REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: MEZI 100 SC

Product name(s): Rumezo Twist 100 SC,

Malton Twist 100 SC

Chemical active substance(s):

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023, October 2024

zRMS Assessment: 24/07/2024

Following commenting period: 21/10/2024

Final version: 18/12/2025

Version history

When	What
July 2024	zRMS assessment
October 2024	Following commenting period
October 2024	Applicant update
December 2025	Final version

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9 Ecotoxicology (KCP 10)

Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for registration data of Calisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Calisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use -No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Maize *Zea mays* ZEAMX	F	Mono- and dicotyledonous weeds	Spray, medium sprayer	BBCH 14-15	a) 1 b) 1	n/a	a) 1.0 L/ha b) 1.0 L/ha	a) 100 g as/ha b) 100 g as/ha	200-300	n/a								
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (field uses)																				
Minor uses according to Article 51 (interzonal uses)																				

* 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

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use

R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) 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
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)Effects on aquatic organisms (KCP 10.2)

In conclusion, the acute, short term risk and long term to bird and mammals from the proposed uses of MEZI 100 SC was found acceptable. MEZI 100 SC no pose any unacceptable risk for birds and mammals according to label.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Basic on RAC=0.77µg/L from *L.gibba* study available in EFSA Journal 2016;14(3):4419 for the protection of aquatic organisms in intended use of product MEZI 100 SC following limitations are necessary to maintain :

- For Poland, Belgium, Czech Republic, Romania, Slovakia, Slovenia are necessary to maintain the 10 meters of vegetative buffer zone and 10 meters of no-spray zone for all pH values.
- For Austria, Hungary and Republic of Ireland, are necessary to reduce application rate from 100 g as/ha to 50 g as/ha, because PECsw/sed values in R3, R4 scenarios (relevant scenarios for these countries) and are necessary to maintain: 20 meters no-spray zone for uses in acid soils (pH=5.1 and pH=6.5) and 20 meters vegetative buffer zone and 20 meters no-spray zone for uses in alkaline soils (pH=7.9).

After redefinition of the risk assessment for aquatic organisms which based on the changing of the RAC values from RAC=0.77µg/L to RAC=2.41 µg/L for the protection of aquatic organisms in intended use of product MEZI 100 SC are necessary to maintain: 10 meters vegetative buffer zone and 10 meters no-spray zone for uses in alkaline and acids soils.

The calculated PEC/RAC ratios for the Mesotrione metabolites indicate an acceptable risk for all groups of aquatic organism for the intended uses in Maize, based on FOCUS Step 1 PECSW calculations. No further assessment is necessary for the relevant metabolites of Mesotrione.

The calculated PEC/RAC ratios for formulation indicate an acceptable risk for all groups of aquatic organism for the intended uses in Maize, when 5 m buffer zone is applied.

The appropriate risk mitigation measures should be considered an the national level.

9.1.1.3

MEZI 100 SC no pose any unacceptable risk for bees according to label.

9.1.1.4 *Effects on arthropods other than bees (KCP 10.3.2)*

All hazard quotients (HQ) are considerably less than trigger values, indicating that MEZI 100 SC applied at the maximum use rate poses no risk to non-target arthropods. No risk mitigation needed.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

MEZI 100 SC pose no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

MEZI 100 SC pose no unacceptable risk to non-target terrestrial plants when 50 m buffer strip or 5 m buffer strip and 90% drift reduction is applied.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Tests on other non-target species are not required.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

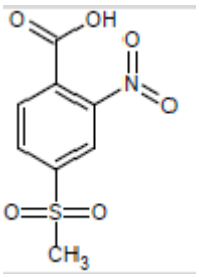
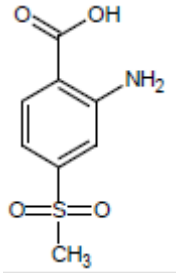
Table 9.1-2: Critical use pattern of MEZI 100 SC grouped according to application rate, number of applications, timing criterion

Grouping according to application rate, number of applications, timing criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Maize	Maize	application rate, number of applications, timing criterion	application rate, number of applications, timing criterion

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of MEZI 100 SC is indicated in the table.

Table 9.1-3 Metabolites of Mesotrione

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
MNBA		245	Soil (lab): max 57.2 % AR Maximum occurrence observed in sediment/ water studies: 7.9 %	Yes
AMBA		215	Soil (Lab): max 9.7 % AR Maximum occurrence observed in sediment/ water studies: 24.6 %	Yes
SYN546974		291	Soil (Lab): mx 1E-10 % AR Maximum occurrence observed in sediment/ water studies: 33%	Yes

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Mesotrione and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on birds of Mesotrione were not evaluated as part of the EU assessment of Mesotrione .

Table 9.2-4: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Bobwhite quail (Colinus virginianus)	Mesotrione	Acute	LD_{50} >2000 mg a.s./kg bw (corrected to 3776 mg a.s./kg bw)	EFSA Journal 2016;14(3):4419
			NOEL= 2000 mg a.s./kg bw	
Mallard duck (Anas platyrhynchos)	Mesotrione	Short-term	LC_{50} >5200 mg/kg diet	EFSA Journal 2016;14(3):4419
			NOEC 5200 mg/kg diet	
Bobwhite quail	Mesotrione	Short-term	LC_{50}	EFSA Journal

Species	Substance	Exposure System	Results	Reference
(Colinus virginianus)			>5200 mg/kg diet NOEC 5200 mg/kg diet	2016;14(3):4419
Bobwhite quail (Colinus virginianus)	Mesotrione	Long-term	NOEC 3000 mg a.s./kg diet	EFSA Journal 2016;14(3):4419
Mallard duck (Anas platyrhynchos)	Mesotrione	Long-term	NOEL 120 mg a.s./kg diet = 20.6 mg a.s./kg bw/d	EFSA Journal 2016;14(3):4419

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9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Maize also covers the risk for birds from all other intended uses in group (see 9.1.2).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds

Intended use	**Maize**					
Active substance/product	Mesotrione					
Application rate (g/ha)	1x100					
Acute toxicity (mg/kg bw)	3776					
TER criterion	10					
Screening step:						
Crop scenario Growth stage	**Indicator species**	**Short cut value**	**Daily Dietary Dose (single)**	**MAF (90)**	**Daily Dietary Dose (Multiple)**	**TER**
Maize- Screening step	Small omnivorous bird	158.8	15.88	1.0	15.88	237.8
Reprod. toxicity (mg/kg bw/d)	20.6					
TER criterion	5					
Screening step						

Crop scenario Growth stage	Indicator species	Short cut value	Daily Dietary Dose (single)	MAF (90)	Daily Dietary Dose (Multiple)	TER
Maize- Screening step	Small omnivorous bird	64.48	6.48	1.0	3.43	6.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.2.2.2 Higher-tier risk assessment

Not required.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since MEZI 100 SC is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 14 L/kg* , Mesotrione belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Maize also covers the risk for birds from all other intended uses in group Maize (see 9.1.2).

Effective application rate (g/ha)	=	100		
Acute toxicity (mg/kg bw)	=	3776	quotient =	0.03
Reprod. toxicity (mg/kg bw/d)	=	20.6	quotient =	4.85

*Considering the worst case KFOC value of 14 L/kg

9.2.2.4 Effects of secondary poisoning

The log K_{ow} of Mesotrione amounts to 0.11 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

In conclusion, the acute, short term risk and long term to bird from the proposed uses of MEZI 100 SC was found acceptable.

zRMS comments:

The risk assessment to birds was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).

The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed and accepted in core assessment endpoints for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for birds resulting from acute and long-term exposure to active substance following use of MEZI 100 SC in compliance with proposed GAP.

A quantitative drinking water risk assessment is not triggered for the proposed use pattern of MEZI 100 SC according to EFSA/2009/1438 criteria and therefore the risk to birds via drinking water is acceptable.

No unacceptable effects to fish-eating and earthworm-eating birds are expected following application of MEZI 100 SC according to the proposed use pattern..

No risk mitigation measures are required.

Conclusion
According to the performed risk assessment there is no potential of risk to birds resulting from exposure to active substances following use of MEZI 100 SC in compliance with proposed GAP.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Mesotrione. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of MEZI 100 SC were not evaluated as part of the EU assessment of Mesotrione.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-6: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Mesotrione	Acute	LD_{50} >5000 mg a.s /kg bw	EFSA Journal 2016;14(3):4419
Rat	MNBA	Acute	$LD_{50.}$ >5000 mg MNBA/kg bw	EFSA Journal 2016;14(3):4419
Rat	MNBA	Acute	LD_{50} >5000 Kg/kg bw	EFSA Journal 2016;14(3):4419
Rat	Mesotrione	long-term	NOEL= 2.5 mg/kg bw feed= 0.3 mg a.s/kg bw/d	EFSA Journal 2016;14(3):4419

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use Maize group also covers the risk for mammals from all other intended uses in Maize group (see 9.1.2).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-7: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of MEZI 100 SC in Maize

Intended use	Maize
Active substance/product	Mesotrione
Application rate (g/ha)	1x100g as/ha
Acute toxicity (mg/kg bw)	5000
TER criterion	10

Screening step						
Indicator species		**Short cut value**	**Daily Dietary Dose (single)**	**MAF (90)**	**Daily Dietary Dose (Multiple)**	**TER**
Small herbivorous mammal		118.4	11.84	1.0	11.84	422.3
Reprod. toxicity (mg/kg bw/d)	0.3					
TER criterion	5					
First Tier Risk Assessment						
Crop scenario Growth stage	**Generic**	**Short cut value**			**TER**	
Maize BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2			**1.3**	
Maize BBCH 10 - 29	Small herbivorous mammal "vole Grass + cereals All maize shoots + later grass	72.3			**0.1**	
Maize BBCH 10 - 29	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8			**0.7**	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietar y dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.3.2.2 Higher-tier risk assessment

Focal species

According to EFSA Journal 2016;14(3):4419 relevant focal species for maize on early stage of germination are omnivorous wood mouse (*Apodemus sylvaticus*) and the herbivorous European brown hare (*Lepus europaeus*).
Based on the a generic field data (Wolf, 2005) for mammalian monitoring study for maize the vole and shrew were not species occurring regularly in maize during pre-emergence and early post emergence. It was concluded that that wood mouse is the relevant focal species for these exposure scenarios.

