differences in the level of weed control or crop safety were seen from the trials conducted in the different EU Member States. In all countries MIGHTY (MESOTRIONE 10% SC) gave good to excellent control of a number of key dicotyledonous weeds found in maize. In all trials, MIGHTY (MESOTRIONE 10% SC) performed similar to the mesotrione reference product.

The proposed label claims of the broadleaved weed spectrum controlled after application of 1.0 L/ha

MIGHTY (MESOTRIONE 10% SC) post-emergence in maize are listed in Table 3.2-25.

Summary and conclusion

Based on the results of 23 field trials carried out in 2015, the following can be concluded for the intended use '*Control of grasses and broadleaved weeds*' from MIGHTY (MESOTRIONE 10% SC) applied post-emergence at the dose rate of 1.0 L/ha in maize:

- MIGHTY (MESOTRIONE 10% SC) provides a high level control of mono- and dicotyledonous weeds, like DIGSS, ECHSS, SETSS, AMASS, CHEAL, LAMPU, SOLNI and STEME and a number of other annual grasses and broadleaved weed species with the recommended dose rate in maize. As weeds often occur as a complex of several weeds with different susceptibility towards mesotrione, one application of MIGHTY (MESOTRIONE 10% SC) at the recommended rate should be used to efficiently control all weeds claimed on the label.
- A high level of control may also be obtained against less susceptible weed species if treated with the recommended dose rate under optimal conditions, i.e. early growth stages and good weather conditions.
- Compared to the mesotrione reference product, the efficacy obtained with MIGHTY (MESOTRIONE 10% SC) is comparable against all weed species.
- The trial results are considered valid for all intended EU Central zone countries.

MIGHTY (MESOTRIONE 10% SC) is suitable for the control of annual grasses and broadleaved weeds in maize.

As it has been demonstrated in 23 efficacy trials, the efficacy and cropsafetyness of MIGHTY (MESOTRIONE 10% SC) in maize is equivalent to the efficacy and cropsafetyness of the standard mesotrione reference products (i.e. Callisto 100 SC) against which MIGHTY (MESOTRIONE 10% SC) was compared.

Therefore, for weeds and dose rates in maize claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in maize where equivalence between the effectiveness of MIGHTY (MESOTRIONE 10% SC) and the reference mesotrione products from Syngenta was demonstrated. The applicant therefore wishes to cite the original registrants data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Rapporteur extrapolate from those data.

In the following table, an overview of the control obtained in the different trials conducted in the four EPPO zones is presented, the weeds classified according to their sensitivity to MIGHTY (MESOTRIONE 10% SC) .

The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4 (October 3rd 2013), however this does not replace individual MS systems for expressing control on national labels:

Susceptibility	**Abbreviation**	**Level of control**
Highly Susceptible	HS	95-100 %
Susceptible	S	85-94.9 %
Moderately Susceptible	MS	70-84.9 %
Moderately tolerant	MT	50-69.9 %
Tolerant	T	0-49.9 %

Table 3.2-30: Annual grass- and broadleaved weed spectrum controlled by the recommended dose rate of MIGHTY (MESOTRIONE 10% SC) after post-emergence application, proven by testing results of the applicant in 2015

Weed	Weed GS at appl. (BBCH)	No. of trials	Maize Maritime zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize North-east zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize South-east zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize Mediterranean zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize, All zones Spring appl. Mean (min-max) 1.0 L/ha	Level of effectiveness
Grass weeds																
AVEFA				11-22	1	2.5 (0-5)							11-22	1	2.5 (0-5)	T
DIGSA										12-15	3	81.9 (71.8-92.8)	12-15	3	81.9 (71.8-92.8)	MS
ECHSS	07-21	3	90.6 (52.9-100)	10-14	12	61.5 (5.0-97.8)				12-13	3	77.7 (52.5-93.9)	07-14	21	72.1 (5.0-100)	MS
LOLPE	40	1	28.8										40	1	28.8	T
PASDS	33	1	72.5										33	1	72.5	MS
POAAN	21-40	1	78.8 (57.5-100)	10-11	1	94.5							10-40	3	84.0 (60-96.8)	MS
SETSS				10-13	1	76.3	10	1	85.0	13-14	2	83.8 (75.1-92.5)	10-14	4	82.2 (75.1-92.5)	MS
GGGGG	07-40	4	77.4 (47.5-99)	12	1	95.0				12	2	57.5 (32.5-82.6)	07-40	7	74.2 (32.5-95.0)	MS
GGGGG		10	69.6 (28.8-100)		17	59.4 (0-97.8)		1	85.0		10	76.2 (32.5-93.9(		38	70.6 (0-100)	MS
Broadleaved weeds																
ADSSP													35	1	95	HS
AMADE	30	1	90							16	1	94.2	16	1	94.2	S
AMAHH										14	1	86.3	14	1	86.3	S
AMARE				10-13	4	91.7 (82.5-100)	11	1	86				07-13	6	92.1 (82.5-100)	S
CAGSE										11	1	83.8	11	1	83.8	MS
CAPBP				10-18	4	98.8 (97.0-100)							10-18	4	98.8 (97.0-100)	HS
CHEAL	12	1	100	10-39	13	96.8 (86.8-100)	12	1	88	11-16	3	92.3 (85.0-98.8)	10-39	23	96.4 (85.0-100)	HS
DATST										11	1	99.9	11	1	99.9	HS
FUMOF	13-14	2	93.7 (92.5-94.9)										21-30	2	90.0 (85.0-95.0)	S
GALAP				12	1	96.0							12	1	96.0	HS
LAMAM				12	1	100.0							12	1	100	HS
LAMPU				10-13	3	99.7 (99.3-100)				12	1	83.8	10-13	6	97.2 (83.8-100)	HS
LAPCO				12-14	1	96.0							12-14	1	96.0	HS
MATCH													12	1	100	HS
MATIN	12-30	2	97.5 (95-100)	10-14	4	79.9 (35-97.5)							10-14	5	83.9 (35.0-100)	MS
POLCO	12	1	100	10-13	4	71.0 (35.0-88.0)							10-17	8	81.6 (35-100)	MS
POLLA				11-15	1	35.0							11-15	1	35.0	T
POLPE				10-11	2	85.6 (71.3-100)							10-17	3	90.4 (71.3-100)	S
POLPI										18	1	92.5	18	1	92.5	S
POROL										12-18	2	17.9 (15.8-20.0)	12-18	2	17.9 (15.8-20.0)	T

Weed	Weed GS at appl. (BBCH)	No. of trials	Maize Maritime zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize North-east zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize South-east zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize Mediterranean zone Mean (min-max) 1.0 L/ha	Weed GS at appl. (BBCH)	No. of trials	Maize, All zones Spring appl. Mean (min-max) 1.0 L/ha	Level of effectiveness
SENVU	07-35	4	96.9 (90-100)							13	1	86.3	13	1	86.3	S
SOLNI	12-30	2	96.9 (93.8-100)	10-13	1	98.0				12-15	3	95.8 (92.5-100)	10-30	6	96.5 (93.8-100)	HS
STEME	12-21	2	97.5 (95.0-100)	10-12	4	84.8 (45.0-100							10-21	6	89.0 (45.0-100)	S
THLAR	17	2	100 (100-100)	n.r.	1	100.0							n.r.	3	100 (100-100)	HS
VERAG				11-12	1	72.5							11-12	1	72.5	MS
VERAR				12	1	93.0				12	1	92.3	12	2	92.7	S
VERPE	17	2	100 (100-100)										17	2	100 (100-100)	HS
VIOAR				10-14	7	87.0 (51.3-100)							10-14	7	87.0 (51.3-100)	S
BBBBB	07-35	4	96.9 (90-100)	12	1	100	11-12	1	86	12	2	95.6 (92.5-98.8)	07-35	8	95.6 (86-100)	HS
BBBBB		17	97.9 (85.0-100)		54	89.5 (35.0-100)		3	86.7 (85-88)		18	83.9 (15.8-100)		92	90.7 (16.8-100)	HS

Evaluation, summary and conclusion by zRMS:

The Applicant has submitted data from 19 efficacy field trials in maize conducted in 2015 from Central EPPO zone: Maritime – 4, North-East – 14, South-East – 1) and Mediterranean EPPO zone- 4. The test from United Kingdom (1) and Mediterranean EPPO zone were treated as supporting the application.
The herbicide Mighty was tested for only 1 year. Due to the known and widely used mesotrione, ZM considers the test results to be sufficient for evaluation.
All of the trials submitted followed the EPPO standards and were conducted in accordance with GEP. The trials were carried out by research institutions organisations that are recognised as competent to carry out efficacy testing.
All trials were conducted in areas representative of those where maize is grown.
In each trial tested herbicide was compared to standard Callisto 100 SC.
The trials have been control weed in the following following tested in order to determine the efficacy of BAS 703 07 F of the following pathogens:
The following weeds have been evaluated in studies carried out to determine the effectiveness of their control in maize cultivation:
AMARE – 5 trials: DE (1) average effectiveness:100%; PL (3) average effectiveness 93.7%; RO (1) average effectiveness 94.7%
ADSSP - 1 trial UK 93.1%
BRSNW - 1 trial PL 70.6%
CAPBP - 5 trials PL(3) 98%; LV (1) 99%
CHEAL - 21 trials: DE (2) effectiveness:99.6%; PL (8) 97.8%; LT (3) 98.9%; LV (2) 94.5%; F (2) 99.3%; IT (2) 95.6%; UK (1) 94.1%; RO (1) 96.2%
ECHCG – 17 trials: DE (2) effectiveness:92.3%; PL (8) 73.9%; LT (2) 96.2%; LV (2) 17.5%; F (1) 70.3%; IT (2) 92.8%
DATST – 1 trial F 98.6%
DIGSA - 3 trials IT (2) 88.8%; ES (1) 86.1%
FUMOF – 1 trial UK 90%

GALAP - 1 trial PL 97.7%
LAMAM - 1 trial PL 100%
LAMPU - 4 trials PL (1) 96.4%; LT (2) 99.6%; IT (1) 39.1%; LT (2) 97.0%
LAPCO - 1 trial PL 99%
LOLPE – 1 trial UK 38.7%
MATCH - 2 trials DE (1) 100%; UK (1) 75.2%
MATIN - 5 trials PL(2) 99.5%; LV (1) 99%
PASDS – 1 trial UK 68.7%
POAAN - 2 trials UK (1) 50.6%; LT (1) 96.3%
POLCO (FALCO) - 6 trials: DE (1) 87.8%; PL (2) 94.4%; LV (2) 66%; F (1) 86.8%
POLLA- 1 trial LV 91.8%
POLPE - 2 trials PL (1) 99.6%; LT (1) 96.9%
POROL - 2 trials: IT, average effectiveness:17.9%
SENVU - 1 trial IT 97.8%
SETPF - 4 trials PL (1) 79.1%; RO (1) 96.3%; IT (2) 99.1%; IT 93.8%; ES (1) 100%
SOLNI - 6 trials DE (1) 100%; PL (1) 96.2; UK (1) 92.1%; F (1) 96.3%
STEME - 5 trials PL (1) 100%; DE (1) 100%; LV (1) 99.0%; LT (1) 98.7%
THLAR - 1 trial PL 100%
VERAG - 1 trial PL 83.65%
VERAR - 2 trials PL (1) 100%; ES (1) 100%
VIOAR - 7 trials PL (6) 94.9 LV (1) 81.15%;

The data have been considered according to the following weed susceptibility rating in Poland:

Susceptible	>85%
Moderately Susceptible	70-85%
Moderately Tolerant	60-70%
Insufficient	<60%

The zRMS considers that there are sufficient data to support of registration herbicide Mighty in Poland
Weeds susceptible:
AMARE, CAPBP, CHEAL, FALCO(POLCO), LAMPU, MATIN,, POLPE, SOLNI, STEME, VIOAR
Weed moderately susceptible
ECHCG

Based on the results from the trials all EPPO zone at rate 1.5 L/ha according with GAP.
Number of recommended treatments: 1 per season.
Recommended date of application: BBCH 10-14
Recommended volume of water: 200 – 600 L/ha.
Recommended medium droplet spraying.

Due to different approaches in MS and what extrapolations may be acceptable, the zRMS has not calculated any susceptibility ratings.

The zRMS considers that sufficient effectiveness data have been provided to demonstrate control of a range of broad-leaved weeds. The specific claims that are supported may vary in each MS.

Applicant requested for modification in dose to 1,0 l/ha due to risk in ecotoxicology section. The following is an opinion for a dose of 1,0 l/ha.

comments of zRMS: dRR point 3.2.3	**Efficacy tests** **<u>Maritime EPPO climate zone</u>** The applicant submitted 4 trials carried out in FR, DE, UK on maize. In the opinion of ZRMS, the number of trials on maize as a major crop is insufficient to conclude on efficacy. **<u>NE EPPO climate zone (PL)</u>** The applicant submitted 14 trials carried out on maize. Weed species have been classified as: susceptible (S) – 85% moderately susceptible (MS) - 70-85% moderately tolerant (MT) - 60-70% tolerant (T) - < 60% <u>At the dose rate 1,0l/ha, the target weed species were categorized as:</u> - susceptible (S): AMARE, CAPBP, CHEAL, LAMPU, VIOAR, SOLNI - moderately susceptible (MS): MATIN, POLCO, POLPE, STEME, - moderately tolerant (MT): ECHCG For SOLNI, one trial from DE was taken into account because of high level of control and similar effects like for PL trial. What is more, the number of trials for the following weeds (1 trial per weed) is insufficient to conclude on efficacy: AVEFA, POAAN, SETPF, GALAP, LAMAM, LAPCO,POLLA, THLAR, VERAG, VERAR. To sum up, it might be concluded that the application of MESOTRIONE 10% SC at dose rate 1,0 l/ha, post-emergence provided benefit against weeds on maize comparable to the standard product. **<u>SE EPPO climate zone</u>** The applicant submitted 1 trial carried out in RO, on maize. In the opinion of ZRMS, the number of trials on maize as a major crop is insufficient to conclude on efficacy. **Comment of SI:** Weed species with only 1 or 2 trials can not be approved. **<u>Comment od SI (the second commenting period):</u>** From the summary table 3.2-20 it is evident that based on trial results, only ECHSS can be approved for Slovenia but based only on data from MAR EPPO zone. Maize is major crop in Slovenia with many grass and broad-leaved weeds present on the fields. The authorisation of the product for only one weed species is not acceptable. If the Applicant cannot submit additional data and information, authorisation in Slovenia can not be granted.

3.3 Information on the occurrence or possible occurrence of the development of

resistance (KCP 6.3)

3.3.1 Summary and Conclusions

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2014[2]) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analyzed following the EPPO-Standard (2003[3]), the classification of the Herbicide Resistance Action Committee (HRAC)[4] and the international Survey of Herbicide Resistant Weeds (Heap, 2016). So far 6 cases of resistance in two dicotyledonous weed species (both *Amaranthus* spp.) have been reported to have developed resistance to mesotrione. All cases have been reported from the United States of America. The active substance is therefore classified as having a low inherent risk.