PD values

Wood mouse
In this hier tier risk assessment for mammals selected diet for wood mouse is default diet as recommended by EFSA (2009), consisting of 25% weeds, 50% weed seeds and 25% ground arthropods.

Brown hare
Relevant diet for brown hares is indicated in Northern Zone Guidance Document.
PD values for brown hares which are presented in table below based on published data from studies carried

out in Sweden (Frylestam 1980a), England (Tapper and Barnes 1986), France (Chapuis 1990) and Denmark (Olesen &Asferg 2006; Hansen 1990).

Crop	Growth stage	Season	PD (fresh weight)		
			Monocotyledons (cereals, grasses)	Dicotyledons (leafy crops, non-grass weeds)	Bush berry plants (buds, leaves)
Maize	BBCH 10-19	Spring	0.84	0.16	-
	BBCH 10-39	Summer	0.72	0.28	-

PD values derived for spring may be also used for risk assessement for mammmals in Central Zone, because they were based on results of the studies performed in Member States of all zones, including Central Zone. Furthermore, all publications were already assessed on the Northern Zone level and there is no reason to challenge derived conclusions .
PD values of 0.84 and 0.16 for monocots and dicots, respectively, as proposed by the Northern Zone Guidance Document may be used also in evaluation performed for the Central Zone.

Food Intake Rate

Wood mouse

The FIR/bw for the wood mouse was performed with consideration of the bodyweight of 21.7 g, as indicated in EFSA (2009) and the mixed diet indicated in EFSA guidance. Calculation was performed in line with indications of Appendix G of EFSA (2009) and is presented below.

Maize	April-May	Plant material[f]	Ground arthropods	Weed seeds
Fraction of food item in mixed diet[a]	PD, fresh (%)	25%	25%	50%
Food energy of food item {i] in mixed diet[b]	FE(kJ/ dry g)	17.6	22.7	21.7
Moisture content of food item {i] in mixed diet[b]	MC (%)	78.4%	68.8%	9.9%
Assimiliation efficiency of food item [i] in mixed diet[c]	AE (%)	47%	87%	84%
Food energy of food item in diet[d]	FE_{item}fresh (kJ/g fresh weight)	0.488	1.54	8.31
Food energy of total diet[d]	FE_{total}fresh (kJ/g fresh weight)	10.2		
Daily energy expenditure[d]	DEE (kJ/day)	59		
Food intake rate of	FIR_{total} fresh	5.76		

total mixed diet[d]	(g fresh weight/day)	
b.w.[e]	(g)	21.7
FIR/b.w.	(g fresh weight/ b.w./day)	**0.27**

a PD for Wood mouse Tier I EFSA mixed diet
b from Table 3 of Appendix G in EFSA(2009)
c from Table 4 of Appendix G in EFSA(2009)
d Calculated according to EFSA (2009, Appendix G)
e Body weight of wood mouse from EFSA guidance
f Plant material is assumed to be- maize shoots (using the default values for grasses and cereal shoots)

The FIR/be of 0.27 will be used in the risk refinement for wood mouse.

Brown hare

The FIR/bw for the brown hare was calculated with consideration of the bodyweight of 3800 g, as indicated in EFSA (2009) and the mixed diet (PD of 0.84 and 0.16 for monocots and dicots, respectively). Calculation was performed in line with indications of Appendix G of EFSA (2009) and is presented below.

		April-May	
Maize		Maize shoots[f]	Non-grass herbs
Fraction of food item in mixed diet[a]	PD, fresh (%)	84%	16%
Food energy of food item {i] in mixed diet[b]	FE(kJ/ dry g)	17.6	17.8
Moisture content of food item {i] in mixed diet[b]	MC (%)	76.4	88.1
Assimiliation efficiency of food item [i] in mixed diet[c]	AE (%)	47	76
Food energy of food item in diet[d]	FE_{item}fresh (kJ/g fresh weight)	1.040	0.258
Food energy of total diet[d]	FE_{total}fresh (kJ/g fresh weight)	1897	
Daily energy expenditure[d]	DEE (kJ/day)	2363.4	
Food intake rate of total mixed diet[d]	FIR_{total} fresh (g fresh weight/day)	1245.61	
b.w.[e]	(g)	3800	
FIR/b.w.	(g fresh weight/ b.w./day)	**0.328**	

a PD for Wood mouse Tier I EFSA mixed diet
b from Table 3 of Appendix G in EFSA(2009)
c from Table 4 of Appendix G in EFSA(2009)
d Calculated according to EFSA (2009, Appendix G)
e Body weight of wood mouse from EFSA guidance

f Plant material is assumed to be- maize shoots (using the default values for grasses and cereal shoots)

For brown hare feeding exclusively with maize shoots, the FIR/bw of 0.32 with consideration of the bodyweight of 3800 g will be used.

Residue decline and fTWA

Maize

In order to determine the DT50 value in maize, are provided a residue decline study by North (2016).

In this study five residue decline field trials on maize were successfully conducted in Northern France and the United Kingdom during 2015.
Residues of Mesotrione in treated maize whole plant samples taken at < 1 hour after application (HAA) were in the range 3.09 to 14.99 mg/kg, at 4 HAA were in the range 2.74 to 12.63 mg/kg, at 10 HAA were in the range 2.05 to 8.61 mg/kg, at 24 HAA were in the range 0.91 to 4.30 mg/kg, at 34 HAA were in the range 0.50 to 2.95 mg/kg, at 48-51 HAA were in the range 0.36 to 1.37 mg/kg, at 72-78 HAA were in the range below the limit of quantification (LOQ: 0.01 mg/kg) to 0.63 mg/kg, and at 96-99 HAA were in the range 0.06 to 0.13 mg/kg.
Residues of MNBA in treated maize whole plant samples taken at < 1 hour after application (HAA) were in the range below the limit of quantification (LOQ: 0.01 mg/kg) to 0.05 mg/kg, at 4 HAA were in the range 0.04 to 0.25 mg/kg, at 10 HAA were in the range 0.07 to 0.36 mg/kg, at 24 HAA were in the range 0.07 to 0.37 mg/kg, at 34 HAA were in the range 0.05 to 0.37 mg/kg, at 48-51 HAA were in the range 0.06 to 0.35 mg/kg, at 72-78 HAA were in the range below the limit of quantification (LOQ: 0.01 mg/kg) to 0.17 mg/kg, and at 96-99 HAA were in the range 0.04 to 0.11 mg/kg.

No residues of mesotrione and MNBA were detected at or above the limit of quantification (LOQ: 0.01 mg/kg) in any of the untreated maize whole plant samples taken in this study.

For purposes of refinement of fTWA which is 0.055 is used worst case DT50 of 0.803 days

Weeds

In order to determine the DT50 value in weeds, is provided a residue decline study by Allen (2019) performed on clover.

In this study twelve (10 + 2 contingency) foliar decline residue field trials on clover were planned, eleven (10 + 1 contingency) were successfully conducted in Northern France, Germany, Poland, Hungary, United Kingdom and Belgium during 2018. One trial was cancelled due to poor crop growth.

Mesotrione was applied to clover as A12738A, a suspension concentrate (SC) formulation containing nominal 480 g mesotrione per litre. One application, applied at BBCH 16-18 was made at a nominal rate of 150 g ai/ha for mesotrione, with the exception of trial SRDE18-001-037HR which was applied at BBCH 12-61 and trial SRDE18-002-037HR which was applied at BBCH 16-81. Untreated immature clover samples were taken from the plot at 0 DBA (days before application). Treated samples of immature clover were taken at 0, 8, 24, 32 and 48 HAA (hours after application) and at 3, 4 and 7 DAA (days after application).

Residue samples were shipped frozen to the analytical facility where they were analysed for mesotrione.

Residues of mesotrione in treated clover taken at < 1 hour after application (HAA) were in the range 3.63 to 11.97 mg/kg. At 8 HAA they were in the range 2.71 to 11.41 mg/kg, at 24 HAA in the range 2.28 to 11.02 mg/kg, at 32 HAA in the range 2.06 to 9.02 mg/kg, at 48 HAA they were in the range 1.78 to 7.14

mg/kg, at 3 days after application (DAA) they were in the range 0.22 – 6.06, 5 DAA in the range 0.08 – 4.37 and 7 DAA 0.05 – 1.70 mg/kg.

No residues of mesotrione and MNBA were detected at or above the limit of quantification (LOQ: 0.01 mg/kg) in any of the untreated clover whole plant samples taken in this study.

Due to reliable DT50 values obtained in 10 trials to use the geometric mean DT50 of 2.19 days for purposes of refinement of fTWA, which is 0.150.

RUD values

Default RUD values in line with EFSA (2009) are used for particular diet components.

According to the study Murfitt et al (2015) of the analysis of the industry residue data in maize at BBCH 10-19 demonstrated that default mean RUD value of 54.2 mg/kg derived for grass+cereals may be replaced by 46.8 mg/kg derive specifically for maize.

Murfitt et al. (2015) analysed a large dataset of industry dietary residue trials performed for spray applications of pesticides in maize at BBCH 10-19 (436 trials: 255 EU-N; 181 EU-S). The initial residues were converted to RUD values using the application rate. Mean and 90th percentile RUD values were calculated across all European trials and subsets covering the Northern and Southern residue regions, in order to check for any potential effect of region on RUD outcome.
Based on obtained results, the mean RUD of 46.8 mg/kg was derived for maize and may potentially be used for purposes of the risk assessment, especially it actually originates from the sufficient dataset derived from residue trials in maize and is more relevant than RUD derived for grass+cereals, excluding residue trials in maize.

PT

Brown hare

For refinement PT value from default value (PT=1) to PT=0.62 provided study by Grimm & Katzschner (2019) monitoring brown hares in two Central Zone countries (Germany and Hungary).

The aim of this generic study was to investigate the use of maize fields as foraging habitat by Brown hare (*Lepus europaeus*) in the Central Europe. Focus was the determination of respective PT values (i.e. proportion of diet obtained in treated area, calculated as proportion of potentially foraging time spent in maize fields by hares) during the early growing period of maize via continuous 24-hour radio-tracking sessions of multiple individual hares. In total, radio-tracking sessions of 21 individual hares at five study sites were performed during the early crop development of maize in Central Europe. Radio-tracking sessions were performed from late April until early June 2018. The number of conducted 24h telemetry sessions was 23 (17 in Germany, six in Hungary), since two individuals were radio tracked twice.

The calculated single PT values ranged from 0.02 to 0.94 resulting in an average of 0.36 (±0.26) and 90th percentile of 0.62. Calculated PT values did not differ substantially between different study sites; mean values were slightly higher in Germany (0.38) than in Hungary (0.31).

Table 9.3-8: Higher-tier assessment of the reproductive risk for mammals due to the use of MEZI 100 SC in Maize

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Intended use **Active substance/product** **Application rate (g/ha)**	Maize Mesotrione 1x100 g as/ha						
Reprod. toxicity (mg/kg bw/d) **TER criterion**	0.3 5						
Focal species	**PD/diet type**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m × TWA**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Brown hare *Lepus europaeus* Maize BBCH 10-29	0.84 maize[a]	0.328[b]	46.8[d]x1	1.0x0.055[e]	0.62[g]	0.044	
	0.16 dicot weeds[a]		28.7[c]x1	1.0x0.150[f]		0.014	
	whole diet					0.058	5.2
	1.0 maize	0.32	46.8[d]x1	1.0x0.055[e]	0.62[g]	0.051	5.9
Intended use **Active sub-stance/product** **Application rate (g/ha)**	Maize Mesotrione 1x100 g as/ha						
Intended use **Active sub-stance/product**	0.3 5						
Small omnivorous mammal "mouse" Combination (inver-tebrates with inter-ception) 25% weeds 50% weed seeds 25% ground arthropods Maize BBCH 10-29	0.25 maize	0.27[b]	46.8[d]x1	1.0x0.055[e]	0.139	0.002	
	0.5 maize seeds		40.2[c]x1	1.0x0.53		0.04	
	0.25 ground arthropods		3.5[c]x1	1.0x0.53		0.002	
	whole diet					0.043	7.0

[a] Northern Zone Guidance Document
[b] Appendix G of Guidance of EFSA Risk Assessment for Birds and Mammals EFSA Journal 2009; 7(12):1438
[c] Appendix F of Guidance of EFSA Risk Assessment for Birds and Mammals EFSA Journal 2009; 7(12):1438
[d] Murfitt R.et al. (2015) Measured residues on maize foliage for use in bird and mammal risk assessment
[e] North L. 2016 Mesotrione - Foliage Decline with A12739A on Maize in Northern France and the United Kingdom in 2015
[f] Allen L 2019 Mesotrione – Mesotrione – Foliage Decline Study on Clover in Hungary, Germany, United Kingdom, Northern France and Belgium in 2018.
[g] Grimm T & Katzschner I (2019) Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a

drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 14 L/kg*, Mesotrione belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use Maize group also covers the risk for mammals from all other intended uses in group Maize (see 9.1.2).
***Considering the worst case KFOC value of 14 L/kg**

Effective application rate (g/ha) = 100
Acute toxicity (mg/kg bw) = 5000 quotient = 0.02
Reprod. toxicity (mg/kg bw/d) = 0.3 quotient = **333.33**

Since the ratio of effective application rate (100 g/ha) to relevant endpoint (0.3 mg/kg bw/d) exceeds the critical value of 50 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is necessary and presented in Table 9.3-6

Table 9.3-6: **Assessment of the risk for mammals due to exposure to Mesotrione** via contaminated drinking water in puddles

Intended use	Maize				
Active substance	Mesotrione				
Application rate (g/ha)	1 × 100g as/ha				
Reprod. toxicity (mg/kg bw/d)	0.3				
TER criterion	5				
Soil-relevant applic. rate (g/ha)	**Koc (L/kg)**	**PEC_{puddle} (mg/L)**	**DW uptake (L/kg bw/d)**	**Daily dose (mg/kg bw/d)**	**TER_{lt}**
100g	14	0.244	0.24	0.0586	5.1

PEC_{puddle}: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

PEC puddle calculated with equation:

$$PEC_{puddle} = \frac{AR/10}{1000\,(w + Koc \times s)}$$

where:

AR = *application rate [g/ha]; divisor of 10 to achieve rate in mg/m²*
w = *0.02 (pore water term; volume)*
s = *0.0015 (soil term: volume, density, organic carbon content*

For the proposed use of 100 g a.s./ha the resulting TER values are above the trigger of 5 indicating acceptable chronic risk to mammals from drinking water from puddles.

9.3.2.4 Effects of secondary poisoning

The log K_{ow} of Mesotrione amounts to 0.11 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

In conclusion, the acute, short term risk and long term to mammals from the proposed use of Mesotrione was found acceptable.
MEZI 100 SC pose no unacceptable to mammals with according to the label.

zRMS comments:

The risk assessment to wild mammals was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).

The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed and accepted in core assessment endpoints for most sensitive species for the active substances and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for birds resulting from acute exposure to active substance following use of MEZI 100 SC in compliance with proposed GAP.

A refined risk assessment for the reproductive risk to mammals was performed by applicant based on the relevant focal species in early maize (BBCH 12-18), PT and PD values, Food Intake Rate, RUD and fTWA values. Generally evaluator agrees with the proposed refinement with the exception of the proposed RUD value. The applicant presented a meta-analysis study by Murfitt et al. (2015) in order to further refine the default RUD value for maize. However, very limited information on the study by Murfitt et al. (2015) has been provided by the Applicant and no background documents were presented. That the study summary was presented as a poster. Taking this into account the zRMS could not confirm validity

of the provided RUD value and this refinement option must be further considered at the national level.

Intended use	Maize
Active substance/product	Mesotrione
Application rate (g/ha)	1x100 g as/ha
Reprod. toxicity (mg/kg bw/d)	0.3
TER criterion	5

Focal species	**PD/diet type**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m × TWA**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Brown hare *Lepus europaeus* Maize BBCH 10-29	0.84 maize[a]	0.328[b]	54.2 x1	1.0x0.055[e]	0.62[g]	0.051	
	0.16 dicot weeds[a]		28.7[c]x1	1.0x0.150[f]		0.014	
	whole diet					0.0649	**4.62**
	1.0 maize	0.32	54.2 x1	1.0x0.055[e]	0.62[g]	0.059	5.08

Intended use	Maize
Active substance/product	Mesotrione
Application rate (g/ha)	1x100 g as/ha
Intended use	0.3
Active substance/product	5

Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods Maize BBCH 10-29	0.25 maize	0.27[b]	54.2 x1	1.0x0.055[e]	0.139	0.0028	
	0.5 maize seeds		40.2[c]x1	1.0x0.53		0.04	
	0.25 ground arthropods		3.5[c]x1	1.0x0.53		0.002	
	whole diet					0.045	6.66

Performed calculations demonstrated acceptable risk to the wood mouse and acceptable risk could be demonstrated for hares feeding exclusively on maize shoots, but unacceptable risk was demonstrated for hares with a TER slightly below the trigger of 5 when a mixed diet was considered.

Using the conservative value of PD=1, the calculated TER_{LT} value is 5.08. Thus, the PD refinement for brown hare was not necessary.

Additionally the RUD value of 54.2 for maize currently included in the B&M EFSA guidance document 2009; 7(12):1438 is likely a conservative value since the trials it is based upon do not include maize, the lower RUD value of 29.7 for maize from the database developed by Lahr et al. (2018) has been proposed in the draft of the new Birds and Mammal guidance document (2021).
Taking into consideration the conservativeness of the approach, the risk to brown hare is considered acceptable by the zRMS.

No unacceptable effects to mammals through drinking water are expected following application of MEZI 100 SC according to the proposed use pattern.

No unacceptable effects to fish-eating and earthworm-eating birds are expected following application of MEZI 100 SC according to the proposed use pattern..

No risk mitigation measures are required.

Conclusion
According to the performed risk assessment there is no potential of risk to mammals resulting from exposure to active substance following use of MEZI 100 SC in compliance with proposed GAP.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No additional studies on other terrestrial vertebrates are required.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Mesotrione and relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Table 9.5-9: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Mesotrione and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Mesotrione	96 h, s	LC50 >120 mg a.s./L ~~s~~ (nom)	EFSA Journal 2016;14(3):4419
Lepomis macrochirus	Mesotrione	96 h, s	LC50 >120 mg a.s./L (nom)	EFSA Journal 2016;14(3):4419
Oncorhynchus mykiss	MNBA	96 h, s	LC50 >120 mg a.s./L ~~s~~ (nom)	EFSA Journal 2016;14(3):4419
Oncorhynchus mykiss	AMBA	96 h, s	LC50 = 150 mg a.s./L ~~s~~ (nom)	EFSA Journal 2016;14(3):4419