The evaluation of the agronomic risk comes to the conclusion, that MIGHTY (MESOTRIONE 10% SC) bears a low risk of resistance.

The Registration of MIGHTY (MESOTRIONE 10% SC) is endorsed.

3.3.2 Active ingredient

Mesotrione was first introduced in 2001. Mesotrione, with the chemical name 2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione (IUPAC), belongs to the chemical group of Triketones. Mesotrione is a new callistemone herbicide that inhibits the HPPD enzyme (p-hydroxyphenylpyruvate dioxygenase), a component of the biochemical pathway that converts tyrosine to plastoquinone and α-tocopherol (Lee et al. 1998; Cornes 2005). Following treatment in sensitive plants, carotenoid biosynthesis is disrupted in the chlorophyll pathway, resulting in a bleaching effect (Wichert et al., 1999). Carotenoid pigments protect chlorophyll from decomposing in sunlight. Injured weeds appear white to translucent rather than chlorotic (yellow).

Mesotrione is a member of the benzoylcyclo-hexane-1,3-dione family of herbicides, which are chemically derived from a natural phytotoxin obtained from the *Callistemon citrinus* (Curtis) Skeels plants.

The chemical structure of mesotrione is shown in Figure 3.3-1.

[2] Heap, I. M., 2014: The International Survey of Herbicide Resistant Weeds. Web site visited Nov 2014. http://www.weedscience.com

[3] EPPO 2003: Standard PP 1/213 (2): Resistance risk analysis.

[4] HRAC: http://www.HRACglobal.com. Web site visited November 2014.

Figure 3.3-1: **Structure of mesotrione (Source: Heap, I. The International Survey of Herbicide Resistant Weeds. Online. Internet. Thursday, August 18, 2016. Available www.weedscience.com)**

3.3.3 Mode of action

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 (WSSA group 27) herbicide:

- Mode of Action: Inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase
- Chemical family: Triketone

3.3.4 Status

Currently, there are no reported cases of weed resistance to mesotrione reported from within the EU (Heap, 2016).

From outside Europe, the following weed cases of mesotrione resistance have been reported:

Year	Species	Country	MoA
2009	*Amaranthus tuberculatus*	USA (Iowa)	B/2, F2/27, C1/5
2009	*Amaranthus tuberculatus*	USA (Illinois)	B/2, F2/27, C1/5
2011	*Amaranthus tuberculatus*	USA (Iowa)	B/2, G/9, F2/27, C1/5
2011	*Amaranthus tuberculatus*	USA (Nebraska)	F2/27
2011	*Amaranthus palmeri*	USA (Nebraska)	F2/27
2009	*Amaranthus palmeri*	USA (Kansas)	B/2, F2/27, C1/5

MoA: F2=HPPD inhibitors; B=ALS inhibitors; C1= Photosystem II inhibitor; G: EPSP synthase inhibitors

3.3.5 Mechanism(s) of resistance

The mechanism for resistance in the two weed species is currently unknown.

3.3.5.1 Cross-resistance

"When a plant expressing resistance to a herbicide also demonstrates resistance to other herbicides that target the same plant process even though the plant has not been exposed to the other herbicides, the resistance is termed cross-resistance" (Prather et al. 2000).

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 six cases reported from the US.

The mesotrione resistant Amaranth species (*Amaranthus tuberculatus* and *Amaranthus palmeri*) populations in Iowa, Illinois and Kansas (USA) mentioned in section 6.2.8.4 were reported to be cross-resistant to ALS inhibitors (HRAC group B/2), Photosystem II inhibitors (HRAC group and/or EPSP synthase inhibitors (HRAC group G/9).

3.3.5.2 Baseline sensitivity

Weeds vary in their sensitivity towards herbicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Synthetic auxins have been tested and used worldwide for almost 15 years, it is therefore difficult to find unexposed weed populations. No true base line sensitivity data can therefore be established.

3.3.6 Use pattern

MIGHTY (MESOTRIONE 10% SC) is based on the activity of mesotrione which is a selective post-emergence herbicide. In the EU Central zone, the formulation is proposed for use against grasses and broadleaved weeds in maize crops. The recommended dose rate is 150 g ai/ha. The maximum number of applications is one application per growing season.

Mesotrione has been used as straight product as well as in mixtures for many years.

3.3.7 Determination of the Agronomic Risk of Resistance

Agronomic parameters reducing the risk of a development of resistance are:

- Weed control strategies including chemical, non-chemical, biological and cultural practices.
- No repeated applications in the same crop per season.
- Wide crop rotations
- Low weed pressure
- Applications in mixture with other (different mode of action) active substances.
- Alternation with other (different modes of action) active substances.
- High level of activity on the target weed species.
- Low residual activity.
- Chemical diversity

Agronomic parameters increasing the risk of a development of resistance are:

- Repeated applications during a crop cycle.
- Control of weeds with a sole active ingredient (mostly meaning a single site of action).
- Mono cropping.
- High weed pressure
- Application of sub-lethal concentrations of the herbicide.

- Long lasting residual activity.
- Chemical similarity

With respect to the above mentioned agronomic parameters and an **unrestricted** use pattern, the following can be stated for MIGHTY (MESOTRIONE 10% SC) :

MIGHTY (MESOTRIONE 10% SC) contains a sole ingredient.

MIGHTY (MESOTRIONE 10% SC) provides no residual activity.

At the intended use rates, MIGHTY (MESOTRIONE 10% SC) is highly active on the target weed species.

Under unlimited conditions, MIGHTY (MESOTRIONE 10% SC) could be applied repeatedly during a crop cycle.

Recommended crop rotations should be employed. When used in maize, MIGHTY (MESOTRIONE 10% SC) should be used in alteration with herbicides employing other modes of action.

Conclusions:

Although MIGHTY (MESOTRIONE 10% SC) is highly active on the target weed species and provides only little residual activity, the agronomic risk for the development of resistance is considered high if the product is used unrestrictedly, since MIGHTY (MESOTRIONE 10% SC) contains a sole active ingredient only, since it could be applied repeatedly during a crop cycle and since other HRAC group F2 herbicides are available for grasses and broadleaved weed control in rotational crops and thus it is not unlikely that HRAC group F2 herbicides are applied in 2 or more consecutive years.

3.3.8 Conclusion on inherent and agronomic risk analysis

Taking into consideration inherent and agronomic risk for resistance development, it can be concluded that measures for resistance management should be established for the control of annual grasses and broadleaved weeds in maize.

3.3.9 Resistance management for MIGHTY (MESOTRIONE 10% SC)

To avoid the development of resistance of annual grasses and broadleaved weed species to MIGHTY (MESOTRIONE 10% SC) , the following measures for resistance management should be established:

Modifiers related to the application of the product:
The number of applications in maize crops should be limited to 1 application per crop cycle.

Alternations:
In case of repeated applications of herbicides for grass- and broadleaved weed control within a cropping season or in consecutive cropping seasons, only herbicides with a different mode of action should be used.

Cultural practices:
Since cross resistance between different modes of action cannot be excluded, application limitations and the alternation of herbicides should be supported by additional agricultural measures. To minimize the weed pressure, deep soil cultivation (plough) and late sowing are recommended.

3.3.10 Implementation of the management strategy

The basic recommendations for resistance risk management (maximum 1 application) will be clearly recommended on the label. Additional recommendations for product alternations and cultural practices will

be given on the label.

3.3.11 Monitoring, reporting and reaction to changes in performance

Allegations of weeds control failures in Europe and around the world are monitored.

Sharda will inform the regulatory authorities of any new confirmed occurrence of resistance regarding the use of MIGHTY (MESOTRIONE 10% SC) .

Evaluation, summary and conclusion by zRMS:

Mighty contain 100 g/L of mesotrione. Mesotrione is a member of the benzoylcyclo-hexane-1,3-dione family of herbicides, chemical family triketone. In the HRAC mode of action classification it is classified as group F2 (WSSA group 27) herbicide.
To avoid the development of resistance of annual grasses and broadleaved weed species to Mighty, the following measures for resistance management should be established:

- The number of applications in maize crops should be limited to 1 application per crop cycle.
- In case of repeated applications of herbicides for grass- and broadleaved weed control within a cropping season or in consecutive cropping seasons, only herbicides with a different mode of action should be used.

The applicant proposed apply of herbicide Mighty one uses per season.
zRMS agrees with the applicant.

Comments of zRMS:	After commenting period SI asked to include the level of resistance risk for mesotrione in zRMS conclusion. No resistance to mesotrione has yet been reported in Europe for over 10 years. ZRMS considers inherent risk of resistance developing to mesotrione to be low. Because target species like CHEAL, AMARE AND ECHCG have an inherently high risk of developing resistance therefore the inherent risk of resistance developing towards the target weeds should be considered moderate to high. ZRMS consider the overall risk of resistance developing to mesotrione for the proposed use low to moderate. To avoid resistance developing in targeted weeds the resistance management strategy proposed by the applicant has to be implemented and placed on the label.

has been authorised as a herbicide in Europe for over a decade now, and despite its widespread use in maize, no resistance to this active substance has yet been reported in Europe. There is currently no resistance to any Group F2 herbicides in Europe. Additionally, no cross resistance to mesotrione is known, although this does not mean it cannot develop.

Resistance to mesotrione has not been reported in any of the target weeds of ‘Juzan Extra 100 SC’. However, it has been reported in two species within the *Amaranthus* genus, and the target weed AMARE is a member of this genus.

The zRMS would consider that inherent risk of resistance developing to mesotrione to be low. Some of the target weeds e.g. AMARE, ECHCG and CHEAL have an inherently high risk of developing resistance. Therefore, the zRMS would consider the inherent risk of resistance developing towards the target organisms to be moderate to high.

Overall, the zRMS considers that the risk of resistance developing to mesotrione from the proposed use of ‘Juzan Extra 100 SC’ is low to moderate. The risk comes predominantly from the inherent risk of some of the target weeds. As a result of this risk, an unrestricted use pattern is not acceptable, and modifiers are

required. The zRMS considers that the resistance management strategy proposed by the applicant will reduce the risk to an acceptable level.

This represents a low rate of resistance development: In terms of the use pattern, 'Juzan Extra 100 SC' can only be applied once per crop and season, which will also minimise the risk of resistance developing.

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	S-E	N-E			
Maize	UK	S + Y + Q	1	-	-	-	2015	GEP	
	Germany	S + Y + Q	2	-	-	-	2015	GEP	
	France	S + Y + Q	1	1	-	-	2015	GEP	
	Poland	S + Y + Q	-	-	-	4	2015	GEP	
	Latvia	S + Y	-	-	-	3	2015	GEP	
	Bulgaria	S + Y + Q	-	-	1	-	2015	GEP	
	Romania	S + Y + Q	-	-	1	-	2015	GEP	
	Spain	S + Y + Q	-	1	-	-	2015	GEP	
	Italy	S + Y + Q	-	1	-	-	2015	GEP	
	Total, maize		**4**	**3**	**2**	**7**			

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(3)
	Specific guidelines	EPPO PP 1/50(3)
Experimental design	Plot design	RCBD (16)
	Plot size	20-33 m²
	Number of replications	4 (16)
Crop	Trials per crop	Maize (16)
	Varieties per crop	Adevey, Amadeo, Coditank, DKC5276, Drim, Farmstar, Hobbit, LG3202, P1028-1255, MAS 29 T, NK Baleric, P90/27, Pioneer P2949, Subito
	Sowing period	from April 10th to May 22nd
Application	Crop stage (BBCH)* at application	from BBCH 12 to BBCH 16
	Number of appl. Intervals between appl.	1 (16 trials) n.a.
	Spray volumes	200-300 L/ha

Assessment	Assessment types	- Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour
	Assessment dates	As a rule 3 to 4 crop injury ratings
Other relevant information	Soil type	Clay loam (4), Loam (1), Loamy sand (5), Sandy clay loam (2), Sandy loam (2), Sandy silt (1), Silt (1)
	Organic matter content	<1.5%(2), 1.5 to 2.49%(4); 2.5 to 3.5%(0), >3.5%(0); not indicated(10)
	Natural / artificial innoculation…	Preferably weed-free conditions
	Field / Greenhouse...	Field

In the selectivity trials, the performance of MIGHTY (MESOTRIONE 10% SC) was measured against a commercial standard formulation of mesotrione. The straight mesotrione standard used were Callisto 100 SC (registered by Syngenta). The trials were carried out on maize.

The reference products used in the trials are listed in Table 3.4-3.

Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates [L/ha]	Indication	Country	N° of trials
Callisto 100 SC	SC	100 g/L mesotrione	1.5 3.0	Control of grasses and broad-leaved weeds	DE UK FR PL LV BG RO ES IT	2 1 2 4 3 1 1 1 1

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of MIGHTY (MESOTRIONE 10% SC) was assessed in maize in 23 efficacy trials (4 MAR, 14 N-E, 1 S-E and 4 MED) where MIGHTY (MESOTRIONE 10% SC) was applied at 0.75 to 1.5 L/ha, and in 16 crop safety trials (4 MAR, 7 N-E, 2 S-E and 3 MED) where MIGHTY (MESOTRIONE 10% SC) was applied at 1.5 and 3.0 L/ha.

The trials were conducted in the Maritime zone (8; Germany (4), the United Kingdom (2) and N-France (2)), the North-east (21; Poland (12), Latvia (6) and Lithuania (3)), the South-east zone (3; Bulgaria (1) and Romania (2)) and the Mediterranean zone (7; Spain (2), Italy (3) and S-France (2)) in 2015 to evaluate the crop safetyness of MIGHTY (MESOTRIONE 10% SC) in maize.

3.4.1.1 Maize

Phytotoxicity was evaluated in trials presented in this dossier including efficacy and weed free trials.

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where MIGHTY (MESOTRIONE 10% SC) was applied post-emergence, when the majority of the crop was at growth stages ranging from BBCH 11 to BBCH 15 (range: BBCH 10-16) at the rate of 0.75 to 3.0 L/ha in maize. The 3.0 L/ha dose rate corresponds to 300% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

Phytotoxicity in maize trials, Maritime EPPO zone

A total of 4 efficacy trials and 4 selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of MIGHTY (MESOTRIONE 10% SC) when applied as recommended in maize. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the four efficacy trials as well as no adverse effects were observed two of the four selectivity trials conducted in the Maritime EPPO zone.

In one of the German selectivity trials, conducted on the variety P90/27, minor adverse effects were recorded as necrosis at the first assessments after application in the plots treated with MIGHTY (MESOTRIONE 10% SC) at the overlapping dose rate (3N). In this trial, the standard reference product Callisto 100 SC caused similar levels of necrosis at recommended and 3N dose rate.

In the other German selectivity trial, also conducted on P90/27, minor reduction in crop vigour and general crop health (recorded as chlorosis) was observed in the plots treated with MIGHTY (MESOTRIONE 10% SC) at proposed as well as the overlapping dose rate (3N). The standard reference product Callisto 100 SC caused similar adverse effects at recommended and 3N dose rate as well. At later assessments, the crop had recovered in both trials. Furthermore, results from maize trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in maize trials, North-east EPPO zone

A total of 14 efficacy trials and 7 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of MIGHTY (MESOTRIONE 10% SC) when applied as recommended in maize. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the fourteen efficacy trials as well as no adverse effects were observed two of the seven selectivity trials conducted in the North-east EPPO zone.