Species	Substance	Exposure System	Results	Reference
Pimephales promelas	Mesotrione	36 d chronic, f	NOEC = 12.5 mg a.s./L ~~mm~~ nom	EFSA Journal 2016;14(3):4419
Daphnia magna	Mesotrione	48 h, s	EC50 >622 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Daphnia magna	MNBA	48 h, s	EC50 = 130 mg a.s./L nom	EFSA Journal 2016;14(3):4419
Daphnia magna	AMBA	48 h, s	EC50 = 160 mg a.s./L nom	EFSA Journal 2016;14(3):4419
Daphnia magna	Mesotrione	21 d, ss	NOEC = 180 mg a.s./L ~~mm~~ (nom)	EFSA Journal 2016;14(3):4419
Pseudokirchneriella subcapitata	Mesotrione	120 h, s	ErC50 = 13 mg a.s./L ~~mm~~ (nom) EbC50 = 3.5 mg a.s./L ~~mm~~ (nom) $NOEC_b$ = 0.75 mg a.s./L (nom) E_bC_{10} = 0.692 mg a.s./L (nom) E_bC_{20} = 0.958 mg a.s./L (nom)	EFSA Journal 2016;14(3):4419
Pseudokirchneriella subcapitata	MNBA	72 h, s	ErC50 = 42 mg a.s./L ~~mm~~ (nom) EbC50 = 38 mg a.s./L ~~mm~~ (nom) $NOEC_{b,r}$ = 32 mg a.s./L (nom) ErC_{10} = 33.4 mg a.s./L (nom) ErC_{20} = 34.9 mg a.s./L (nom)	EFSA Journal 2016;14(3):4419
Pseudokirchneriella subcapitata	AMBA	72 h, s	ErC50 = 14 mg a.s./L ~~mm~~ (nom) EbC50 = 9.4 mg a.s./L ~~mm~~ (nom) $NOEC_{b,r}$ = 7.7 mg a.s./L (nom) E_bC_{10} = 2.58 mg a.s./L (nom) E_bC_{20} = 4.04 mg a.s./L (nom)	EFSA Journal 2016;14(3):4419
Lemna gibba	Mesotrione	14 d, ss	EbC50 frond no.= 0.022 mg a.s./L ~~mm~~ (nom) EbC50 dry weight = 0.0077 mg a.s./L ~~mm~~ (nom) $NOEC_b$ dry weight = 0.002mg a.s./L (nom) EyC_{10} dry weight = 0.0014 mg a.s./L (nom) EyC_{20} dry weight = 0.0022 mg a.s./L (nom)	EFSA Journal 2016;14(3):4419

Species	Substance	Exposure System	Results	Reference
Lemna gibba	Mesotrione	7 d, ss	ErC50 frond no or biomass = 0.0241 mg a.s./L nom EbC50 yield = 0.0045 mg a.s./L nom	Hengsberger and Wydra, 2015 ZA1296_10438
Myriophyllum spicatum	Mesotrione	14d, ss	E_rC_{50} total shoot length = 0.0287 mg a.s./L $_{nom}$ E_yC_{50} yield = 0.00255 mg a.s./L $_{nom}$	Gonsior 2017 ZA1296_10504
Aquatic macrophytes	Mesotrione	Geometric mean	ErC50 = 0.0263 mg a.s./L EyC50 = 0.00339 mg a.s./L	geometric mean of ErC50 and EyC50 values from studies Hengsberger and Wydra, (2015) and Gonsior (2017)
Lemna gibba	MNBA	7 d, ss	ErC50 >97 mg a.s./L ~~T~~ (mm) EyC50 >97 mg a.s./L ~~T~~ (mm) NOEC frond no. = 3.3 mg a.s./L (mm) EC_{10} all $_{>}$ 97 mg a.s./L (mm) EC_{20} all > 97 mg a.s./L (mm)	EFSA Journal 2016;14(3):4419
Lemna gibba	AMBA	7 d, ss	ErC50 >90 mg a.s./L ~~T~~ (mm) EyC50 >90 mg a.s./L ~~T~~ (mm) NOEC for both = 90 mg a.s./L (mm) EyC_{10} frond no. $_{>}$ 24 mg a.s./L (mm) EC_{20} all > 90 mg a.s./L (mm)	EFSA Journal 2016;14(3):4419
Lemna gibba	SYN546974	7 d, ss	ErC50 >95 mg a.s./L ~~nom~~ (mm) EyC50 = 93 mg a.s./L ~~nom~~ (mm) NOEC frond no. = 2.9 mg a.s./L (mm) EyC_{10} frond no. $_{=}$ 9.9 mg a.s./L (mm) EyC_{20} frond no. = 21 mg a.s./L (mm)	EFSA Journal 2016;14(3):4419
Higher-tier studies (micro- or mesocosm studies)				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-10: Endpoints and effect values relevant for the risk assessment for aquatic organisms –

Species	Substance	Exposure System	Results	Reference
Cyprinus carpio	Callisto 100 SC	96 h, s	LC50 = 71 mg product/L nom	EFSA Conclusion 2016 (2005), [redacted]
Daphnia magna	Callisto 100 SC	48 h, s	EC50 = 49 mg product/L nom	EFSA Conclusion 2016 Ricketts D., Langridge G (2005), . Syngenta File No ZA1296/2042
Pseudokirchneriella subcapitata	Callisto 100 SC	96 h, s	ErC50 > 100 mg product/L nom EbC50 = 72 mg product/L nom	EFSA Conclusion 2016 Volz E., (2005), Syngenta File No ZA1296/2049 Dark R., (2012), Syngenta File No A12739A_10427
Lemna gibba	Callisto 100 SC	7 d, ss	ErC50 = 0.117 mg product/L nom EyC50 = 0.0269 mg product/L nom	EFSA Conclusion 2016 Zawadsky C. (2013) Syngenta File No A12739A_10273
Higher-tier studies (micro- or mesocosm studies)				
N/A				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Maize also covers the risk for aquatic organisms from all other intended uses in Maize groups (see 9.1.2).

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100SC in Maize (Application rate 100g as/ha, pH=5.1)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher- plants**	**Higher- plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemma gibba (the lowest ErC50 for aquatic macrophyte)***	***Lemma gibba***
Endpoint (µg/L)		LC50>120 000	NOEC= 12500	EC_{50} >622 000	NOEC = 180 000	ErC50 = 13 000	ErC50= 24.1	EbC50>7.7*
AF		100	10	100	10	10	10	10
RAC (µg/L)		1200	1250	6220	1800	1300	2.41	0.77
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	28.49	- 0.024	- 0.023	- 0.005	- 0.016	- 0.022	11.82157676	37
Step 2								
N-Europe	4.26	-	-	-	-	-	1.767634855	5.532467532
Step 3								
D3/ditch	0.5247	-	-	-	-	-	0.217717842	0.681428571
D4/pond	0.04485	-	-	-	-	-	0.018609959	0.058246753

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Higher- plants	Higher- plants
D4/stream	0.4513	-	-	-	-	-	0.187261411	0.586103896
D5/pond	0.03121	-	-	-	-	-	0.012950207	0.040532468
D5/stream	0.4762	-	-	-	-	-	0.197593361	0.618441558
D6/ditch	0.5278	-	-	-	-	-	0.219004149	0.685454545
R1/pond	0.08008	-	-	-	-	-	0.033228216	0.104
R1/stream	**1.692**	-	-	-	-	-	0.702074689	**2.197402597**
R2/stream	**1.266**	-	-	-	-	-	0.525311203	**1.644155844**
R3/stream	**3.249**	-	-	-	-	-	**1.34813278**	**4.219480519**
R4/stream	**3.542**	-	-	-	-	-	**1.469709544**	**4.6**
Step 4- 10 meters vegetative buffer zone and 10 meters no-spray buffer zone								
D3/ditch	**-**	-	-	-	-	-	-	-
D4/pond	-	-	-	-	-	-	-	-
D4/stream	-	-	-	-	-	-	-	-
D5/pond	-	-	-	-	-	-	-	-
D5/stream	-	-	-	-	-	-	-	-
D6/ditch	-	-	-	-	-	-	-	-
R1/pond	-	-	-	-	-	-	-	-
R1/stream	0.7659	-	-	-	-	-	0.31780083	**0.994675325**
R2/stream	**0.9189**	-	-	-	-	-	0.381286307	**1.193376623**
R3/stream	**1.466**	-	-	-	-	-	0.608298755	**1.903896104**
R4/stream	**1.610**	-	-	-	-	-	0.668049793	**2.090909091**
Step 4- 20 meters vegetative buffer zone and 20 meters no-spray buffer zone								

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher- plants	Higher- plants
D3/ditch	-	-	-	-	-	-	-	-
D4/pond	-	-	-	-	-	-	-	-
D4/stream	-	-	-	-	-	-	-	-
D5/pond	-	-	-	-	-	-	-	-
D5/stream	-	-	-	-	-	-	-	-
D6/ditch	-	-	-	-	-	-	-	-
R1/pond	-	-	-	-	-	-	-	-
R1/stream	-	-	-	-	-	-	-	-
R2/stream	0.2892	-	-	-	-	-	0.12	0.375584416
R3/stream	**0.7667**	-	-	-	-	-	0.31813278	**0.995714286**
R4/stream	**0.8437**	-	-	-	-	-	0.350082988	**1.095714286**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100SC in Maize (Application rate= 100 g as/ha pH=7.9)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher- plants	Higher- plants
Test species		***Oncorhynchus mykiss***	**Pimephales promelas**	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemma gibba (the lowest ErC50 for aquatic macrophyte)***	**Lemma gibba**
Endpoint		LC50>120 000	NOEC=	EC_{50} >622 000	NOEC = 180 000	ErC50 = 13 000	ErC50= 24.1	EbC50>7.7

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher- plants**	**Higher- plants**
(µg/L)			12500					
AF		100	10	100	10	10	10	10
RAC (µg/L)		1200	1250	6220	1800	1300	2.41	0.77
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	33.50						13.90041494	43.50649351
Step 2								
N-Europe	3.47						1.439834025	4.506493506
Step 3								
D3/ditch	0.5248	-	-	-	-	-	0.217759336	0.681558442
D4/pond	0.02119	-	-	-	-	-	0.008792531	0.027519481
D4/stream	0.4494	-	-	-	-	-	0.186473029	0.583636364
D5/pond	0.02117	-	-	-	-	-	0.008784232	0.027493506
D5/stream	0.4689	-	-	-	-	-	0.194564315	0.608961039
D6/ditch	0.5240	-	-	-	-	-	0.217427386	0.680519481
R1/pond	0.02840	-	-	-	-	-	0.011784232	0.036883117
R1/stream	**1.090**	-	-	-	-	-	0.452282158	**1.415584416**
R2/stream	**3.174**	-	-	-	-	-	**1.317012448**	**4.122077922**
R3/stream	**3.835**	-	-	-	-	-	**1.591286307**	**4.980519481**
R4/stream	**4.186**	-	-	-	-	-	**1.736929461**	**5.436363636**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher- plants	Higher- plants
Step 4- 10 meters vegetative buffer zone and 10 meters no-spray buffer zone								
D3/ditch	-	-	-	-	-	-	-	-
D4/pond	-	-	-	-	-	-	-	-
D4/stream	-	-	-	-	-	-	-	-
D5/pond	-	-	-	-	-	-	-	-
D5/stream	-	-	-	-	-	-	-	-
D6/ditch	-	-	-	-	-	-	-	-
R1/pond	-	-	-	-	-	-	-	-
R1/stream	0.4474	-	-	-	-	-	0.185643154	0.581038961
R2/stream	**1.401**	-	-	-	-	-	0.581327801	**1.819480519**
R3/stream	**1.731**	-	-	-	-	-	0.718257261	**2.248051948**
R4/stream	**1.903**	-	-	-	-	-	0.789626556	**2.471428571**
Step 4- 20 meters vegetative buffer zone and 20 meters no-spray buffer zone								
R2/stream	0.7256	-	-	-	-	-	-	0.94
R3/stream	**0.9058**	-	-	-	-	-	-	**1.18**
R4/stream	**0.9972**	-	-	-	-	-	-	**1.30**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100SC in Maize (Application rate= 50 g as/ha pH=5.1)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Higher- plants**	**Higher- plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. sub-capitata***	***Lemma gibba (the lowest ErC50 for aquatic macro-phyte)***	**Lemma gibba**
Endpoint (µg/L)		LC50>120 000	NOEC= 12500	EC_{50} >622 000	NOEC = 180 000	ErC50 = 13 000	ErC50= 24.1	EbC50>7.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		1200	1250	6220	1800	1300	2.41	0.77
FOCUS Sce-nario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	14.25	-	-	-	-	-	5.912863071	18.50649351
Step 2								
N-Europe	2.13	-	-	-	-	-	0.883817427	2.766233766
Step 3								
D3/ditch	0.2624	-	-	-	-	-	0.108879668	0.340779221
D4/pond	0.02235	-	-	-	-	-	0.009273859	0.029025974
D4/stream	0.2257	-	-	-	-	-	0.093651452	0.293116883
D5/pond	0.01546	-	-	-	-	-	0.006414938	0.020077922
D5/stream	0.2380	-	-	-	-	-	0.098755187	0.309090909

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Higher- plants	Higher- plants
D6/ditch	0.2637	-	-	-	-	-	0.109419087	0.342467532
R1/pond	0.04007	-	-	-	-	-	0.016626556	0.052038961
R1/stream	**0.8474**	-	-	-	-	-	0.351618257	**1.100519481**
R2/stream	0.6129	-	-	-	-	-	0.254315353	**0.795974026**
R3/stream	**1.594**	-	-	-	-	-	0.661410788	**2.07012987**
R4/stream	**1.749**	-	-	-	-	-	0.725726141	**2.271428571**
Step 4- none vegetative buffer zone and 10 meters no-spray buffer zone								
D3/ditch	-	-	-	-	-	-		
D4/pond	-	-	-	-	-	-		
D4/stream	-	-	-	-	-	-		
D5/pond	-	-	-	-	-	-		
D5/stream	-	-	-	-	-	-		
D6/ditch	-	-	-	-	-	-		
R1/pond	-	-	-	-	-	-		
R1/stream	0.3835						0.159128631	0.498051948
R2/stream	-	-	-	-	-	-	-	-
R3/stream	0.7191	-	-	-	-	-	0.298381743	0.933896104
R4/stream	**0.7950**	-	-	-	-	-	0.329875519	**1.032467532**
Step 4- 20m vegetative buffer zone and 20 meters no-spray buffer zone								
D3/ditch	-	-	-	-	-	-	-	-
D4/pond	-	-	-	-	-	-	-	-
D4/stream	-	-	-	-	-	-	-	-

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Higher- plants	Higher- plants
D5/pond	-	-	-	-	-	-	-	-
D5/stream	-	-	-	-	-	-	-	-
D6/ditch	-	-	-	-	-	-	-	-
R1/pond	-	-	-	-	-	-	-	-
R1/stream	-	-	-	-	-	-	-	-
R2/stream	-	-	-	-	-	-	-	-
R3/stream	-	-	-	-	-	-	-	-
R4/stream	0.4166	-	-	-	-	-	0.172863071	0.541038961

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100SC in Maize (Application rate= 50 g as/ha pH=7.9)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Higher- plants	Higher- plants
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Lemma gibba (the lowest ErC50 for aquatic*	Lemma gibba

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher- plants**	**Higher- plants**
							macrophyte)	
Endpoint (µg/L)		LC50>120 000	NOEC= 12500	EC_{50} >622 000	NOEC = 180 000	ErC50 = 13 000	ErC50= 24.1	EbC50>7.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		1200	1250	6220	1800	1300	2.41	0.77
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	16.75	-	-	-	-	-	**6.950207469**	**21.75324675**
Step 2								
N-Europe	1.74	-	-	-	-	-	0.721991701	**2.25974026**
Step 3								
D3/ditch	0.2624	-	-	-	-	-	0.108879668	0.340779221
D4/pond	0.01059	-	-	-	-	-	0.004394191	0.013753247
D4/stream	0.2248	-	-	-	-	-	0.093278008	0.291948052
D5/pond	0.01059	-	-	-	-	-	0.004394191	0.013753247
D5/stream	0.2346	-	-	-	-	-	0.097344398	0.304675325
D6/ditch	0.2620	-	-	-	-	-	0.108713693	0.34025974
R1/pond	0.01442	-	-	-	-	-	0.005983402	0.018727273
R1/stream	0.5470	-	-	-	-	-	0.226970954	0.71038961

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Higher- plants	Higher- plants
R2/stream	**1.573**	-	-	-	-	-	0.652697095	**2.042857143**
R3/stream	**1.921**	-	-	-	-	-	0.797095436	**2.494805195**
R4/stream	**2.089**	-	-	-	-	-	0.108879668	~~0.340779221~~ **2.71**
Step 4- 10 meters vegetative buffer zone and 10 meters no-spray buffer zone								
D3/ditch	**-**	-	-	-	-	-	-	-
D4/pond	-	-	-	-	-	-	-	-
D4/stream	-	-	-	-	-	-	-	-
D5/pond	-	-	-	-	-	-	-	-
D5/stream	-	-	-	-	-	-	-	-
D6/ditch	-	-	-	-	-	-	-	-
R1/pond	-	-	-	-	-	-	-	-
R1/stream	-	-	-	-	-	-	-	-
R2/stream	0.6945	-	-	-	-	-	0.288174274	**0.901948052**
R3/stream	0.8670	-	-	-	-	-	0.359751037	**1.125974026**
R4/stream	0.9498	-	-	-	-	-	0.394107884	**1.233506494**
Step 4- 20m vegetative buffer zone and 20 meters no-spray buffer zone								
D3/ditch	-	-	-	-	-	-	-	-
D4/pond	-	-	-	-	-	-	-	-
D4/stream	-	-	-	-	-	-	-	-
D5/pond	-	-	-	-	-	-	-	-
D5/stream	-	-	-	-	-	-	-	-

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Higher- plants	Higher- plants
D6/ditch	-	-	-	-	-	-	-	-
R1/pond	-	-	-	-	-	-	-	-
R1/stream	-	-	-	-	-	-	-	-
R2/stream	-	-	-	-	-	-	-	-
R3/stream	~~0.4984~~ 0.4537*	-	-	-	-	-	0.206804979	~~0.647272727~~ 0.5892
R4/stream	~~0.5073~~ 0,4977*	-	-	-	-	-	0.210497925	~~0.658831169~~ 0.6463

* Corrected according to Part B8

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (MNBA) of Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100 SC in maize. (Application rate 100g as/ha)

MNBA					
Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} >120000	EC_{50} =130000	ErC50=42000	EC50> 97000
AF		100	100	10	10
RAC (µg/L)		1200	1300	4200	9700
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1 pH 5.1 and pH 6.5 and pH 7.9					
PEC/RAC	15.67	- 0.01	- 0.01	- 0.004	- 0.002

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (AMBA) of Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100 SC in maize. (Application rate 100g as/ha)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	*Pseudokirchneriella subcapitata*	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} >150000	EC_{50} =160000	ErC50=14000	ErC50=90000
AF		100	100	10	10
RAC (µg/L)		1500	1600	1400	9000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1 pH 7.9					
PEC/RAC	7.19	- 0.005	- 0.004	0.005135714	- 0.001
Step 1 pH 5.1					
PEC/RAC	6.50	0.004	0.004	0.005	0.001
Step 1 pH 6.5					
PEC/RAC	6.96	0.005	0.004	0.005	0.001

Table 9.5-8 Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite (SYN 546974) of Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100 SC in maize. (Application rate 100 g as/ha)

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella***	***Lemna Gibba***
Endpoint (µg/L)		-	-	-	EyC50> 95000
AF		-	-	-	10
RAC (µg/L)		-	-	-	9500
Exposure	**PEC gl-max (µg/L)**				
Step 1 pH 5.1 and pH 6.5 and pH 7.9					
	1.07	-	-	-	1.13E-4

For the intended uses Maize , calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Mesotrione* as characterised by an ErC_{50} and E_bC_{50} for *L.gibba* of E_rC_{50}= 24.1µg/L and E_bC_{50}> 7.7µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

9.5.3 Overall conclusions

Basic on RAC=0.77µg/L from *L.gibba* study available in EFSA Journal 2016;14(3):4419 for the protection of aquatic organisms in intended use of product MEZI 100 SC following limitations are necessary to maintain :

- For Poland, Belgium, Czech Republic, Romania, Slovakia, Slovenia are necessary to maintain the 10 meters of vegetative buffer zone and 10 meters of no-spray zone for all pH values.
- For Austria, Hungary and Republic of Ireland, are necessary to reduce application rate from 100 g as/ha to 50 g as/ha, because PECsw/sed values in R3, R4 scenarios (relevant scenarios for these countries) and are necessary to maintain: 20 meters no-spray zone for uses in pH=5.1 and 20 meters vegetative buffer zone and 20 meters no-spray zone for uses in pH=7.9.

After redefinition of the risk assessment for aquatic organisms which based on the changing of the RAC values from RAC=0.77µg/L to RAC=2.41µg/L for the protection of aquatic organisms in intended use of product MEZI 100 SC are necessary to maintain: 10 meters vegetative buffer zone and 10 meters no-spray zone for uses in alkaline and acids soils.