In five of the seven selectivity trials conducted in the North-east zone, adverse effects as chlorosis, necrosis, stunting, deformations, bleaching and/or reduced vigour was observed primarily in the overlapping dose rate (3.0 L/ha), but also at the proposed dose rate in four of the five trials. In the trials, the standard reference product Callisto 100 SC caused similar levels of adverse effects at recommended and 3N dose rate. At later assessments, the crop had recovered in all five trials. Furthermore, results from maize trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in maize trials, South-east EPPO zone

One efficacy trial and two selectivity trials were conducted in the South-east EPPO zone to assess the crop safety of MIGHTY (MESOTRIONE 10% SC) when applied as recommended in maize. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in the Romanian efficacy trial and the two selectivity trials conducted in the South-east EPPO zone. Furthermore, results from maize trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in maize trials, Mediterranean EPPO zone

A total of four efficacy trials and three selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of MIGHTY (MESOTRIONE 10% SC) when applied as recommended in maize. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in three of the four efficacy trials and two of the three selectivity trials conducted in the Mediterranean EPPO zone.

In an Italian efficacy trial, conducted on the variety P 1028-1255, moderate incidence of chlorosis was observed at the first assessment timing in the plots treated with MIGHTY (MESOTRIONE 10% SC) at the recommended dose rate. No adverse effects were observed in the plots treated with the reference product Callisto.

In the Italian selectivity trial, also conducted on P 1028-1255, minor reduction of general crop health was observed in the plots treated with MIGHTY (MESOTRIONE 10% SC) at the overlapping dose rate (3N). The standard reference product Callisto 100 SC caused minor reductions in crop vigour at recommended and 3N dose rate. In the beginning of September, the number of plants was counted in a defined row in the treated plots, and results here demonstrated that the treatments did not have any adverse effects on the number of plants. Furthermore, results from maize trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

3.4.1.2 Overall conclusion

Maize crops are claimed on the label. The claims of crop safety on these crops are supported with a total of 39 trials conducted in England, Germany, France, Poland, Latvia, Lithuania, Bulgaria, Romania, Spain and Italy. MIGHTY (MESOTRIONE 10% SC) applied at the proposed rate and 3n overlapping rate is safe when used post-emergence on maize.

As this document also clearly demonstrates, then the efficacy and crop safety of MIGHTY (MESOTRIONE 10% SC) is equivalent to the standard mesotrione products to which it was compared. The applicant wishes to cite the original registrant's data on mesotrione now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Table 3.4-4: Phytotoxicity (of product

Number of trials with…		Selectivity trials (16 trials)				Efficacy trials (23 trials)	
		Test product		Standard 1		Test product	Standard 1
		1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha	1.5 L/ha	1.5 L/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	15	10	15	10	22	23
	>5% to 10%	1	3	1	2	0	0
	>10% to 15%	0	1	0	2	0	0
	>15 %	0	2	0	2	1	0
Level of symptoms at the last assessments	0% to 5%	16	16	16	16	23	23
	>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

Evaluation, summary and conclusion by zRMS:

The applicant submitted 13 selectivity tests from the Central EPPO zone and as supporting 3 trials from

the Mediterranean EPPO zone. Phytotoxicity was evaluated in all 23 efficacy trials too.
The crop safety of Mighty has been tested on a wide range of varieties No phytotoxicity symptoms caused by Mighty were observed. Based on the results can be concluded that Mighty is selective in maize at dose 1.5 L/ha.

The amount of performed selectivity trials meets requirements containing in the EPPO guideline PP 1/226 "Number of efficacy trials". Selectivity trials were done according EPPO guideline PP 1/135(3).

No further information is required.

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

Sixteen selectivity trials were conducted and harvested in 2015 to evaluate the effect of MIGHTY (MESOTRIONE 10% SC) on yield of maize crops.

MIGHTY (MESOTRIONE 10% SC) was applied on maize crops at growth stages ranging from BBCH 12 to BBCH 16, i.e. post-emergence. All harvested trials presented in this Biological Assessment Dossier were located within the Maritime zone (4), the North-east (7), the South-east zone (2) and the Mediterranean zone (3) as defined by EPPO Standard PP1/241(1).

3.4.2.1 Materials and methods

Plot yields, as fresh weight plant material, were measured at harvest and converted to t/ha. The data of the treated plots are presented as relative values in relation to the fresh- and/or dry weight for the untreated plots. For further information on materials and methods please refer to section KCP 6.4.2.

3.4.2.2 Summary and evaluation of the field trials conducted in maize, treated post-emergence

A summary of the mean yield assessments expressed as %-relative of the untreated, from trials treated once, conducted in the Maritime zone, the North-east zone, the South-east zone and the Mediterranean zone, are presented in Table 3.4-5.

Maize

A total of sixteen selectivity trials in maize were harvested. The trials were conducted in N-France (1), Germany (2), the UK (1), Poland (4), Latvia (3), Bulgaria (1), Romania (1), Italy (1), Spain (1) and S-France (1) in 2015. MIGHTY (MESOTRIONE 10% SC) was applied post-emergence at 1.5 L/ha and 3.0 L/ha in the selectivity trials. The trials were sprayed at crop growth stages ranging between BBCH 12 and BBCH 16.

Neither MIGHTY (MESOTRIONE 10% SC) nor the mesotrione reference product (Callisto 100 SC) significantly affected the yield (Table 3.4-5) when applied at 1.5 L/ha as well as at the 3n overlapping dose rate (3.0 L/ha) in any of the 16 trials. The results obtained in the trials supports the label claim that MIGHTY (MESOTRIONE 10% SC) is safe to be applied at the recommended dose rate to maize in the spring.

Table 3.4-5: Maritime, North-east, South-east and Mediterranean zone – Crop yield (t fresh weight/ha [WEIFRE] and/or t dry weight/ha [WEIDRY]) of maize treated with MIGHTY (MESOTRIONE 10% SC) , single application, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	MIGHTY (MESOTRIONE 10% SC) at:		Mesotrione Ref. prod. At:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha

Crop, trial type	No. of trials	Untreated	MIGHTY (MESOTRIONE 10% SC) at:		Mesotrione Ref. prod. At:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha
Maize, Fresh weight						
Maritime EPPO zone	3	40.9 (33.4-45.0)	109 (100-114)	113 (101-124)	110 (100-118)	108 (102-114)
Mediterranean EPPO zone	2	46.2 (35.0-57.5)	99 (-)	100 (95-104)	100 (94-105)	100 (95-106)
Maize, Dry weight						
Maritime EPPO zone	4	12.1 (5.6-16.8)	103 (90-114)	109 (100-120)	105 (92-118)	105 (89-120)
North-east EPPO zone	7	19.3 (4.2-43.1)	101 (97-103)	106 (98-112)	106 (100-118)	104 (94-124)
South-east EPPO zone	2	5.7 (5.2-6.2)	96 (91-102)	93 (85-101)	90 (81-100)	86 (72-101)
Mediterranean EPPO zone	3	14.2 (12.0-16.7)	101 (90-109)	96 (90-101)	99 (87-109)	99 (89-107)

3.4.2.3 Conclusion

MIGHTY (MESOTRIONE 10% SC) applied at the proposed dose rate in maize did not affect crop yield nor the quality of the crop yield significantly in any of the 16 trials conducted on maize. In all trials, MIGHTY (MESOTRIONE 10% SC) applied at 3.0 L/ha – representative for sprayer overlap – did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that MIGHTY (MESOTRIONE 10% SC) is as safe to the crop as the reference product (Callisto 100 SC) used in the trials.

As this document clearly demonstrates, the efficacy and crop safety of MIGHTY (MESOTRIONE 10% SC) is equivalent to the standard mesotrione product to which it was compared. The applicant therefore wishes to cite the original registrant's data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Table 3.4-6: Relationship between phytotoxicity and yield, from selectivity trials harvested

Test report	Variety	Maximum phyto. At 1.5 L/ha rate (%) (DAA)		Maximum phyto. At 3.0 L/ha rate (%) (DAA)		Yield in the untreated control Absolute figures (unit)	Yield at 1.5 L/ha as % of untreated (%-rel.)		Yield at 3.0 L/ha rate as % of untreated (%-rel.)	
		Test product	Standard 1	Test product	Standard 1		Test product	Standard 1	Test product	Standard 1
S15-01092-02	P1028-1255	0.0 (14) PHYGEN 100 (14) Vigour	0.0 (14) PHYGEN 97.3 (14) Vigour	2.8 (14) PHYGEN 100 (14) Vigour	0.0 (14) PHYGEN 93.6 (14) Vigour	12.0 (100)	12.3 (103)	12.1 (101)	11.6 (97)	12.0 (100)
S15-01093-03	P90/27	0.0 (-) Necrosis 97.5 (18) Vigour	1.3 (12) Necrosis 95.0 (18) Vigour	1.3 (18) Necrosis 96.3 (18) Vigour	0.5 (18) Necrosis 95.0 (18) Vigour	5.6 (100)	5.1 (90)	5.2 (92)	5.6 (100)	5.0 (89)
S15-01093-04	P90/27	2.4 (16) Chlorosis 95.0 (16) Vigour	6.3 (16) Chlorosis 95.0 (16) Vigour	11.3 (16) Chlorosis 95.0 (16) Vigour	15.0 (16) Chlorosis 95.0 (16) Vigour	14.3 (100)	14.4 (101)	14.1 (99)	14.4 (101)	14.5 (102)
fiHPwKu-15-43	MAS 29.T	4.3 (7) Chlorosis 0.0 (-) Necrosis	4.5 (7) Chlorosis 0.0 (-) Necrosis	23.8 (7) Chlorosis 5.5 (14) Necrosis	26.3 (7) Chlorosis 5.3 (14) Necrosis	14.3 (100)	14.4 (101)	14.1 (99)	14.4 (101)	14.5 (102)
H-15-1-14-ZM-2260	Drim	0.0 (-) Chlorosis 99.0 (-) Vigour	0.0 (-) Chlorosis 99.0 (-) Vigour	7.0 (14) Chlorosis 93.0 (14) Vigour	10.0 (14) Chlorosis 90.0 (14) Vigour	28.9 (100)	29.8 (103)	34.1 (118)	30.6 (106)	35.6 (124)
H-15-1-14-ZM-2261	Coditank	0.0 (-) Chlorosis 100.0 (-) Vigour	0.0 (-) Chlorosis 100.0 (-) Vigour	7.0 (14) Chlorosis 93.0 (14) Vigour	10.0 (14) Chlorosis 90.0 (14) Vigour	43.1 (100)	43.0 (100)	45.2 (105)	48.3 (112)	43.8 (102)

Test report	Variety	Maximum phyto. At 1.5 L/ha rate (%) (DAA)		Maximum phyto. At 3.0 L/ha rate (%) (DAA)		Yield in the untreated control Absolute figures (unit)	Yield at 1.5 L/ha as % of untreated (%-rel.)		Yield at 3.0 L/ha rate as % of untreated (%-rel.)	
		Test product	Standard 1	Test product	Standard 1		Test product	Standard 1	Test product	Standard 1
H-15-1-14-ZM-2262	Drim	0.0 (-) Chlorosis 0.0 (-) Deformation 0.0 (-) Stunting 100.0 (-) Vigour	0.0 (-) Chlorosis 0.0 (-) Deformation 0.0 (-) Stunting 100.0 (-) Vigour	10.0 (14) Chlorosis 5.0 (14) Deformation 5.0 (31) Stunting 85.0 (14) Vigour	15.0 (14) Chlorosis 5.0 (14) Deformation 0.0 (-) Stunting 80.0 (14) Vigour	43.1 (100)	43.7 (101)	46.2 (107)	44.7 (104)	42.4 (98)
S15-01093-05	NK Baleric	8.0 (14) Bleaching	30.0 (14) Bleaching	4.3 (14) Bleaching	30.0 (14) Bleaching	4.2 (100)	4.1 (97)	4.4 (105)	4.5 (107)	3.9 (94)

Evaluation, summary and conclusion by zRMS:

The applicant provided 13 selectivity studies from the Central EPPO zone and as supporting 3 trials from the Mediterranean EPPO zone. The data from selectivity trials prove that Mighty has no negative impact on yield in the maize.
The amount of performed selectivity trials meets requirements containing in the EPPO guideline PP 1/226 "Number of efficacy trials". Selectivity trials were done according EPPO guideline PP 1/135.
No further information is required.

The ecotoxicology section has change the max. dose – 1,0 l/ha of the product, therefore max dose of 1,0 l/ha can be accepted by the efficacy section. All field trials have been conducted at higher dose (1,5 l/ha) than is currently proposed (1,0 l/ha). Selectivity data presented for the higher dose stay valid for the lower dose.

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

Sixteen selectivity trials treated with MIGHTY (MESOTRIONE 10% SC) were harvested and yields recorded. In these, assessments were conducted on the potential impact of treatment on oil content, protein content, starch content, Thousand Grain weight and moisture content of the harvested crop.

Moisture content

The results obtained on moisture content of the harvested maize crop are presented in Table 3.4-7.

In the trials evaluated, MIGHTY (MESOTRIONE 10% SC) had no detrimental effect on the moisture content of the harvested maize crops. When comparing the results obtained with MIGHTY (MESOTRIONE 10% SC) against the results obtained with the mesotrione reference product at the applied dose rates, both products performed statistically similar.

Table 3.4-7: Maritime, North-east, South-east and Mediterranean zone – Moisture content of harvested maize crops – crop treated with MIGHTY (MESOTRIONE 10% SC) with single application, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	MIGHTY (MESOTRIONE 10% SC) at:		Mesotrione Ref. prod. At:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		%	1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha
Maize, selectivity trials						
Maritime EPPO zone	4	53.7 (21.9-73.8)	101 (100-102)	100 (98-101)	100 (97-101)	99 (97-100)
North-east EPPO zone	1	21.9	100	100	103	101
South-east EPPO zone	2	12.0 (10.2-13.7)	100 (98-102)	99 (98-100)	100 (99-101)	100 (100-101)
Mediterranean EPPO zone	3	49.1 (16.3-71.0)	97 (93-103)	100 (95-102)	100 (97-103)	99 (97-102)

Oil content

The results obtained on oil content of the harvested maize grains are presented in Table 3.4-8.

In the trials evaluated, MIGHTY (MESOTRIONE 10% SC) had no detrimental effect on the oil content of the harvested maize grains. When comparing the results obtained with MIGHTY (MESOTRIONE 10% SC) against the results obtained with the mesotrione reference product at the applied dose rates, both products performed statistically similar.

Table 3.4-8: North-east zone – Oil content of harvested maize grains – crop treated with MIGHTY (MESOTRIONE 10% SC) with single application, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	MIGHTY (MESOTRIONE 10% SC) at:		Mesotrione Ref. prod. At:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		%	1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha
Maize, selectivity trials						
North-east EPPO zone	2	5.2 (5.1-5.3)	103 (101-105)	103 (101-105)	103 (101-105)	103 (99-107)

Protein content

The results obtained on protein content of the harvested maize grains are presented in Table 3.4-9.

In the trials evaluated, MIGHTY (MESOTRIONE 10% SC) had no detrimental effect on the protein content of the harvested maize grains. When comparing the results obtained with MIGHTY (MESOTRIONE 10% SC) against the results obtained with the mesotrione reference product at the applied dose rates, both products performed statistically similar.

Table 3.4-9: North-east zone – Protein content of harvested maize grains – crop treated with MIGHTY (MESOTRIONE 10% SC) with single application, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	MIGHTY (MESOTRIONE 10% SC) at:		Mesotrione Ref. prod. At:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		%	1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha
Maize, selectivity trials						
North-east EPPO zone	2	11.8 (-)	113 (112-114)	111 (110-112)	112 (111-113)	111 (110-113)

Starch content

The results obtained on starch content of the harvested maize grains are presented in Table 3.4-10.

In the trials evaluated, MIGHTY (MESOTRIONE 10% SC) had no detrimental effect on the starch content of the harvested maize grains. When comparing the results obtained with MIGHTY (MESOTRIONE 10% SC) against the results obtained with the mesotrione reference product at the applied dose rates, both products performed statistically similar.

Table 3.4-10: North-east zone – Starch content of harvested maize grains – crop treated with MIGHTY (MESOTRIONE 10% SC) with single application, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	MIGHTY (MESOTRIONE 10% SC) at:		Mesotrione Ref. prod. At:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		%	1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha
Maize, selectivity trials						
North-east EPPO zone	2	52.1 (49.7-54.6)	97 (96-98)	98 (96-99)	99 (98-99)	98 (-)

Thousand Grain Weight

The results obtained on Thousand Grain Weight of the harvested maize grains are presented in Table 3.4-11.

In the trials evaluated, MIGHTY (MESOTRIONE 10% SC) had no detrimental effect on the Thousand Grain Weight of the harvested maize grains. When comparing the results obtained with MIGHTY (MESOTRIONE 10% SC) against the results obtained with the mesotrione reference product at the applied dose rates, both products performed statistically similar.

Table 3.4-11: North-east zone – Thousand Grain Weight of harvested maize grains – crop treated with MIGHTY (MESOTRIONE 10% SC) with single application, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	MIGHTY (MESOTRIONE 10% SC) at:		Mesotrione Ref. prod. At:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		%	1.5 L/ha	3.0 L/ha	1.5 L/ha	3.0 L/ha
Maize, selectivity trials						
North-east EPPO zone	3	281.6 (240-318)	101 (99-104)	102 (99-107)	101 (100-101)	103 (98-110)

3.4.3.1 Conclusion

MIGHTY (MESOTRIONE 10% SC) applied at the proposed dose rate in maize did not affect crop yield nor the quality of the crop yield significantly in any of the 16 trials conducted on maize. In all trials, MIGHTY (MESOTRIONE 10% SC) applied at 3.0 L/ha – representative for sprayer overlap – did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that MIGHTY (MESOTRIONE 10% SC) is as safe to the crop as the reference product (Callisto 100 SC) used in the trials.

As this document clearly demonstrates, the efficacy and crop safety of MIGHTY (MESOTRIONE 10% SC) is equivalent to the standard mesotrione product to which it was compared. The applicant therefore wishes to cite the original registrant's data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Evaluation, summary and conclusion by zRMS:

In selectivity trials assessments were conducted on the potential impact of treatment MIGHTY on oil content, protein content, starch content, Thousand Grain weight and moisture content of the harvested crop. The yield quality data prove that Mighty has no negative impact on crop yield nor the quality of the crop yield significantly, when it is used according to the GAP.

No further information is required.

The ecotoxicology section has change the max. dose – 1,0 l/ha of the product, therefore max dose of 1,0 l/ha can be accepted by the efficacy section. All field trials have been conducted at higher dose (1,5 l/ha) than is currently proposed (1,0 l/ha). Selectivity data presented for the higher dose stay valid for the lower dose.

3.4.4 Effects on transformation processes (KCP 6.4.4)

MIGHTY (MESOTRIONE 10% SC) is composed of mesotrione which has been widely used for a number years on maize crops without identifying any quality problems on the treated crops.

MIGHTY (MESOTRIONE 10% SC) is applied early in the season (up to BBCH 14), before inflorescence emergence and heading, and as the active ingredient is not systemic, it is therefore not expected that the active ingredient is transferred to the grains. For further information on residues, please refer to Part B, Section 4: Metabolism and residues.

Evaluation, summary and conclusion by zRMS:

The applicant has not submitted data.
zRMS agrees. New tests are not necessary.

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

Mesotrione is applied early in the season (early post-emergence) and as the active ingredient is not systemic, it is therefore not expected that the active ingredient is transferred to grains. Thus, no influence on the ability of plant parts from treated crops to germinate is expected.

Evaluation, summary and conclusion by zRMS:

The applicant has not submitted data.
zRMS agrees. New tests are not necessary.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Summaries of the studies submitted in support of this application with regard to toxicity to non-target plants are included below. The seedling emergence and vegetative vigour studies, included below, test the formulation A12739A, but they are used to address the risk from both the active substance mesotrione and the formulation.

Guideline(s)

Proposal for Updated Guideline 208: Terrestrial Non-Target Plant Test: 208A: Seedling Emergence and Seedling Growth Test (July 2000)

GLP: Yes

Executive Summary

The effect of mesotrione 100g/L SC formulation A12739A on seedling emergence in the monocotyledonous species, *Allium cepa, Avena sativa* and *Lolium perenne*, and the dicotyledonous species, *Brassica oleracea, Brassica rapa, Cucumis sativa, Glycine max, Lactuca sativa, Linum usitatissimum* and *Lycopersicon esculentum*, was assessed in a glasshouse test. Pots, sown with seeds of these species, were treated with A12739A at test rates between 1.9 and 150 g a.s./ha. The seeds were then allowed to grow for 21 days after treatment, under controlled conditions in a glasshouse. Seedling emergence, seedling survival, height and shoot weight were determined at the end of the test.

No statistically significant effects on emergence were detected at any of the tested application rates, up to and including 150g a.s./ha. Similarly, rates up to and including 150 g a.s./ha did not have significant effects greater than 50% on shoot height or dry weight in *A. sativa, L. perenne, C. sativa, G. max* and *L. usitatissimum*. The remaining five species experienced reductions of 50% or more in height and/or dry weight at one or more of the rates tested. The most sensitive variable in all cases was biomass and the ER50 values produced for each species are given in Table B.9.11.2-1.

Table B.9.6.2-1: Effects of A12739A on the biomass of non-target plants following pre-emergent application

Species	Family	Seedling emergence ER50 Biomass (g a.s./ha)
MAGNOLIIDAE (dicotyledons)		
Brassica oleracea (cabbage)	Brassicaceae	19.8
Brassica rapa (turnip)	Brassicaceae	20.6
Cucumis sativa (cucumber)	Cucurbitaceae	>150
Glycine max (soybean)	Fabaceae	>150
Lactuca sativa (lettuce)	Asteraceae	16.6
Linum usitatissimum (flax)	Linaceae	>150
Lycopersicon esculentum (tomato)	Solanaceae	23.6
LILIIDAE (monocotyledons)		
Allium cepa (onion)	Liliaceae	39.8
Avena sativa (oat)	Poaceae	>150
Lolium perenne (perennial ryegrass)	Poaceae	>150

Materials and methods Test Material:	A12739A, Mesotrione 100 SC Callisto	
Description:	Tan liquid	
Lot/Batch #:	SAF2B059AA[GB]	
Contents of active ingredients (measured):	96.9 g/L	
CAS #:	104206-82-8	
Treatments		
Test rates:		Nominal: 1.9, 5.6, 16.7, 50.0, and 150 g a.s./ha
Positive control:		Reverse osmosis purified well water
Spray volume:		200 L/ha (±10%)
Application method:		Calibrated Track Sprayer (spray booth) (pressure 1.38 bar). Nozzle suspended at approximately 41cm above target.
Test organisms		
Species tested:		Three monocotyledonous species; *Allium cepa* (Liliaceae), *Avena sativa* (Poaceae) and *Lolium perenne* (Poaceae), Seven dicotyledonous species; *Brassica oleracea* (Brassicaceae), *Brassica rapa* (Brassicaceae), *Cucumis sativa* (Cucurbitaceae), *Glycine max* (Fabaceae), *Lactuca sativa* (Asteraceae), *Linum usitatissimum* (Linaceae) and *Lycopersicon esculentum* (Solanaceae)
Planting information		
Test soil:		Sandy Loam (55 % sand, 26 % silt, 19 % clay with organic matter content of 2 %, analysed by Agvise Laboratories, Inc., Northwood, North Dakota). Created from a mixture of kaolinite clay, industrial quartz sand and peat mixed in a ratio of 4:50:2. Slow-release fertilizer and limestone were also added for nutrients and to buffer pH respectively.
Planting dates:		03 March 2003: *A. cepa*, *L. sativa*, *L. perenne*, *L. usitatissimum* and *L. esculentum* 04 March 2003: *A. sativa*, *B. oleracea*, *B. rapa*, *C. sativa* and *G. max*

Plant pots:	Dimensions approximately depth 16 cm, height 12 cm (volume 1940 cm3). Soil added to pots and gently compacted using a template, leaving 10 uniform holes for planting.
Planting:	*A. sativa*, *C. sativa* and *G. max* planted at depth of approximately 20 mm. All other species planted at a depth of 6 mm.
Test design	
Number of seeds per pot:	10
Replication:	4 pots per species per treatment group
Environmental test conditions	
Watering:	Provided via sub-irrigation with well water (periodically tested for metals and pesticides). Irrigation trays filled to uniform depth when watering occurred. *A. cepa*, *L. sativa*, *L. perenne*, *L. usitatissimum* and *L. esculentum* watered every 2 to 4 days. *A. sativa*, *B. oleracea*, *B. rapa*, *C. sativa* and *G. max* watered every 1 to 5 days.
Photoperiod:	14 h light : 10 h dark (Natural light supplemented with artificial light) Moles of Photosynthetically Active Radiation: *A. cepa*, *L. sativa*, *L. perenne*, *L. usitatissimum* and *L. esculentum* Mean 15.5 (max 18.7, min 12.2) *A. sativa*, *B. oleracea*, *B. rapa*, *C. sativa* and *G. max* Mean 15.6 (max 18.7, min 12.2)
Temperature:	*A. cepa*, *L. sativa*, *L. perenne*, *L. usitatissimum* and *L. esculentum* Mean 21.8 ºC (max 30.2 ºC, min 16.4 ºC) *A. sativa*, *B. oleracea*, *B. rapa*, *C. sativa* and *G. max* Mean 21.9 ºC (max 30.2 ºC, min 16.67 ºC)
Humidity:	*A. cepa*, *L. sativa*, *L. perenne*, *L. usitatissimum* and *L. esculentum* Mean 39.1 % (max 79.7 %, min 10.3 %) *A. sativa*, *B. oleracea*, *B. rapa*, *C. sativa* and *G. max* Mean 39.8 % (max 79.7 %, min 10.3 %)

Study Design and Methods

The experimental design consisted of five treatment groups and a negative control for each of seven dicot species and three monocot species. Each treatment group had four replicate pots with ten seeds planted in each pot. Data collected from all replicates within a treatment group were combined for determining the lowest-observed-effect-rate (LOER), no-observed-effect-rate (NOER), ER25, and ER50 values, when possible. A single application of A12739A (formulated product) was made to the treatment groups, while the negative control group was sprayed with water. Spray mixtures were applied at a nominal spray volume of approximately 200 L/ha. The nominal spray application rates were 1.9, 5.6, 16.7, 50.0, and 150 g mesotrione (the active substance of A12739A) per hectare (g a.s./ha).

Test mixtures were applied on two consecutive days, with all the treatments for a species being applied on the same day. On the day of application 3.75 mL of the test substance was diluted to 500 mL with reverse

osmosis purified water, to produce a stock solution of 150 g a.s./ha at the application rate. This was then serially diluted to produce the test solutions. Either control solutions were applied first then test rates in order of increasing test rate to avoid cross-contamination, or spray booth lines were cleaned before changing test solutions. Samples of the test solutions were collected for analytical determination of the actual test rates (three samples from the highest and lowest test rates, one from the other solutions including the controls).

Seeds were impartially assigned to, and planted in, pre-labelled growth pots on the day of test initiation. Treatment application occurred on the day of planting. The replicate pots were placed in a randomised block design on a glasshouse table after spray mixtures were applied. Observations of emergence were made on Days 7, 14, and 21. Height and plant condition were assessed only on Day 21. Dry weights were determined from seedling shoots, cut at the soil surface, collected on Day 21.

Seedling emergence was recorded as the number of emerged seedlings at 21 days after treatment. Survival was recorded as the number of living plants per replicate. Biomass was recorded as the total dry shoot weight per replicate of surviving plants at 21 days after treatment. Height was recorded as the total height of surviving plants per replicate to the nearest centimetre (seedlings less than 1 cm tall were assigned a value of 0.25 cm). The mean seedling emergence, survival, biomass and height of the control and treatment groups were compared using a Dunnett's t-test. Effect rates (ERx) and their confidence limits were determined using non-linear regression analysis using the NLIN procedure in SAS version 8. These were determined using treatment group mean values. Effect rates were only determined where one or more treatment groups showed a ≥ 25 % reduction relative to the control for the variable of interest.

Results and Discussion

Analytical Verification of Spray Mixtures:

The control samples showed no indication of the presence of the test substance or of the presence of a co-eluting substance at the characteristic retention time of the test substance. Samples collected on March 3, 2003 to verify test substance concentrations for the 1.9 and 150 g a.s./ha spray mixtures had means of 1.55 and 129 g a.s./ha, respectively. All samples were between 81 to 86 % of nominal concentrations.

Samples collected on March 4, 2003 to verify test substance concentrations for the 1.9 and 150 g a.s./ha spray mixtures had means of 1.72 and 135 g a.s./ha, respectively. All samples were between 90 to 95 % of nominal concentrations.

Biological Results:

The results for survival, height, biomass and seedling emergence are outlined below (Table B.9.11.2-2).