The calculated PEC/RAC ratios for the Mesotrione metabolites indicate an acceptable risk for all groups of aquatic organism for the intended uses in Maize, based on FOCUS Step 1 PECSW calculations. No further assessment is necessary for the relevant metabolites of Mesotrione.

zRMS comments:

For the risk assessment in general the UE agreed endpoints for the active substance, its metabolites, formulation and the worst-case PECsw values were used.

Mesotrine

According to the EFSA aquatic guidance (2013): "*According to the data requirements, additional testing may be required by the Member State competent authorities on other macrophyte species depending on the mode of action of the substance, or if clear indications of higher toxicity are apparent to dicotyledonous (for example auxin inhibitor, broad leaf herbicides) or other monocotyledonous (e.g. grass herbicides) plant species from efficacy or testing with terrestrial non-target plants. Additional aquatic macrophyte species tests may be undertaken on a dicotyledonous species, such as Myriophyllum spicatum, Myriophyllum aquaticum or a monocotyledonous species, such as aquatic grass Glyceria maxima, as appropriate*." And "*Growth rate is the preferred endpoint to be used since it is more robust considering varying test conditions*."

In EFSA Journal 2016;14(3):4419, for aquatic macrophyte data only for *Lemna gibba* is available and the EU agreed endpoint is not based on growth rates.

The applicant provided results of two additional unprotected studies on toxicity of mesotrione to *Lemna gibba* (Hengsberger & Wydra, 2015) and *Myriophyllum spicatum* (Gonsior, 2017) These studies were assessed an accepted in Core dossier for Callisto 100 SC.

For aquatic macrophytes two approaches in the risk assessment were considered by the Applicant:
- based on the lowest ErC50, in line with EFSA aquatic guidance (2013),
- based on EbC50, EU agreed endpoint (EFSA Journal 2016;14(3):4419)

Taking into account the risk assessment based on EbC50 value for aquatic macrophytes, calculations performed with consideration of Tier 1 toxicity data were checked by the zRMS and considered acceptable. However, it should be noted that the use of EbC50 values is not in line with EFSA aquatic guidance (2013) and should be thus dealt with at the national level.

The PEC/RAC calculations at pH 6.5 for application rate 100 g a.s./ha and 50 g a.s./ha were omitted by Applicant. For completeness calculations are presented below:

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100SC in Maize (Application rate 100g as/ha, pH=6.5)

Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inverteb. pro-longed**	**Algae**	**Higher-plants**	**Higher-plants**
Test spe-cies		***Oncorhyn-chus mykiss***	***Pimephale s promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudo-kirchn. sub-capitata***	***Lemma gibba (the lowest ErC50 for aquatic macro-phyte)***	***Lemma gibba***
End-point (µg/L)		LC50>120 000	NOEC= 12500	EC_{50} >622 000	NOEC = 180 000	ErC50 = 13 000	ErC50 = 24.1	EbC50>7.7 *

AF		100	10	100	10	10	10	10
RAC (µg/L)		1200	1250	6220	1800	1300	2.41	0.77
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	33.08	0.03	0.03	0.01	0.02	0.03	**13.73**	**42,96**
Step 2								
N-Europe	4.39	-	-	-	-	-	**1.82**	**5.70**
Step 3								
D3/ditch	0.5249	-	-	-	-	-	0.22	0.07
D4/pond	0.02161	-	-	-	-	-	0.009	0.03
D4/stream	0.4506	-	-	-	-	-	0.19	0.56
D5/pond	0.0218	-	-	-	-	-	0.01	0.03
D5/stream	0.4716	-	-	-	-	-	0.22	0.61
D6/ditch	0.5259	-	-	-	-	-	0.22	0.68
R1/pond	0.05291	-	-	-	-	-	0.02	0.07
R1/stream	**1.130**	-	-	-	-	-	0.47	**1.47**
R2/stream	**2.445**	-	-	-	-	-	1.01	**3.18**
R3/stream	**4.216**	-	-	-	-	-	**1.75**	**5.48**
R4/stream	**4.259**	-	-	-	-	-	**1.77**	**5.53**
Step 4- 10 meters vegetative buffer zone and 10 meters no-spray buffer zone								
R1/stream	0.4638	-	-	-	-	-	-	0.60
R2/stream	**1.079**	-	-	-	-	-	**-**	**1.40**
R3/stream	**1.903**	-	-	-	-	-	0.79	**2.47**
R4/stream	**1.936**	-	-	-	-	-	0.80	**2.51**
	Step 4- 20 meters vegetative buffer zone and 20 meters no-spray buffer zone							
R2/stream	0.5585	-	-	-	-	-	-	0.73
R3/strea	**0.9957**	-	-	-	-	-	**-**	**1.29**

m								
R4/stream	**1.014**	-	-	-	-	-	**-**	**1.32**

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MEZI 100SC in Maize (Application rate= 50 g as/ha pH=6.5)

		Group						
		Fish acute	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher-plants**	**Higher-plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	**Lemma gibba *(the lowest ErC50 for aquatic macrophyte)***	**Lemma gibba**
Endpoint (µg/L)		LC50>120 000	NOEC= 12500	EC_{50} >622 000	NOEC = 180 000	ErC50 = 13 000	ErC50 = 24.1	EbC50>7.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		1200	1250	6220	1800	1300	2.41	0.77
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	16.03	0.01	0.01	0.00	0.01	0.01	**6.65**	**20.82**
Step 2								
N-Europe	2.19	-	-	-	-	-	0.91	**2.84**
Step 3								
D3/ditch	0.2626	-	-	-	-	-	-	0.34
D4/pond	0.01092	-	-	-	-	-	-	0.01
D4/stream	0.2257	-	-	-	-	-	-	0.29
D5/pond	0.01094	-	-	-	-	-	-	0.01
D5/stream	0.2361	-	-	-	-	-	-	0.31
D6/ditch	0.2629	-	-	-	-	-	-	0.34
R1/pond	0.02624	-	-	-	-	-	-	0.03
R1/stream	0.5668	-	-	-	-	-	-	0.74

R2/stream	**1.246**	-	-	-	-	-	-	**1.62**
R3/stream	**2.109**	-	-	-	-	-	-	**2.74**
R4/stream	**2.130**	-	-	-	-	-	-	**2.77**
	Step 4- none vegetative buffer zone and 10 meters no-spray buffer zone							
R2/stream	0.5500	-	-	-	-	-	-	0.71
R3/stream	**0.9522**	-	-	-	-	-	-	**1.24**
R4/stream	**0.9680**	-	-	-	-	-	-	**1.26**
	Step 4- none vegetative buffer zone and 20 meters no-spray buffer zone							
R3/stream	0.4984	-	-	-	-	-		0.65
R4/stream	0.5073	-	-	-	-	-		0.66

Based on the PEC/RAC calculations (with ErC50 accepted in the Core dossier for Callisto 100 SC) the risk to aquatic organisms is acceptable when:

for the application rate at 100 g a.s./ha:

- pH 5.1
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 pond, R1 stream and R2 stream (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R3 stream and R4 stream when 10 m VFS and 10 m buffer zone is applied;

- pH 6.5
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 pond, R1 stream and R2 stream(without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R3 stream and R4 stream when 10 m VFS and 10 m buffer zone is applied;

- pH 7.9
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 pond and R1 stream (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R2 stream, R3 stream and R4 stream when 10 m VFS and 10 m buffer zone is applied;

for the application rate at 50 g a.s./ha:

- pH 5.1, pH 6.5, 7.9
  - acceptable risk is demonstrated with FOCUS Step 2 PECsw values (without risk mitigation measures).

Based on the PEC/RAC calculations (with EbC50 EU agreed endpoint) the risk to aquatic organisms is acceptable when:

for the application rate at 100 g a.s./ha:

- pH 5.1
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch and R1 pond (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R1 stream when 10 m VFS and 10 m buffer zone is applied;
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R2 stream when 20 m VFS and 20 m buffer zone is applied;
  - no acceptable risk is demonstrates for R3 stream and R4 stream scenarios

- pH 6.5
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch and R1 pond, (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R1 stream when 10 m VFS and 10 m buffer zone is applied;
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R2 stream when 20 m VFS and 20 m buffer zone is applied;
  - no acceptable risk is demonstrates for R3 stream and R4 stream scenarios

- pH 7.9
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch and R1 pond (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R1 stream when 10 m VFS and 10 m buffer zone is applied;
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R2 stream when 20 m VFS and 20 m buffer zone is applied;
  - no acceptable risk is demonstrates for R3 stream and R4 stream scenarios

for the application rate at 50 g a.s./ha:

- pH 5.1
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 pond and R2 stream (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R1 stream and R3 stream when 10 m buffer zone is applied;
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R4 stream when 20 m VFS and 20 m buffer zone is applied;

- pH 6.5
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch and R1 pond and R1 stream (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R2 stream when 10 m buffer zone is applied;

- acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R3 stream and R4 stream when 20 m buffer zone is applied;

- pH 7.9
  - acceptable risk is demonstrated with FOCUS Step 3 PECsw values for scenarios D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 pond and R1 stream (without risk mitigation measures);
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R2 stream when 10 m VFS and 10 m buffer zone is applied;
  - acceptable risk is demonstrated with FOCUS Step 4 PECsw values for scenarios R3 stream and R4 stream when 20 m VFS and 20 m buffer zone is applied;

Metabolites of mesotrione
The risk assessment for metabolites MNBA, AMBA and SYN 5469774 was accepted using FOCUE Step 1 PECsw values.

Formulation MEZI 100 SC
Based on the acute toxicity studies performed with the formulation, *Lemna gibba* is the most sensitive species (ErC50 = 0.117 mg a.s./L).

The proposed mitigation measures considering the drift exposure was assessed by evaluator for application rate 100 g a.s./ha

PEC/RAC ratio for MEZI 100 SC considering exposure mitigation measures for the use in maize

		Fish acute	Inverteb. acute	Algae	Aquatic macrophyte (based on E_rC_{50})	Aquatic macrophyte (based on E_yC_{50})
RAC (µg/L)		710	490	>10000	11.7	2.69
buffer zone (m)	**PEC (µg/L)**	PEC/RAC	PEC/RAC	PEC/RAC	PEC/RAC	PEC/RAC
1	7.0543	0.01	0.01	<0.0010	0.60	**2.62**
5	1.9121	-	-	-	-	0.71

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

The PEC/RAC ratio for formulation, based on ErC50 value (in line with EFSA, 2013), is less than the trigger value of 1 when 5 m buffer zone is applied.