Table B.9.6.2-2: Summary of survival, height, biomass and seedling emergence results for plant species, exposed to A12739A

Application rate (g a.s./ha)	**Seedling emergence 21 days after treatment Mean ± SD (% reduction) a**	**Survival Mean per replicate ± SD (% reduction) a**	**Biomass (g) Mean ± SD (% reduction) a**	**Height (cm) Mean ± SD (% reduction) a**
Allium cepa				
Control	8.00 ± 8.82	7.75 ± 1.26	0.070 ± 0.0235	5.4 ± 1.27
1.9	8.00 ± 2.00 (0%)	7.25 ± 1.71 (6%)	0.069 ± 0.0214 (2%)	5.4 ± 1.75 (0%)
5.6	8.50 ± 0.58 (-6%)	7.50 ± 0.58 (3%)	0.062 ± 0.0210 (12%)	5.1 ± 1.28 (6%)
16.7	8.50 ± 0.58 (-6%)	6.25 ± 1.26 (19%)	0.070 ± 0.0161 (0%)	5.2 ± 1.52 (3%)
50.0	10.00 ± 0.00 (-25%)	2.50 ± 2.08 * (68%)	0.019 ± 0.0161 * (74%)	1.9 ± 1.60 * (65%)
150.0	8.75 ± 1.26 (-9%)	2.00 ± 1.15 * (74%)	0.012 ± 0.0083 * (83%)	1.2 ± 0.83 * (78%)
Avena sativa				
Control	10.00 ± 0.00	10.00 ± 0.00	2.12 ± 0.204	31.8 ± 1.58

1.9	9.75 ± 0.50 (3%)	9.75 ± 0.50 (3%)	1.91 ± 0.212 (10%)	30.1 ± 1.57 (5%)
5.6	9.50 ± 0.58 (5%)	9.50 ± 0.58 (5%)	2.01 ± 0.089 (5%)	30.1 ± 1.36 (5%)
16.7	9.25 ± 0.96 (8%)	9.25 ± 0.96 (8%)	1.95 ± 0.130 (8%)	28.7 ± 2.31 (10%)
50.0	9.75 ± 0.50 (3%)	9.75 ± 0.50 (3%)	2.15 ± 0.172 (-2%)	31.9 ± 2.86 (0%)
150.0	9.50 ± 1.00 (5%)	9.50 ± 1.00 (5%)	1.76 ± 0.318 * (17%)	28.2 ± 4.27 (11%)
Lolium perenne				
Control	10.00 ± 0.00	10.00 ± 0.00	0.556 ± 0.0520	17.0 ± 1.49
1.9	9.25 ± 0.50 (8%)	9.25 ± 0.50 (8%)	0.431 ± 0.1659 (23%)	14.0 ± 1.49 * (18%)
5.6	9.75 ± 0.50 (3%)	9.75 ± 0.50 (3%)	0.486 ± 0.0482 (13%)	14.8 ± 1.33 (13%)
16.7	9.75 ± 0.50 (3%)	9.50 ± 1.00 (5%)	0.528 ± 0.1527 (5%)	14.1 ± 2.49 (17%)
50.0	9.50 ± 1.00 (5%)	9.50 ± 1.00 (5%)	0.533 ± 0.1508 (4%)	15.2 ± 1.83 (11%)
150.0	9.25 ± 0.96 (8%)	8.50 ± 0.58 * (15%)	0.362 ± 0.0934 (35%)	12.1 ± 1.68 * (29%)
Brassica oleracea				
Control	9.75 ± 0.50	9.50 ± 0.58	2.07 ± 0.286	10.0 ± 0.90
1.9	9.50 ± 0.58 (3%)	9.50 ± 0.58 (0%)	1.96 ± 0.102 (5%)	9.5 ± 0.67 (5%)
5.6	10.00 ± 0.00 (-3%)	9.50 ± 1.00 (0%)	1.70 ± 0.141 * (18%)	8.3 ± 0.53 * (17%)
16.7	10.00 ± 0.00 (-3%)	8.75 ± 0.96 (8%)	1.12 ± 0.338 * (46%)	6.4 ± 1.30 * (37%)
50.0	10.00 ± 0.00 (-3%)	6.75 ± 1.26 * (29%)	0.42 ± 0.192 * (80%)	3.0 ± 0.50 * (70%)
150.0	10.00 ± 0.00 (-3%)	1.25 ± 1.50 * (87%)	0.04 ± 0.042 * (98%)	0.5 ± 0.58 * (95%)
Brassica rapa				
Control	9.50 ± 0.58	9.50 ± 0.58	3.23 ± 0.141	10.5 ± 0.89
1.9	9.00 ± 1.15 (5%)	9.00 ± 1.15 (5%)	3.45 ± 0.295 (-7%)	10.8 ± 0.86 (-3%)
5.6	10.00 ± 0.00 (-5%)	9.00 ± 1.15 (5%)	3.17 ± 0.138 (2%)	9.7 ± 1.33 (7%)
16.7	10.00 ± 0.00 (-5%)	7.50 ± 0.58 * (21%)	2.16 ± 0.768 * (33%)	7.7 ± 1.50 * (27%)
50.0	9.00 ± 0.82 (5%)	2.50 ± 1.91 * (74%)	0.16 ± 0.257 * (95%)	1.4 ± 1.11 * (87%)
150.0	10.00 ± 0.00 (-5%)	0.50 ± 0.58 * (95%)	0.00 ± 0.001 * (100%)	0.3 ± 0.43 * (97%)
Cucumis sativa				
Control	9.75 ± 0.50	9.75 ± 0.50	3.37 ± 0.297	7.2 ± 0.69
1.9	9.50 ± 0.58 (3%)	9.50 ± 0.58 (3%)	3.05 ± 0.223 (9%)	6.6 ± 0.62 (8%)
5.6	9.25 ± 0.50 (5%)	9.25 ± 0.50 (5%)	2.75 ± 0.204 * (18%)	6.3 ± 0.24 (13%)
16.7	9.75 ± 0.50 (0%)	9.50 ± 0.58 (3%)	2.98 ± 0.478 (11%)	6.1 ± 0.24 (15%)
50.0	9.50 ± 1.00 (3%)	9.50 ± 1.00 (3%)	2.84 ± 0.283 (16%)	6.5 ± 1.05 (9%)
150.0	9.25 ± 0.96 (5%)	8.50 ± 1.29 (13%)	2.45 ± 0.439 * (27%)	6.4 ± 1.14 (12%)
Glycine Max				

Control	9.75 ± 0.50	9.75 ± 0.50	3.67 ± 0.311	12.5 ± 1.15
1.9	9.00 ± 0.82 (8%)	9.00 ± 0.82 (8%)	3.61 ± 0.248 (2%)	11.6 ± 1.37 (7%)
5.6	8.75 ± 0.96 (10%)	8.75 ± 0.96 (10%)	3.71 ± 0.405 (-1%)	11.2 ± 1.72 (10%)
16.7	9.50 ± 0.58 (3%)	9.50 ± 0.58 (3%)	3.90 ± 0.197 (-6%)	13.0 ± 2.40 (-4%)
50.0	8.50 ± 1.29 (13%)	8.50 ± 1.29 (13%)	3.84 ± 0.431 (-5%)	11.5 ± 2.23 (8%)
150.0	8.75 ± 0.50 (10%)	8.75 ± 0.50 (10%)	3.55 ± 0.263 (3%)	11.4 ± 0.55 (9%)
Lactuca sativa				
Control	6.75 ± 0.96	6.75 ± 0.96	0.627 ± 0.1237	3.6 ± 0.48
1.9	7.75 ± 0.00 (-15%)	7.00 ± 0.00 (-4%)	0.518 ± 0.0651 (17%)	3.3 ± 0.64 (8%)
5.6	7.25 ± 0.96 (-7%)	7.25 ± 0.96 (-7%)	0.514 ± 0.1875 (18%)	3.4 ± 0.64 (4%)
16.7	7.75 ± 0.50 (-15%)	4.50 ± 1.00 * (33%)	0.283 ± 0.2541 * (55%)	1.8 ± 1.33 * (51%)
50.0	7.25 ± 0.96 (-7%)	1.00 ± 0.82 * (85%)	0.078 ± 0.1268 * (88%)	0.4 ± 0.33 * (89%)
150.0	8.00 ± 0.82 (-19%)	0.50 ± 0.58 * (93%)	0.005 ± 0.0090 * (99%)	0.1 ± 0.06 * (99%)
Linum usitatissimum				
Control	9.75 ± 0.50	9.75 ± 0.50	0.310 ± 0.0517	9.4 ± 0.94
1.9	9.00 ± 0.00 (8%)	9.00 ± 0.00 (8%)	0.267 ± 0.0728 (14%)	8.6 ± 1.03 (9%)
5.6	10.00 ± 0.00 (-3%)	9.75 ± 0.50 (0%)	0.292 ± 0.0635 (6%)	9.5 ± 0.90 (-1%)
16.7	9.50 ± 0.58 (3%)	9.50 ± 0.58 (3%)	0.249 ± 0.0238 (19%)	8.6 ± 0.62 (9%)
50.0	9.50 ± 0.58 (3%)	9.25 ± 0.96 (5%)	0.322 ± 0.0816 (-4%)	9.0 ± 0.95 (5%)
150.0	9.50 ± 0.58 (3%)	9.50 ± 0.58 (3%)	0.246 ± 0.0670 (21%)	8.0 ± 1.23 (15%)
Lycopersicon esculentum				
Control	8.25 ± 2.22	8.00 ± 2.00	0.862 ± 0.2154	6.2 ± 1.78
1.9	8.25 ± 0.96 (0%)	7.75 ± 1.26 (3%)	0.866 ± 0.1849 (0%)	5.7 ± 1.10 (9%)
5.6	8.50 ± 1.73 (-3%)	8.00 ± 2.16 (0%)	0.722 ± 0.2264 (16%)	5.6 ± 1.91 (9%)
16.7	9.00 ± 0.82 (-9%)	8.50 ± 1.00 (-6%)	0.604 ± 0.0966 (30%)	5.4 ± 0.72 (13%)
50.0	7.75 ± 1.50 (6%)	1.00 ± 1.41 * (88%)	0.084 ± 0.0973 * (90%)	0.6 ± 0.73 * (90%)
150.0	7.00 ± 1.41 (15%)	0.25 ± 0.50 * (97%)	0.002 ± 0.0030 * (100%)	0.1 ± 0.15 * (99%)

[a] % reduction in comparison to the control, negative values indicate an increase relative to the control.

** Treatment group mean is significantly different to the control mean Dunnett's t-test ($p < 0.05$)*

The LOER, NOER, ER_{25}, and ER_{50} for each of the ten test species are presented below (Table B.9.11.2-3).

Table B.9.6.2-3: Effects of A12739A on the emergence, survival and growth of non-target plants following pre-emergent application

Species	**21-day Emergence**	**21-day Survival**

	LOER	NOER	ER25	ER50	LOER	NOER	ER25	ER50
	(All units g a.s./ha)							
Monocots:								
Allium cepa (onion)	>150	150	>150	>150	50.0	16.7	13.3	40.0
Avena sativa (oat)	>150	150	>150	>150	>150	150	>150	>150
Lolium perenne (ryegrass)	>150	150	>150	>150	150	50.0	>150	>150
Dicots:								
Brassica oleracea (cabbage)	>150	150	>150	>150	50.0	16.7	46.5	72.5
Brassica rapa (turnip)	>150	150	>150	>150	16.7	5.6	16.7	31.2
Cucumis sativa (cucumber)	>150	150	>150	>150	>150	150	>150	>150
Glycine max (soybean)	>150	150	>150	>150	>150	150	>150	>150
Lactuca sativa (lettuce)	>150	150	>150	>150	16.7	5.6	10.2	21.3
Linum usitatissimum (flax)	>150	150	>150	>150	>150	150	>150	>150
Lycopersicon esculentum (tomato)	>150	150	>150	>150	50.0	16.7	19.5	30.1
	21-day Height				**21-day Biomass**			
	LOER	**NOER**	**ER25**	**ER50**	**LOER**	**NOER**	**ER25**	**ER50**
Monocots:	**(All units g a.s./ha)**							
Allium cepa (onion)	50.0	16.7	19.1	45.8	50.0	16.7	18.3	39.8
Avena sativa (oat)	>150	150	>150	>150	150	50.0	>150	>150
Lolium perenne (ryegrass)	150	50.0	>150	>150	>150	150	148	>150
Dicots:								
Brassica oleracea (cabbage)	5.6	1.9	12.6	26.7	5.6	1.9	9.75	19.8
Brassica rapa (turnip)	16.7	5.6	13.0	23.0	16.7	5.6	14.3	20.6
Cucumis sativa (cucumber)	>150	150	>150	>150	150	50.0	>150	>150
Glycine max (soybean)	>150	150	>150	>150	>150	150	>150	>150
Lactuca sativa (lettuce)	16.7	5.6	9.33	17.2	16.7	5.6	8.67	16.6
Linum usitatissimum (flax)	>150	150	>150	>150	>150	150	>150	>150
Lycopersicon esculentum (tomato)	50.0	16.7	18.4	27.2	50.0	16.7	15.8	23.6

Endpoints calculated based on nominal test rates

No indications of phytotoxic effects, at moderate of serve classifications, were observed in the control treatments of any species.

Conclusions

Pre-emergence applications of A12739A at rates up to and including 150 g a.s./ha did not have a significant effect on the emergence of those species tested. Similarly, rates up to and including 150 g a.s./ha did not have significant effects greater than 50% on shoot height or dry weight in *A. sativa, L. perenne, C. sativa, G. max* and *L. usitatissimum*. The remaining five species experienced reductions of 50% or more in height and/or dry weight at one or more of the rates tested. The single most sensitive ER_{50} was biomass for *L. sativa* (ER_{50} = 16.6).

(Porch JR, Martin, KH and Krueger HO 2003b)

RMS Comments

This study meets the validity criteria as specified in the finalised guideline OECD 208 (2003). The emergence rate for all species control groups was > 65 %. All species survival post emergence was > 90 % for control groups. There was no evidence of widespread phytotoxic effects in the control plants. The validity criteria are not specifically addressed in the study report and these data have been calculated from the results by the evaluator.

It is noted that the laboratory used to test the soil composition is not explicitly stated to be Good Laboratory Practice compliant. It is noted that the photoperiod maintained during the course of this study was 14 h light : 10 h dark whilst the guideline recommends 16 h : 8 h. This is not considered problematic, as the performance of seedlings upon emergence was acceptable for all species. The relative humidity was low

compared to the guideline recommendation of 70 % to 90 % humidity, having averaged 39 %. Due to the acceptable performance within the control groups this is not considered significant.

It is noted that no phytotoxic effects were observed in the control groups. It is also noted that phytotoxic symptoms, classified as either moderate of severe, were observed at treatment rates below the ER_{50} for several species. In all these cases the lowest ER_{50}, for *L. sativa*, would be considered protective. In the case of *L. sativa*, severe phytotoxic effects were observed at rates below the ER_{50} for biomass in three plants and slight effects in two plants. If this endpoint were the most sensitive generated for non-target plants this may require consideration or discussion in the risk assessment, though the impact appears likely to be limited.

It is also noted that the control group of *L. esculentum* had not achieved 50 % emergence by day 7 (45% observed), as such the subsequent observation period was less than that recommended in the guidance. This is not one of the validity criteria and as the control group was close to achieving 50 % emergence this is not considered significantly problematic. Also based on the phytotoxicity assessment only three plants were in poor condition at the end of the assessment, and therefore likely to change during a short extension of the studies duration.