The PEC/RAC ratio for formulation, based on EyC50 value (not in line with EFSA, 2013), is less than the trigger value of 1 when 5 m buffer zone is applied.

Conclusion
According to the performed risk assessment there is no potential of risk for aquatic organisms resulting from acute and long-term exposure to active substance following use of MEZI 100 SC in compliance with proposed GAP when the appropriate risk mitigation measures were applied.

The risk mitigation measures should be considered on the national level.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Mesotrione. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of MEZI 100 SC were not evaluated as part of the EU assessment of Mesotrione, New data submitted with this application are listed in Błąd: nie znaleziono źródła odwołania and summarised in Appendix 2.

Table 9.6-12: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Mesotrione	48h Oral	LD50 >11 µg a.s./bee	EFSA Journal 2016;14(3):4419
Apis mellifera	Mesotrione	48h Contact	LD50 >100 µg a.s./bee	EFSA Journal 2016;14(3):4419
Apis mellifera	Mesotrione (formulated as A12739A)	Semi-chronic larval toxicity (7 day study)	LD50 = 118.5 µg a.s./larva NOED = 57.8 µg a.s./larva	EFSA Journal 2016;14(3):4419
Apis mellifera	Mesotrione (formulated as A12739A)	Chronic adult toxicity (10 days)	LD50 = 19.2 µg a.s./bee/day NOED = 8.1 µg a.s./bee/day	EFSA Journal 2016;14(3):4419
Apis mellifera	MEZI 100 SC	Chronic oral	LDD50>10.06 µg of the test item/ bee/day] NOEDD= 45.44 µg of the test item/ bee/day]	Zaworska K., 2023 Study code: 0038/0178/E
Apis mellifera	MEZI 100 SC	Semi-chronic larval toxicity (4 days study)	LD50 >100.00 [µg of test item/larva] NOED ≥100.00 [µg of test item/larva]	Woźniak A., 2023 Study code: 0038/0176/E
Apis mellifera	Callisto 100 SC (A12739A)	Acute Oral	LD50=79.7 µg a.s./bee (equivalent to 877.4 µg A12739A /bee)* NOED = 25.0 µg a.s./bee	EFSA Journal 2016;14(3):4419
Apis mellifera	Callisto 100 SC (A12739A)	Acute Contact	LD50=52.5 µg a.s./bee (equivalent to 578.2 µg A12739A /bee)	EFSA Journal 2016;14(3):4419

Species	Substance	Exposure System	Results	Reference
			NOED = 32.4 µg a.s./bee	
Bumblebee	Callisto 100 SC (A12739A)	Acute Oral	LD50=87.74 µg A12739A /bee	Extrapolated from bee study and divide by factor 10 as a worst case
Bumblebee	Callisto 100 SC (A12739A)	Acute Contact	LD50= 57.82 µg A12739A /bee	Extrapolated from bee study and divide by factor 10 as a worst case
Higher-tier studies (tunnel test, field studies)				
Not relevant				

* As uncertainties were noted around this endpoint (poor fitting of the oral 48-hour mortality data curve) the lower limit of the 95% confidence interval (42.86 µg a.s./bee) was used for the risk assessment reported below.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

9.6.2.1 Hazard quotients for bees

Table 9.6-13: First-tier assessment of the risk for bees due to the use of MEZI 100 SC in Maize (use/use group)

Intended use	Maize		
Active substance	Mesotrione		
Application rate (g as/ha)	1x100 g as/ha		
Test design	**LD_{50} (lab.) (µg as /bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	11	100	9.09
Contact toxicity	100		1
Intended use	Maize		
Active substance	Callisto 100 SC		
Application rate (g/ha)	1x1098 g/ha		
Test design	**LD_{50} (lab.) (µg formulation/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	877.4	1098	1.25
Contact toxicity	578.2		1.9

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

Screening step and first-tier assessment of the chronic risk for bees and assessment for honey bees larvae due to the use of MEZI 100 SC.

This assessment was done by Bee Tool v.3.

a) Screening step

Table 9.6-2: Screening step assessment of the chronic risk for bees and assessment for honey bees larvae due to the use of MEZI 100 SC in Maize.

Intended uses **Product** **Application rate (g product/ha)**	Maize MEZI 100 SC 1x 1098			
Test design	**Endpoints (µg/bee/d or µg/larva)**	**Ef x SV**	**ETR**	**Trigger**
Chronic oral toxicity	NOEDD= 45.44 µg of the test item/ bee/day]	7.6	**0.184**	0.03
Larvae toxicity	NOED ≥100.00 [µg of test item/larva]	4.4	0.05	0.2

The calculated ETR values of honey bees larvae is lower than the trigger values of 0.2, therefore Tier 1 assessment is not required.

The calculated ETR values of chronic oral toxicity for adult bees is higher than the trigger values of 0.03,therefore Tier 1 assessment is required and provided below.

b) First Tier assessment

Table 9.6-3: First Tier assessment of the chronic oral risk for bees due to the use of in maize.

Intended use **Product** **Application rate (g product/ha)**	Maize MEZI 100 SC 1x1098					
Test design	**Scenario/BBCH**	**Shortcut Value (downward spray)**	**TWA**	**fDep/ Ef**	**ETR**	**Trigger**
Chronic oral toxicity NOEDD= 45.44 µg of the test item/ bee/day]	treated crop/BBCH 10-29	0.92	0.72	1	0.016	<0.03
	weeds/BBCH 10-29	2.9	0.72	1	**0.050**	
	field margin/BBCH 10-29	2.9	0.72	0.0092	0.000	
	adjacent crop/ BBCH 10-29	5.8	0.72	0.0033	0.000	

	next crop/ BBCH 10-29	0.54	0.72	1	0.009	

The calculated ETR value of chronic oral toxicity for adult bees for treated crop, field margin, adjacent crop, next crop scenario are lower than the trigger value of 0.03, so it pose acceptable risk to bees following application of at the proposed label rate.

The calculated ETR value of chronic oral toxicity for adult bees for weeds scenario is higher than the trigger values of 0.03, so it pose unacceptable risk to bees following application of MEZI 100 SC at the proposed label rate.

Table 9.6-4 : Uses not passing the 1st oral tier risk assessment of MEZI 100 SC.

Crop group	Scenario/BBCH	Max. single application rate [kg prod/ha]	ETR values	Trigger value
Maize	weeds/BBCH 10-29	1.089	**0.050**	<0.03

c) Risk refinements

Considering that MEZI 100 SC is intended to be used just after weed emergence there is acceptable chronic risk to bees, because MEZI 100 SC has herbicidal properties and it eliminate weeds before flowering period.

According to residue decline study by Allen 2019 after application of the product A12738A the residues of Mesotrione in clover were determinated.
In this study samples were collected at <1, 8 ,24,32,48 hours and 3,4,7 after application A12738A on a plants. Samples were collected also from untreated field at 0 days before application.
As time passed after application, the content of Mesotrione residues in clover decreased. No Mesotrione residues were detected at or above the limit of quantification (LOQ: 0.01 mg/kg) in any of the untreated whole-plant clover samples collected in this study. The obtained residue results made it possible to determine the DT50 value for Mesotrione. The geomean DT 50 value for Mesotrione determined in this study is 2.19 days. Over time, the concentration of Mesotrione residue decreased, which indicates the Mesotrione has quick degradation and the low content of residues of this substance in plants. This indicates that after application of A12738A, there is acceptable chronic risk to bees that will forage on plants sprayed with this product.

Conclusion:

According to Central zone MEZI 100 SC pose acceptable risk for bees in application rate:

- 1x 1.0 L prod/ha at BBCH 14-15 for maize

According to Polish national requirements MEZI 100 SC pose acceptable risk for bees in application rate:

- 1x 1.0 L prod/ha at BBCH 14-15 for maize

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Table 9.6 4: First-tier assessment of the acute risk for bumblebee due to the use of MEZI 100SC in Maize.

Intended use	Maize		
Product	Callisto 100 SC		
Application rate (g/ha)	1x1098 g/ha		
Test design	**LD_{50} (lab.) (µg formulation/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	87.74	1098	12.51
Contact toxicity	57.82		18.99

9.6.4 Effects on solitary bees

No data or information is currently available for solitary bees.

9.6.5 Overall conclusions

MEZI 100 SC no pose any unacceptable risk for bees according to label.

zRMS Comments:

The submitted risk assessment is based on the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) and new EU guidance (2013).
The EU agreed endpoints for active substance were used in risk assessment. The acute toxicity data for mesotrione and Callisto (A12739A) are in line with EU agreed endpoints reported in EFSA Journal 2016;14(3):4419.
In addition to that, the Applicant submitted studies on chronic toxicity of formulation MEZI 100 SC to adult bees and larvae. New studies were accepted. Therefore, the requirements set out in Regulation 284/2013 are considered fulfilled.

The acute risk assessment performed in accordance with the SANCO guidance presented by the Applicant was accepted.

There is currently no EU agreed chronic risk assessment scheme for bees. However, as agreed in the Central Zone a risk assessment based on the EFSA bee GD is presented below for illustrative purposes.

Effects on bumblebees and solitary bees
No data with the active substances or the formulated product is available.

An acceptable risk to bees of the formulation MEZI 100 SC can be concluded, based on the risk assessment scheme of the Guidance Document on Terrestrial Eco-toxicology (SANCO/10329/2002 rev 2).

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Mesotrione Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of MEZI 100 SC were not evaluated as part of the EU assessment of Mesotrione .