It is noted that the study uses the total weight of surviving plants in a replicate to determine biomass, or total height of surviving plants per replicate. These results should be reported as weight per surviving plant, or height per surviving plant. As this would then remove the effect of mortality from these variables. Using the total weight/height per replicate for species where mortality has occurred will result in more conservative and variable data. If no mortality occurred the values would represent true parameter estimates, but mortality was observed in all species for some treatments.

Finally, it is noted that the analysed concentrations for the test mixtures applied on 3rd March 2003 were only 81 to 86 % of the nominal concentrations. Due to this discrepancy the endpoints for the species sprayed on this day should be adjusted. Therefore the endpoints have been multiplied by the average percentage, relative to the nominal concentration, of the concentrations analysed on that day (83.4 %). See below for the adjusted values.

The agreed endpoints are (only the most sensitive endpoints of those tested are listed):

- *Allium cepa* (onion) $ER_{50\ Biomass}$ = 33.2 g a.s./ha*
- *Avena sativa* (oat) $ER_{50\ Biomass}$ > 150 g a.s./ha
- *Lolium perenne* (ryegrass) $ER_{50\ Biomass}$ > 125 g a.s./ha*
- *Brassica oleracea* (cabbage) $ER_{50\ Biomass}$ = 19.8 g a.s./ha
- *Brassica rapa* (turnip) $ER_{50\ Biomass}$ = 20.6 g a.s./ha
- *Cucumis sativa* (cucumber) $ER_{50\ Biomass}$ > 150 g a.s./ha
- *Glycine max* (soybean) $ER_{50\ Biomass}$ > 150 g a.s./ha
- *Lactuca sativa* (lettuce) $ER_{50\ Biomass}$ = 13.8 g a.s./ha*
- *Linum usitatissimum* (flax) $ER_{50\ Biomass}$ > 125 g a.s./ha*
- *Lycopersicon esculentum* (tomato) $ER_{50\ Biomass}$ = 19.7 g a.s./ha*

(* = Modified to account for accuracy of spray concentrations)

Another supporting data:

Report	"Mesotrione 10% SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test" Weronika Dec. 2017, Study code: G/246/15. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline 208
Deviations:	Yes. Four deviations from the Study Plan were recorded. 1. The humidity in the test room was between 44.9 – 64.2%. According to the

Study Plan, it should be 70 ± 25%. It was a short-term deviation (about one hour) which did not affect the result of the experiment.
2. The study was finished in January 2017 and not in August 2016.
3. The RTF II meter was used instead of TZ 18 td thermohygrograph.
4. The SUP-100G with the digital temperature controller was used in the experiment instead of the SUP-100G without the digital temperature controller laboratory dryer.

The deviations did not affect the results of the study..

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Materials

Test item:
Description: Mesotrione 10% SC
Production batch: SWEPL-41203
Active ingredients content: mesotrione - 10.2% w/v
Vehicle and control: Distilled water
Test system:
Species: pea (*Pisum sativum*), sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), tomato (*Solanum lycopersicon*), corn (*Zea mays*), and oats (*Avena sativa*).

Experimental conditions:

Test species	Light intensity [lx]	Photoperiod day/night [h]	Humidity [%]	Temperature [°C]	CO_2 concentration [ppm]
Pea *(Pisum sativum)*	5030 – 5200	16:08	44.9 – 64.2	22.1 – 27.1	330 - 386
Sunflower *(Helianthus annus)*	4900 – 5100	16:08	44.9 – 64.2	22.1 – 27.1	330 - 386
White mustard *(Sinapis alba)*	4900 – 5120	16:08	44.9 – 64.2	22.1 – 27.1	330 - 386
Tomato *(Solanum lycopersicon)*	5080 – 5280	16:08	44.9 – 64.2	22.1 – 27.1	330 - 386
Corn *(Zea mays)*	4800 – 5030	16:08	44.9 – 64.2	22.1 – 27.1	330 - 386
Oats *(Avena sativa)*	5010 - 5220	16:08	44.9 – 64.2	22.1 – 27.1	330 - 386

Study design and methods

Experimental period:	08/07/2016 – 26/0/2016
Test design and treatment:	number of concentrations: 7 application rates + a control number of replicates: 4 replicates of each application rate and the control (pea, sunflower, white mustard, tomato, oats); 10 replicates of each application rate and the control (corn) number of seeds: 5 seeds/replicate (pea, sunflower, white mustard, tomato, oats); 2 seeds/replicate (corn) test termination: 14 days after the emergence of 50% of the control seedlings Agricultural soil (Sandy loam soil) was used in the study collected from the place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna (49˚ 59', 780 N; 18˚55', 190 E) where no plant protection products or organic and inorganic fertilizers had been used. Test item application rates were selected on the basis of the maximum recommended rate, i.e. 1500 mL/ha (i.e. 140.4 g a.s./ha). Seven rates of the test item were used. These were 2.06, 6.17, 18.52, 55.56, 166.67, 500.0 and 1500.0 mL/ha (i.e. 0.2, 0.6, 1.7, 5.2, 15.6, 46.8 and 140.4 g a.s./ha). One untreated control group was used for each species. The test system was the same for all test species. The test item was sprayed onto the soil using a suitable spraying chamber. The experiment was conducted in a special room where suitable environmental conditions were provided. The experiment finished 14 days after the emergence of 50% of the control seedlings. During the experiment, the plants were observed for emergence (every day and then every 2 – 3 days) and visual phytotoxicity (7 and 14 days after the emergence of 50% of the control seedlings). At the end of the experiment, the plants were counted, cut down, measured, dried to a constant weight at 60°C, and weighed.
Statistics:	ER_{10}, ER_{25}, ER_{50} – probit analyses NOER – Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Fisher's Exact Binomial Test with Bonferroni Correction, Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment.

Results

Results are displayed on the tables below:

Phytotoxic symptoms on pea (pisum stivum)

After the application of the test item at the rates ranging from 166.67 to 1500 mL/ha, the mean plant damage was from 18.8 to 72.5% at the end of the test. At lower application rates plant damage was not observed (Table below). Phytotoxic symptoms, i.e. stunted growth, witling, chlorosis and dead plants were noticed.

Table 10. Pea *(Pisum sativum)* – plant damage.

Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
2.06	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
6.17	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
18.52	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
55.56	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
166.67	1	5	5.0	chl	20	18.8	chl, sg, w
	2	5			15		
	3	10			20		
	4	0			20		
500	1	15	11.3	chl, sg	50	55.0	chl, sg, w, d
	2	10			60		
	3	15			50		
	4	5			60		
1500	1	40	42.5	chl. sg	70	72.5	chl, sg, w, d
	2	45			70		
	3	45			80		
	4	40			70		

* **nc** – no changes, **sg** – stunted growth, **w** – witling, **chl** – chlorosis, **d** – dead plant

Phytotoxic symptoms of sunflower (*Helianthus annuus)*

After the application of the test item at the rates ranging from 166.67 to 1500 mL/ha, the mean plant damage was from 31.3 to 57.5% at the end of the test. At lower application rates plant damage was not observed (Table below). Phytotoxic symptoms, i.e. stunted growth, witling, chlorosis, and dead plants were noticed.

Table 15. Sunflower *(Helianthus annuus)* – plant damage.

Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
2.06	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
6.17	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
18.52	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
55.56	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
166.67	1	5	6.3	chl	30	31.3	sg, chl, w, d
	2	5			30		
	3	5			25		
	4	10			40		
500	1	20	20.0	sg, chl	30	35.0	sg, chl, w
	2	20			35		
	3	20			35		
	4	20			40		
1500	1	25	25.0	sg, chl	50	57.5	sg, chl, w, d
	2	25			70		
	3	25			50		
	4	25			60		

* **nc** – no changes, **sg** – stunted growth, **w** – witling, **chl** – chlorosis, **d** – dead plants

Phytotoxic symptoms of white mustard (*Sinapsis alba*)

After the application of the test item at the rates ranging from 55.56 to 1500 mL/ha, the mean plant damage was between 26.3 – 70.0% at the end of the test. At lower application rates plant damage was not observed (Table below). Phytotoxic symptoms, i.e. stunted growth, witling, chlorosis and dead plants were noticed.

Table 20. White mustard *(Sinapis alba)* – plant damage.

Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
2.06	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
6.17	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
18.52	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
55.56	1	10	12.5	sg, chl	20	26.3	sg, chl, w
	2	15			25		
	3	10			30		
	4	15			30		
166.67	1	15	15.0	sg, chl	30	35.0	sg, chl, w
	2	20			30		
	3	10			40		
	4	15			40		
500	1	20	15.0	sg, chl	45	50.0	sg, chl, w, d
	2	10			45		
	3	15			55		
	4	15			55		
1500	1	45	42.5	sg, chl	70	70.0	sg, chl, w, d
	2	45			80		
	3	35			60		
	4	45			70		

* **nc** – no changes, **sg** – stunted growth, **w** – witling, **chl** – chlorosis, **d** – dead plants

Phytotoxic symptoms of Tomato (*Solanum lycopersicon*)

After the application of the test item at the rates ranging from 2.06 to 1500 mL/ha, the mean plant damage was between 0.0 – 100% at the end of the test. At lower application rates plant damage was not observed (Table below). Phytotoxic symptoms, i.e. stunted growth, witling, chlorosis, and dead plants were noticed.

Table 25. Tomato *(Solanum lycopersicon)* – plant damage.

Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage*
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
2.06	1	0	0.0	nc	0	2.5	sl
	2	0			0		
	3	0			0		
	4	0			10		
6.17	1	0	0.0	nc	10	2.5	sl
	2	0			0		
	3	0			0		
	4	0			0		
18.52	1	0	0.0	nc	0	2.5	sl
	2	0			10		
	3	0			0		
	4	0			0		
55.56	1	0	0.0	nc	10	10.0	w
	2	0			10		
	3	0			10		
	4	0			10		
166.67	1	5	10.0	sg, chl, w	10	15	sg, w, chl, sl
	2	15			20		
	3	5			10		
	4	15			20		
500	1	45	48.8	sg, chl, w	80	80	sg, w, chl, sl
	2	50			80		
	3	50			80		
	4	50			80		
1500	1	80	75.0	sg, chl, w	100	100.0	sl
	2	60			100		
	3	80			100		
	4	80			100		

* **nc** – no change, **sg** – stunted growth, **w** – witling, **chl** – chlorosis, **d** – dead plants

Phytotoxic symptoms of corn (*Zea mays*)

After the application of the test item at the rates ranging from 2.06 to 1500 mL/ha, no plant damage was observed at the end of the test.

Phytotoxic symptoms of Oats (*Avena sativa*)

After the application of the test item at the rates ranging from 2.06 to 1500 mL/ha, no plant damage was observed at the end of the test

The EC50 and NOER values determined on the basis of plant number, shoot length and dry shoot weight measurements expressed as ml of formulation/ ha for all test species are given below.

	Pea	Sunflower	White mustard	Tomato	Corn	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Zea mays*	*Avena sativa*
Plant number at the end of the experiment						
ER_{10}	> 1500	238.3 (40.3 – > 1500)	31.2 (< 2.06 – 197.3)	10.0	> 1500	> 1500
ER_{26}	> 1500	> 1500 (577.9 – > 1500)	209.2	42.5	> 1500	> 1500
ER_{50}	> 1500	> 1500	> 1500 (261.3 – > 1500)	211.3	> 1500	> 1500
NOER	≥1500	≥1500	500	166.67	> 1500	≥1500
Post-emergence survival						
ER_{10}	> 1500	1153.7	472.5 (184.9 – 682.6)	33.1	> 1500	> 1500
ER_{26}	> 1500	> 1500	709.4 (403.6 – 974.8)	89.6	> 1500	> 1500
ER_{50}	> 1500	> 1500	1114.3 (798.2 – >1500)	271.1	> 1500	> 1500
NOER	≥1500	≥1500	500	166.67	> 1500	> 1500

	Pea	Sunflower	White mustard	Tomato	Corn	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Zea mays*	*Avena sativa*
Shoot length (plants without roots)						
ER_{10}	80.5 (43.3 – 119.7)	146.5 (106.7 – 186.6)	12.9 (< 2.06 – 31.0)	30.5 (< 2.06 – 77.4)	> 1500	> 1500
ER_{26}	190.7 (130.5 – 249.2)	410.8 (347.0 – 473.3)	47.5 (15.7 – 87.7)	73.3 (2.4 – 148.8)	> 1500	> 1500
ER_{50}	496.9 (396.5 – 630.8)	1291.1 (1121.1 – > 1500)	202.7 (114.2 – 380.5)	194.3 (75.6 – 784.4)	> 1500	> 1500
NOER	55.56	55.56	18.52	55.56	≥1500	≥1500
Plant dry weight (plants without roots)						
ER_{10}	33.0 (4.1 – 77.7)	16.3 (2.1 – 42.1)	7.1 (< 2.06 – 21.0)	28.0 (12.8 – 42.7)	> 1500	> 1500
ER_{26}	112.5 (35.3 – 202.7)	83.9 (28.7 – 156.0)	29.9 (6.3 – 64.4)	55.0 (33.7 – 74.2)	> 1500	> 1500
ER_{50}	439.4 (251.2 – 894.7)	517.0 (289.1 – 1194.8)	147.8 (69.7 – 339.9)	116.6 (88.5 – 153.9)	> 1500	> 1500
NOER	55.56	55.56	18.52	18.52	≥1500	≥1500

The EC_{50} and NOER values determined on the basis of plant number, shoot length and dry shoot weight measurements expressed as g of active substance / ha for all test species are given below.

	Pea	Sunflower	White mustard	Tomato	Onion	Oats
	Pisum sativum	*Helianthus annuus*	*Sinapis alba*	*Solanum lycopersicon*	*Allium cepa*	*Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 140.4	> 140.4	> 140.4 (24.5 – > 140.4)	19.8	> 140.4	> 140.4
NOER	≥ 140.4	≥ 140.4	46.8	15.6	> 140.4	≥ 140.4
Post-emergence survival at the end of the experiment						
ER_{50}	> 140.4	> 140.4	104.3 (74.7 – >140.4)	25.4	> 140.4	> 140.4
NOER	≥ 140.4	≥140.4	46.8	15.6	> 140.4	> 140.4
Shoot length (plants without roots)						
ER_{50}	46.5 (37.1 – 59.0)	120.8 (104.9 – >1140.4)	19.0 (10.7 – 35.6)	18.2 (7.1 – 73.4)	> 140.4	> 140.4
NOER	5.2	5.2	1.7	5.2	≥ 140.4	≥ 140.4
Plant dry weight (plants without roots)						
ER_{50}	41.1 (23.5 – 83.7)	48.4 (27.1 – 111.8)	13.8 (6.5 – 31.8)	10.9 (8.3 – 14.4)	> 140.4	> 140.4
NOER	5.2	5.2	1.7	1.7	≥ 140.4	≥ 140.4

Conclusion

1. The test item i.e. Mesotrione 10% SC had a varied impact on the growth and seedling emergence of the test plant species. The impact depended on the concentration and species.
2. After the application of the test item at the rates ranging from 2.06 to 1500 mL/ha all test plant species: pea (Pisum sativum), sunflower (Helianthus annuus), white mustard (Sinapis alba), tomato (Solanum lycopersicon), corn (zea mays), and oats (Avena sativa) emerged. After the application of the test item at rates ranging from 2.06 to 1500 mL/ha, all test species emergence was not delayed in comparison to the control.
3. The death of pea and white mustard plants was noticed at application rates of 500 and 1500 mL/ha. The death of sunflower was noticed at application rates of 166.67 and 1500 mL/ha. The death of tomato plant was noticed almost at the all application rates, only at the application rate of 55.56 mL/ha the death of tomato was not recorded. The death of corn and oats was not observed at rates ranging from 2.06 to 1500 mL/ha.
4. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length and shoot dry weight, it was proved that the test item inhibited the process of growth of pea, sunflower, white mustard and tomato.
5. Phytotoxic symptoms were observed. They were stunted growth, witling, chlorosis and dead plants for pea, sunflower, white mustard and tomato. For corn and oats no phytotoxic symptoms were recorded.
6. The lowest ER_{50} values determined on the basis of the plant number, post-emergence survival, shoot length and shoot dry weight at the end of the experiment were equal to 211.3, 271.1, 194.3 and 116.6 mL/ha (i.e. 19.8, 25.4, 18.2 and 10.9 g a.s./ha) respectively and they were calculated for tomato.

7. The following order of the test plant sensitivity was noticed:
tomato > white mustard > pea, sunflower > corn, oats.

Reference:	KCP 10.6.2-02
Report	"Terrestrial Plant Test: Vegetative Vigour Test of Mesotrione 10% SC on Plants" Dr. T. S. Sadamanda, 2019, Study number: BIO-ETX 034. Bioneeds India Privated Limited
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Mesotrione 10% SC; Batch Number SCL-96311; active substance: mesotrione 10.4% (w/v)
Test species:	Lettuce (*Lactuca sativa*), Dwarf bean, French bean, Garden bean (*Phaseolus vulgaris*), Carrot (*Daucus carota*), Sugar beet (*Beta vulgaris*), Chinese cabbage (*Brassica campestris var. chinensis*), Flax (*Linum usitatissimum*), Onion (*Allium cepa*), Wheat (*Triticum aestivum*)
Soil:	Clay loam soil containing 1.5% organic carbon
Study design:	number of rates: 7 application rates + control; number of replicates: 4 pots/application rate and 5 seeds/plot. test termination: 21 days after the spraying.
Application rates:	Water control, 0.02, 0.05, 0.09, 0.19, 0.38, 0.75 and 1.5 L test item/ha Volume of deionised water used to prepare the highest rate: 200 L water/ha
Test conditions:	temperature: 22.9-29.8ºC, humidity: 70.0 – 84.0%, light – dark cycles (16h:8h), light intensity: 6599 – 8241 lux, carbon dioxide concentration: 344 – 398 ppm.
Statistical analysis:	The EC_{10}, EC_{25}, EC_{50} and NOEC values were determined by using a Probit analysis and one-way ANOVA followed by Dunnett´s test using SPSS Software version 22, respectively.
Endpoints:	EC_{10}, EC_{25}, EC_{50} and NOER

Results and Conclusions

The test item, i.e. Mesotrione 10% SC applied at rates ranging from 0.02 to 1.5 L test item/ha had a varied impact on vegetative vigour of all the plant species tested. The impact depended on the rate of the test item and species used.
There was mortality observed for all the plant species tested at rates ranging from 0.0125 to 0.2 kg test item/ha. The phytotoxic symptoms for all plant species tested were observed at all the rates of the test item used.
The endpoint values showing the impact of the test item on vegetative vigour of the plant species tested are presented in table given below:

Endpoint value		**Dicotyledonous**						**Monocotyledonous**	
		Lettuce (*Lactuca sativa*)	**Dwarf bean (*Phaseolus vulgaris*)**	**Carrot (*Daucus carota*)**	**Sugar beet (*Beta vulgaris*)**	**Chinese cabbage (*Brassica campestris*)**	**Flax (*Linum usitatissimum*)**	**Onion (*Allium cepa*)**	**Wheat (*Triticum aestivum*)**
Plant number									
ER_{10}	L/ha	>1.50	>1.50	>1.50	n.d.	n.d.	>1.50	n.d.	>1.50

ER_{20}	L/ha	>1.50	>1.50	>1.50	n.d.	n.d.	>1.50	n.d.	>1.50
ER_{50}	L/ha	>1.50	>1.50	>1.50	n.d.	n.d.	>1.50	n.d.	>1.50
NOER	L/ha	≥1.50	≥1.50	≥1.50	0.75	0.75	≥1.50	0.75	≥1.50
Fresh shoot weight									
ER_{10}	L/ha	0.04	0.05	0.02	0.08	0.06	0.03	0.03	0.04
ER_{20}	L/ha	0.09	0.11	0.06	0.15	0.14	0.06	0.09	0.10
ER_{50}	L/ha	0.24	0.27	0.20	0.34	0.38	0.14	0.28	0.28
NOER	L/ha	0.02	0.02	0.02	0.05	0.05	>0.02	0.02	0.05
Dry shoot weight									
ER_{10}	L/ha	0.03	0.05	0.01	0.07	0.07	0.02	0.04	0.04
ER_{20}	L/ha	0.08	0.11	0.03	0.13	0.15	0.04	0.09	0.10
ER_{50}	L/ha	0.21	0.24	0.12	0.27	0.35	0.09	0.23	0.24
NOER	L/ha	<0.02	0.02	0.02	0.05	0.05	<0.02	0.05	0.05
Shoot height									
ER_{10}	L/ha	0.05	0.07	0.012	0.05	0.05	0.01	0.03	0.05
ER_{20}	L/ha	0.12	0.15	0.093	0.10	0.11	0.03	0.07	0.12
ER_{50}	L/ha	0.36	0.35	0.28	0.22	0.29	0.11	0.22	0.33
NOER	L/ha	0.05	0.05	0.02	0.02	0.02	0.02	0.02	0.02

VALIDITY OF THE TEST

The following criteria have satisfied in the control, hence the test results are considered to be valid:

- The seedling emergence for all the plants tested was 100% (validity criterion: at least 70%).
- The control plants did not exhibit any visible phytotoxic effects. Plants exhibited normal variation in growth and morphology for that particular species.
- The mean survival of the emerged control seedlings was 100% in case of all experimental species (validity criterion: at least 90%),
- Environmental conditions for a particular species were identical and growing media contained the same amount of soil matrix, support media, or substrate from the same source.

TABLE 11. PERCENT INHIBITION OF PLANT NUMBER DURING THE MAIN STUDY

Group	Application rate (L test item/ha)	Percent inhibition of plant number							
		Dicotyledonous						Monocotyledonous	
		Lettuce (*Lactuca sativa*)	Dwarf bean (*Phaseolus vulgaris*)	Carrot (*Daucus carota*)	Sugar beet (*Beta vulgaris*)	Chinese cabbage (*Brassica campestris*)	Flax (*Linum usitatissimum*)	Onion (*Allium cepa*)	Wheat (*Triticum aestivum*)
G1	0.0	-	-	-	-	-	-	-	-
G2	0.02	0	0	0	0	0	0	0	0
G3	0.05	0	0	0	0	0	0	0	0
G4	0.09	0	0	0	0	0	0	0	0
G5	0.19	0	0	0	0	0	0	0	0
G6	0.38	0	0	0	0	0	0	0	0
G7	0.75	0	0	0	0	0	0	0	0
G8	1.50	0	0	0	100*	100*	0	100*	0
#G9	1200 mL glyphosate/ acres	95*	90*	0	95*	0	0	95*	90*

-: Not applicable; #: Positive control Broadband herbicide (Roundup ultra mix), Glyphosate 41% SL; *: Statistical significance at $P < 0.05$

TABLE 12. PERCENT INHIBITION OF FRESH SHOOT WEIGHT OF PLANTS DURING THE MAIN STUDY

Group	Application rate (L test item/ha)	Percent inhibition of fresh shoot weight							
		Dicotyledonous						Monocotyledonous	
		Lettuce (*Lactuca sativa*)	Dwarf bean (*Phaseolus vulgaris*)	Carrot (*Daucus carota*)	Sugar beet (*Beta vulgaris*)	Chinese cabbage (*Brassica campestris*)	Flax (*Linum usitatissimum*)	Onion (*Allium cepa*)	Wheat (*Triticum aestivum*)
G1	0.0	-	-	-	-	-	-	-	-
G2	0.02	6.88	2.31	8.81	0.41	1.75	10.79*	2.68	3.99
G3	0.05	11.91*	14.30*	32.70*	7.99	8.39	30.85*	22.35*	14.54
G4	0.09	23.74*	19.30*	33.96*	16.50*	19.91*	47.68*	32.35*	26.58*
G5	0.19	41.49*	29.33*	46.54*	25.87*	25.51*	67.36*	38.87*	36.66*
G6	0.38	55.89*	51.23*	57.23*	58.90*	45.43*	87.09*	48.99*	47.08*
G7	0.75	79.10*	79.51*	71.19*	71.47*	72.77*	91.72*	72.69*	72.20*
G8	1.50	92.45*	94.06*	90.60*	100*	100*	99.02*	100*	90.08*
#G9	1200 mL glyphosate/ acres	93.66*	97.34*	86.06*	95.06*	96.92*	98.71*	90.66*	91.95*

-: Not applicable; #: Positive control Broadband herbicide (Roundup ultra mix), Glyphosate 41% SL; *: Statistical significance at $P < 0.05$

TABLE 13. PERCENT INHIBITION OF DRY SHOOT WEIGHT OF PLANTS DURING THE MAIN STUDY

Group	Application rate (L test item/ha)	Percent inhibition of dry shoot weight							
		Dicotyledonous						Monocotyledonous	
		Lettuce (*Lactuca sativa*)	Dwarf bean (*Phaseolus vulgaris*)	Carrot (*Daucus carota*)	Sugar beet (*Beta vulgaris*)	Chinese cabbage (*Brassica campestris*)	Flax (*Linum usitatissimum*)	Onion (*Allium cepa*)	Wheat (*Triticum aestivum*)
G1	0.0	-	-	-	-	-	-	-	-
G2	0.02	11.18*	1.84	18.00	1.04	1.71	12.05*	6.11	2.01
G3	0.05	10.62*	15.25*	32.00*	5.95	5.21	31.09*	6.89	19.43
G4	0.09	24.68*	22.99*	51.03*	20.33*	16.33*	51.27*	36.89*	28.13*
G5	0.19	45.71*	31.31*	60.00*	29.73*	20.37*	70.55*	43.07*	37.98*
G6	0.38	54.28*	56.30*	59.00*	61.23*	49.71*	91.26*	60.95*	55.68*
G7	0.75	82.65*	83.82*	79.00*	84.39*	81.00*	95.19*	80.13*	77.94*
G8	1.50	93.68*	95.73*	93.00*	100*	100*	99.57*	100.0*	93.92*
#G9	1200 mL glyphosate/ acres	96.10*	97.87*	92.43*	97.91*	98.43*	99.52*	92.77*	93.56*

-: Not applicable; #: Positive control Broadband herbicide (Roundup ultra mix), Glyphosate 41% SL; *: Statistical significance at $P < 0.05$*

TABLE 14. PERCENT INHIBITION OF SHOOT HEIGHT OF PLANTS DURING THE MAIN STUDY

Group	Application rate (L test item/ha)	Percent inhibition of shoot height							
		Dicotyledonous						Monocotyledonous	
		Lettuce (*Lactuca sativa*)	Dwarf bean (*Phaseolus vulgaris*)	Carrot (*Daucus carota*)	Sugar beet (*Beta vulgaris*)	Chinese cabbage (*Brassica campestris*)	Flax (*Linum usitatissimum*)	Onion (*Allium cepa*)	Wheat (*Triticum aestivum*)
G1	0.0	-	-	-	-	-	-	-	-
G2	0.02	5.50	0.29	2.44	2.27	4.59	11.24	7.34	2.85
G3	0.05	8.43*	9.69	21.19*	10.14*	9.61*	37.87*	18.06*	8.58*
G4	0.09	23.20*	23.93*	32.19*	30.81*	18.74*	52.12*	34.57*	28.36*
G5	0.19	29.74*	36.14*	47.69*	39.01*	31.61*	67.96*	44.92*	41.61*
G6	0.38	33.76*	43.01*	56.45*	57.48*	56.12*	76.67*	55.27*	49.23*
G7	0.75	63.70*	61.23*	61.66*	89.65*	80.54*	85.73*	81.90*	59.56*
G8	1.50	91.50*	91.20*	86.16*	100*	100*	91.99*	100*	88.26*
#G9	1200 mL glyphosate/ acres	96.43*	93.93*	91.28*	92.07*	95.63*	94.97*	93.13*	93.87*

-: Not applicable; #: Positive control Broadband herbicide (Roundup ultra mix), Glyphosate 41% SL; *: Statistical significance at $P < 0.05$

TABLE 6. SUMMARY OF PLANT OBSERVATION DUIRNG THE MAIN STUDY

Group	Application rate (L test item/ha)	Dicotyledonous						Monocotyledonous	
		Lettuce (*Lactuca sativa*)	Dwarf bean (*Phaseolus vulgaris*)	Carrot (*Daucus carota*)	Sugar beet (*Beta vulgaris*)	Chinese cabbage (*Brassica campestris*)	Flax (*Linum usitatissimum*)	Onion (*Allium cepa*)	Wheat (*Triticum aestivum*)
G1	0	20(1)	20(1)	20(1)	20(1)	20(1)	20(1)	20(1)	20(1)
G2	0.02	18 (1), 2(2)	5(2,3),15(5)	18(1),2(2)	15(1),5(2)	18(2,3),2(10)	17(2),3(1)	11(1),9(2)	16(1),4(2)
G3	0.05	9(2),6(3),5(4)	5(2,3),15(5)	12(2),6(3), 2(10)	12(1),8(2,5)	20(2,3,4)	12(3,4,2), 8(10)	12(1),5(2,3), 3(5)	14(2), 6(5)
G4	0.09	9(2,3), 11(5,4)	9(2,3), 11(5,4)	16(4,2,3),4(10)	10(1),10(2,5)	17(2,3,4), 3(3)	14(3,4,2), 6(10)	15(1),5(3,2,5)	16(2), 4(5)
G5	0.19	15(5),5(2,3)	7(2,3,4),13(5)	20(2,5)	11(1), 9(2,5)	20(4,5)	3(2,3), 17(4,10)	12(1),5(2, 3),3(5)	12(2,3), 8(5)
G6	0.38	20(2,4)	8(3,2,10,4),12(5)	20(2,5)	20(4,5)	20(4,5)	12(2,3), 8(10,4)	8(2,3), 12(5)	13(2,3),7(5)
G7	0.75	20(2,4)	15(2,3,4,10),5(5)	20(2,5)	20(4,5)	20(10,5)	3(2,3), 11(10,4), 6(5)	16(2,3,10), 4(5)	18(5), 2(3,10)
G8	1.50	20(2,5)	20(2,5)	20(5)	20(*5)	20(*5)	20(2,5)	20(*5)	20(5,3,10)
#G9	1200 mL glyphosate/ acres	1(5), 19(5*)	2(5), 18(5*)	20(5)	1(5), 19(5*)	20(5)	20(5)	1(5), 19(*)	1(5), 19(*)