Table 9.7-14: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	Callisto 100 SC	Laboratory test glass plates (2D)	LR50 = 93.11 g a.s./ha ER50 >81 g a.s./ha	EFSA Journal 2016;14(3):4419
Aphidius rhopalosiphi (adults)	Callisto 100 SC	Laboratory test glass plates (2D)	LR50 = 43.56 g a.s./ha ER50 >25.6 g a.s./ha	EFSA Journal 2016;14(3):4419
Typhlodromus pyri (protonymphs)	Callisto 100 SC	Extended laboratory test maize leaves (2D)	LR50 >300 g a.s./ha ER50 >150 g a.s./ha	EFSA Journal 2016;14(3):4419
Aphidius rhopalosiphi (adults)	Callisto 100 SC	Extended laboratory test barley leaves (3D)	LR50 >225 g a.s./ha ER50 >225 g a.s./ha	EFSA Journal 2016;14(3):4419
Aleochara bilineata (adults)	Callisto 100 SC	Extended laboratory test sand (2D)	ER50 >200 g a.s./ha	EFSA Journal 2016;14(3):4419
Pardosa sp. (adults)	Callisto 100 SC	Extended laboratory test soil (2D)	LR50 >150 g a.s./ha ER50 >150 g a.s./ha	EFSA Journal 2016;14(3):4419
Field or semi-field tests				

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

Table 9.7-15: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of MEZI 100 SC in Maize

Intended use	Maize
Active substance/product	MEZI 100 SC
Application rate (g/ha)	1x100g

MAF	1		
Test species Tier I	**ER_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>81 g a.s./ha	100	1.23
Aphidius rhopalosiphi	>25.6 g a.s./ha		**3.91**
Test species Tier II	**ER_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 1**
Typhlodromus pyri	>150 g a.s./ha	100	0.67
Aphidius rhopalosiphi	>225 g a.s./ha		0.44
Aleochara bilineata	>200 g a.s./ha		0.5
Pardosa sp.	>150 g a.s./ha		0.67

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-16: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of MEZI 100 SC in Maize

Intended use	Maize				
Active substance/product	Mesotrione				
Application rate (g/ha)	1 × 100				
MAF	1				
vdf	10 (Tier 1)				
Test species Tier I	**ER_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>81 g a.s./ha	0.0277	0.277	~~5~~ 10	~~0.02~~ 0.03
Aphidius rhopalosiphi	>25.6 g a.s./ha				~~0.01~~ 0.1
Intended use	Maize				
Active substance/product	Mesotrione				
Application rate (g/ha)	1 × 100				
MAF	1				
vdf	1 (Tier 2)				
Test species Tier II	**ER_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 1**
Typhlodromus pyri	>150 g a.s./ha	0.0277	2.77	5	~~0.02~~ 0.09
Aphidius rhopalosiphi	>225 g a.s./ha				~~0.01~~ 0.06

Aleochara bilineata	>200 g a.s./ha				~~0.01~~ 0.07
Pardosa sp.	>150 g a.s./ha				~~0.02~~ 0.09

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

All hazard quotients (HQ) are considerably less than trigger values, indicating that MEZI 100 SC applied at the maximum use rate poses no risk to non-target arthropods. No risk mitigation needed.

zRMS Comments:
The submitted risk assessment based on the "Guidance Document on Terrestrial Ecotoxicology" (2002) was accepted.

As Plant Protection Product MEZI 100 SC (Product name(s): Rumezo Twist 100 SC, Malton Twist 100 SC is chemically equivalent to CALLISTO 100 SC (product code A12739A) therefore data on the formulation Callisto 100 SC (representative formulation of the latest EU evaluation of the active substance mesotrione) were considered at Tier-1 and Tier-2 level by the applicant.

Acceptable risk may be concluded for in-field and of-field populations of non-target arthropods from the intended uses of Callisto.

Conclusion
The risk to arthropods other than bees is acceptable if the MEZI 100 SC is applied in accordance with proposed use pattern.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with active substance 1 and its relevant metabolites. Full details of these studies are provided in the respective EU DAR.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of MEZI 100 SC were not evaluated as part of the EU assessment of Mesotrione.

Table 9.8-17: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Mesotrione (formulated as A12739A)	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 10.85 mg a.s./kg dw * NOECcorr= 5.425 mg as/kg dw EC_{10} = 5.91 mg a.s./kg dw	EFSA Journal 2016;14(3):4419
Eisenia fetida	MNBA	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 1050 mg/kg dw EC_{10} >1050 mg/kg dw	EFSA Journal 2016;14(3):4419
Eisenia fetida	AMBA	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 1050 mg/kg dw EC_{10} >1050 mg/kg dw	EFSA Journal 2016;14(3):4419
Folsomia candida	Mesotrione (formulated as A12739A)	Mixed into substrate 28 db, chronic 5 % peat content	NOEC = 50.54 mg a.s./kg dw* NOECcorr=25.25 mg as/ kg dw EC_{10} = 37.5 mg a.s./kg dw	EFSA Journal 2016;14(3):4419
Folsomia candida	MNBA	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 100 mg/kg dw	Dickinson, 2015 CA3511_10011
Hypoaspis aculeifer	Mesotrione (formulated as A12739A)	Mixed into substrate 14 dc, chronic 5 % peat content	NOEC = 90.9 mg a.s./kg dw* NOECcorr= 45.45 mg as/kg dw EC_{10} > 1000 mg A12739A /kg d.w. soil	EFSA Journal 2016;14(3):4419
Hypoaspis aculeifer	MNBA	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 1050 mg/kg dw EC_{10} could not be calculated	Ramsden, 2015 CA3511_10010
Field studies				
Litter bag test				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for Mesotrione.

Table 9.8-18: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of MEZI 100 SC in Maize

Intended use	Maize		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required			
Not required			
Chronic effects on earthworms			
Product/active substance	**NOEC/EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Mesotrione	~~5.425~~ 5.91	0.1334	~~40.67~~ 44.30
MNBA	1050	~~0.0175~~ 0.0550*	~~60000~~ 19091
AMBA	1050	~~0.0073~~ 0.0081*	~~143835,6~~ 129630
Chronic effects on other soil macro- and mesofauna *(Folsomia)*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Mesotrione	~~25.25~~ 37.5	0.1334	~~189.28~~ 281.11
MNBA	100	~~0.0175~~ 0.0550*	~~5714,29~~ 1818.18
AMBA	3.75	0.0081	463
Chronic effects on other soil macro- and mesofauna *(Hypoaspis)*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Mesotrione	~~45.45~~ 90.9	0.1334	~~340.70~~ 681

MNBA	1050	~~0.0175~~ 0.0550*	~~60000~~ 19091
AMBA	9.09	0.0081	1122

TER values shown in bold fall below the relevant trigger.
*Correction according to Part B8

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

MEZI 100 SC pose no unacceptable risk to non-target soil meso- and macrofauna.

zRMS comments:
For the risk assessment the EU agreed endpoints were used.

Additional the Applicant provided results of unprotected studies on toxicity of metabolite MNBA to *Folsomia candida* and *Hypoaspis aculeifer*. These studies were assessed and accepted in Core dossier for Callisto 100 SC and their results were consider in the risk assessment.

No additional studies on toxicity of metabolite AMBA to *Folsomia candida* and *Hypoaspis aculeifer* were provided. Therefore the risk assessment should be performed with the assumption that this metabolite is 10 times more toxic than the parent.

The lower of NOEC and EC_{10} value should be used in the risk assessment.

All TER values are above trigger value of 5.

Conclusion:
According to the performed risk assessment there is low chronic risk to earthworms and other non-target organisms resulting from long-term exposure to active substances following use of MEZI 100 SC in compliance with proposed GAP.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with MEZI 100 SC and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of MEZI 100 SC were not evaluated as part of the EU assessment of Mesotrione.

Table 9.9-19: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Mesotrione (tested as formulation A12739A)	28 d, aerobic soil type	Nitrate formation rate 5.84 mg A12739A/kg soil dw 7.8 % (< 25 % effect at up to 0.53 mg a.s./kg soil dw)	EFSA Journal 2016;14(3):4419
N-mineralisation	MNBA	28 d, aerobic soil type	Nitrate formation rate 1.13 mg/kg soil dw - 7.6 % (< 25 % effect at up to 1.13 mg/kg soil dw)	EFSA Journal 2016;14(3):4419
N-mineralisation	AMBA	28 d, aerobic soil type	Nitrate formation rate 1.13 mg/kg soil dw - 4.8 % (< 25 % effect at up to 1.13 mg/kg soil dw)	EFSA Journal 2016;14(3):4419

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Table 9.9-20: Assessment of the risk for effects on soil micro-organisms due to the use of MEZI 100 SC in Maize

Intended use	Maize BBCH 14-15		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Mesotrione	0.53 mg a.s./kg soil dw (at 28 d)	0.1334	yes
MNBA	1.13 mg/kg soil dw (at 28 d)	~~0.0175~~ 0.0550*	yes
AMBA	1.13 mg/kg soil dw (at 28 d)	~~0.0073~~ 0.0081*	yes
*Correction according to Part B8			

9.9.3 Overall conclusions

Risk assessments for effect on soil microorganisms due to the use of MEZI 100 SC in Maize is acceptable for active substance: Mesotrione and metabolites: MNBA, AMBA because PEC soil values are below max concentration with effects.

zRMS comments:
For the risk assessment the EU agreed endpoints were used.

Conclusion:
According to the performed risk assessment there is low risk to soil microorganisms resulting from exposure to active substances following use of MEZI 100 SC in compliance with proposed GAP.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Mesotrione. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target terrestrial plants of MEZI 100 SC were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

Table 9.10-21: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Pea *Pisum sativum*	MEZI 100 SC	21 d Seedling emergence	ER50 (Emergence of plants)> 1000.00 ER50 (Survival of plant)> 1000.00 ER50 (Shoot length)=603.85 ER50 (Shoot dry weight)=617.37 ER50 (Plant damage)=193.00	Czarnynoga M.,(2023) Study code; G-51-23

Species	Substance	Exposure System	Results	Reference
Pea *Pisum sativum*	MEZI 100 SC	21 d Vegetative vigour	ER50 (Plant number at the end of the ex-periment)> 1000.00 ER50 (Shoot length)=85.21 ER50 (Shoot dry weight)=59.90 ER50 (Plant damage)=17.35	Czarnynoga M.,(2023) Study code; G-50-23
Sunflower *Helianthus annuus*