1: Normal; 2: Chlorosis; 3: Death of plant tissues; 4: Defoliation; 5: Dried leaves or stem; 10: In the process of drying; *: Complete plant dried; 5*: Completely dried leave and stem, plant observed complete mortality; Value inside the bracket and value outside the bracket signifies the clinical symptom code and number of plants exhibiting that particular symptom; #: Positive control Broadband herbicide (Roundup ultra mix), Glyphosate 41% SL

Evaluation, summary and conclusion by zRMS:

The Applicant has not submitted tests.
zRMS accepts the Applicant's proposal that the following information should appear on the label:
"If the crop has to be abandoned after application in the spring, maize can be re-seeded immediately. Ploughing is recommended prior to reseeding. Mighty poses no threat to succeeding crops in the normal crop cycle."

comments of zRMS: dRR point 3.5.1

Vegetative vigour_BIO-ETX 034 -test
Seedling Emergence and Seedling Growth Test

ER_{10}-values (g/ha) of different test plants

Common name	**ER_{10} (ml/ha)**
Lettuce	30

Dwarf bean	50
Carrot	10
Sugar beet	50
Chinese cabbage	50
Flax	10
Onion	30
Wheat	40
Pea	33
Sunflower	16,3
White mustard	7,1
Tomato	10
Corn	>1500
Oats	>1500

bulk density of soil = 1.5 g/cm^3 and soil depth 5 cm
DT50 – 43,4 days

PEC-values and TER-calculation of Mesotrion 10% SC

Crop	ER10 mg/kg soil	Days after application	PEC		TER	
			mg/kg soil soil depth 5 cm	mg/kg soil soil depth 20 cm	e.g. 5 cm	e.g. 20 cm
Lettuce	0,044	1	0,1476	0,0369	0,2963	**1,1853**
		2	0,1453		0,3011	
		4	0,1407		0,3109	
		7	0,1341		0,3261	
		14	0,1199		0,3647	
		21	0,1073		0,408	
		48	0,0697		0,6277	
		80	0,0418		**1,0464**	
Dwarf been	0,073	1	0,1476	0,0369	0,4938	**1,9755**
		2	0,1453		0,5018	
		4	0,1407		0,5181	
		7	0,1341		0,5435	
		14	0,1199		0,6078	
		21	0,1073		0,6797	
		28	0,0959		0,7601	
		48	0,0697		**1,0462**	

	Carrot	0,015	1	0,1476	0,0369	0,0988	0,3951
			2	0,1453	0,0363	0,100364	0,4015
			4	0,1407	0,0352	0,1036	0,4145
			7	0,1341	0,0335	0,1087	0,4348
			14	0,1199	0,0300	0,1216	0,4863
			48	0,0697	0,0174	0,2092	0,8369
			60	0,0575	0,0144	0,2534	**1,0138**
			100	0,0304		0,4801	
			150	0,0137		**1,0669**	
	Sugar beet	0,073	1	0,1476	0,0369	0,4938	**1,9755**
			2	0,1453		0,5018	
			4	0,1407		0,5181	
			7	0,1341		0,5435	
			14	0,1199		0,6078	
			21	0,1073		0,6797	
			28	0,0959		0,7601	
			48	0,0697		**1,0462**	
	Chinise cabbage	0,073	1	0,1476	0,0369	0,4938	**1,9755**
			2	0,1453		0,5018	
			4	0,1407		0,5181	
			7	0,1341		0,5435	
			14	0,1199		0,6078	
			21	0,1073		0,6797	
			28	0,0959		0,7601	
			48	0,0697		**1,0462**	
	Flax	0,015	1	0,1476	0,0369	0,0988	0,3951
			2	0,1453	0,0363	0,100364	0,4015
			4	0,1407	0,0352	0,1036	0,4145
			7	0,1341	0,0335	0,1087	0,4348
			14	0,1199	0,0300	0,1216	0,4863
			48	0,0697	0,0174	0,2092	0,8369

			60	0,0575	0,0144	0,2534	**1,0138**
			100	0,0304		0,4801	
			150	0,0137		**1,0669**	
	Onion	0,044	1	0,1476	0,0369	0,2963	**1,1853**
			2	0,1453		0,3011	
			4	0,1407		0,3109	
			7	0,1341		0,3261	
			14	0,1199		0,3647	
			21	0,1073		0,408	
			48	0,0697		0,6277	
			80	0,0418		**1,0464**	
	Wheat	0,058	1	0,1476	0,0369	0,3951	**1,5804**
			2	0,1453		0,4015	
			4	0,1407		0,4145	
			7	0,1341		0,4348	
			14	0,1199		0,4863	
			21	0,1073		0,5438	
			48	0,0697		0,8370	
			60	0,0575		**1,0138**	
	White mustard	0,01	1	0,1476	0,0369	0,068	0,271
			2	0,1453	0,0363	0,069	0,275
			4	0,1407	0,0352	0,071	0,284
			7	0,1341	0,0335	0,074	0,298
			48	0,0697	0,0174	0,144	0,574
			100	0,0304	0,0076	0,329	**1,317**
			180	0,0085		**1,18**	
	In the opinion of ZRMS, in case of treated maize crop failure (e.g. by hail, disease, pests or frost), maize may be sown on the field. After harvesting maize grown under normal growing conditions, winter cereals can be sown after deep ploughing (at least 20 cm). In the spring all crops can be cultivated. According to the literature, sensitive crops such as oilseed rape, vegetable beet, legumes, sunflowers and early-sown winter cereals under unfavourable conditions for the decomposition of the active substance can cause crop damage.						

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

During the conduct of efficacy trials and phytotoxicity trials no observations about negative or positive effects on other plants or neighbouring crops were reported.

EPPO guidelines PP1/256 is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model and on the bio assay results from the Vegetative vigour test and from the seedling emergence study TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are > 5. Then no further testing is necessary.
- If the TER values are ≤ 5. Damage to the relevant succeeding crop is possible and further field testing is necessary as described in the EPPO guideline.

In the studies summarized in the peer review (EFSA Journal 2016; 14(3): 4419, 103pp), 10 representative species (7 dicotyledonous species (cabbage, turnip, soybean, cucumber, tomato, linseed and lettuce) and three monocotyledonous species (onion, oat and ryegrass)) were tested.

These studies are presented in the table below.

Table 3.5-1: Effects of mesotrione on shoot fresh weight, obtained from vegetative vigour and seedling emergence study (DAR B.9.9.2)

Species	Shoot Fresh Weight ER_{50}			
	Vegetative vigour		Seedling Emergence	
	[L/ha]	[g mesotrione/ha]	[L/ha]	[g mesotrione/ha]
Oats	>5.000	>500	>1.250	>125
Ryegrass	>5.000	>500	>1.250	>125
Onion	0.089	8.93	0.332	33.2
Cabbage	0.062	6.18	0.198	19.8
Turnip	0.023	2.27	0.206	20.6
Soybean	0.067	6.70	>1.500	>150
Linseed	2.640	264	>1.250	>125
Cucumber	0.015	1.53	>1.500	>150
Lettuce	**0.0088**	**0.883**	**0.138**	**13.8**
Tomato	0.0015	1.50	0.197	19.7

In both tests (vegetative and seedling), lettuce (*Lactuca sativa*) was the most sensitive species with an ER_{50} value of 0.883 g mesotrione/ha (0.00883 L/ha) and 13.8 g mesotrione/ha (0.138 L/ha), respectively. The most sensitive endpoint was on vegetative vigour of lettuce with an ER_{50} = 0.883 g mesotrione/ha and the results obtained will be used in the table below to assess the TER and compare it to the trigger value of 5 (SANCO 10329/2002, rev. 2).

Risk assessment

The risk was assessed by calculation of the toxicity to exposure ratio (TER), and comparison of this value with the trigger of 5.

Results are presented in the table below:

Table 3.5-2: Effects on non-target plants, early post-emergence application

Test substance	Buffer distance (m)	Application rate (g a.s./ha)	Drift value[a] (%)	Drift Reduction (%)	EC_{50} (g a.s./ha)	PER_{drift} (g ai/ha)	TER	Trigger
Mesotrione	1	150	2.77	0	0.883	4.16	0.21	5
				50		2.08	0.43	
				75		1.04	0.85	
				90		0.42	2.13	
	5	150	0.57	0	0.883	0.86	1.03	5

				50		0.43	2.07	
				75		0.21	4.13	
				90		0.09	**10.33**	
	10	150	0.29	0	0.883	0.44	2.03	5
				50		0.22	4.06	
				75		0.11	**8.12**	
				90		0.04	**20.30**	
	20	150	0.15	0	0.883	0.23	3.92	5
				50		0.11	**7.85**	
				75		0.06	**15.70**	
				90		0.02	**39.24**	

[a] Drfit estimates are based on 90th percentile values for field crops (BBA 2000); *EC_{50} on lettuce, as the worst case

Based on this assessment, a TER trigger of 5 (according to SANCO 10329/2002, rev. 2) is achieved when taking a buffer zone of 5 m and a 90% drift reduction into account, a buffer zone of 10 m and a drift reduction of 75% or a buffer zone of 20 m and a drift reduction of 50%.

The effect endpoints used in the terrestrial non-target plant risk assessment (i.e. EC_{50} from 10 plant species tested in seedling emergence and vegetative vigour studies) were re-evaluated to construct a species sensitive distribution from which an HC_5 was obtained. HC_5 evaluations are based on the results of the tests conducted with Callisto 100 SC.

Based on this methodology, the lowest endpoints for each species (biomass) from the vegetative vigour test resulted in a HC_5 of 0.173 g mesotrione/ha.

According to the Guidance Document on Terrestrial Ecotoxicology SANCO/10329/2002, Rev. 2 (final), the risk for terrestrial plants is assumed to be acceptable if the ER/EC50 for less than 5% of the species is below the highest predicted exposure level. As this is the case for terrestrial non-target plants, for the refined risk assessment, the TER values considering the HC_5 are compared to a trigger of 1.

Table 3.5-3: Effects on non-target plants, early post-emergence application

Test substance	Buffer distance (m)	Application rate (g a.s./ha)	Drift value[a] (%)	Drift Reduction (%)	EC_{50} (g a.s./ha)	PER_{drift} (g ai/ha)	TER	Trigger
Mesotrione	1	150	2.77	0	0.173	4.16	0.04	1
				50		2.08	0.08	
				75		1.04	0.17	
				90		0.42	0.42	
	5	150	0.57	0	0.173	0.86	0.20	1
				50		0.43	0.40	
				75		0.21	0.81	
				90		0.09	**2.02**	
	10	150	0.29	0	0.173	0.44	0.40	1
				50		0.22	0.80	
				75		0.11	**1.59**	
				90		0.04	**3.98**	
	20	150	0.15	0	0.173	0.23	0.77	1
				50		0.11	**1.54**	
				75		0.06	**3.08**	
				90		0.02	**7.69**	

Based on this refined assessment, the results are the same, i.e. a TER trigger of 1 (according to SANCO 10329/2002, rev. 2) is achieved when taking a buffer zone of 5 m and a 90% drift reduction into account, a buffer zone of 10 m and a drift reduction of 75% or a buffer zone of 20 m and a drift reduction of 50%. crops is expected, if a buffer zone as well as drift reducing nozzles are employed.

Conclusion

Evaluation, summary and conclusion by zRMS:

The applicant has not submitted additional tests. During the conduct of efficacy trials and phytotoxicity trials no observations about negative or positive effects on other plants or neighbouring crops were re-

ported.

The applicant provided an analysis of the effect on other plants including adjacent crops based on the TER value. The results confirm that no further testing is necessary and no adverse effects on adjacent crops are expected if a buffer zone and drift reducing nozzles are used.

zRMS agrees. New tests are not necessary.

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

From the experimentation carried out with MIGHTY (MESOTRIONE 10% SC) in 2015, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6.

Evaluation, summary and conclusion by zRMS:

The applicant has not submitted tests.
zRMS agrees. New tests are not necessary.

3.5.4 Tank cleaning

Report:	**KCP 4.2, M. Berrios Caballero, 2016**
Title:	Physical and chemical properties and accelerated storage stability test for mesotrione 10 % SC (Suspension Concentrate, 10.2 % w/w Mesotrione).
Document No:	E-15/0004/2016
Guidelines:	PSD Efficacy Guideline 302 PSD Efficacy Guideline 305
GLP	Yes

Method and result

An amount of 27.9 mg (low-dose, 0.25% v/v) or 86.1 mg (high-dose, 0.75% v/v) of the test substance was taken into 500 ml beaker and mixed with 300 ml of Standard Water D, stirred well with a glass rod. After 2 minutes of stirring, the appropriate amount of a tank partner was added. Aliquots, 100 mL, were transferred into three polyethene bottles, capped and allowed to stand at room temperature for 24 hours.
The next day each polyethylene bottle was inverted twice to resuspend any settled material, and the content was discarded from each bottle. 10 mL of tap water was added and inverted twice, and the rinsed with water was discarded. This procedure was repeated three times. Then, the empty polyethylene bottle was rinsed with methanol 10 mL, shaken to coat all surfaces, and the rinsed solution was analysed under HPLC-DAD. The recovered active ingredient was not detected, and the total washed content of Mesotrione 10% SC was determined to be 100 %.

Conclusion

From the determined results, it was concluded that the percentage of Mesotrione 10% SC removed by water was 100 %.

Study Comments: Tank cleaning procedure	Studies are acceptable

The Applicant presented data obtained from the study conducted according to Efficacy Guideline 305 and 302 Three rinse procedure of tank cleaning proposed by the Applicant was sufficient to ensure that residues of plant protection products do not remain in the pesticide application equipment (PAE) after cleaning and that there is no unacceptable risk to subsequently treated crops.

3.6 Other/special studies

No other studies were conducted

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

			Year and trial type	
			2015	
			Maize	
Testing facility	**Zone**	**Country**	**Efficacy**	**Selectivity**
Eurofins AgroScience Services	MAR	DE	2	2
Eurofins AgroScience Services	MAR	UK	1	1
Eurofins AgroScience Services	MAR	FR	1	1
Inst. Of Plant Protection, Poznan	N-E	PL	7	2
Inst. Of Plant Protection, Sosnicowice	N-E	PL		1
Eurofins AgroScience Services	N-E	PL	1	1
Latvian Plant Protection Research Centre	N-E	LV	3	3
Lithuanian Institute of Agriculture	N-E	LT	3	
Eurofins AgroScience Services	S-E	BG		1
Eurofins AgroScience Services	S-E	RO	1	1
Eurofins AgroScience Services	MED	ES	1	1
Eurofins AgroScience Services	MED	IT	2	1
Eurofins AgroScience Services	MED	FR	1	1
Total			**23**	**16**

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
CP 6.0-001	Anonymous	2016	Biological Assessment Dossier: MIGHTY (MESOTRIONE 10% SC) (100 g/L mesotrione) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA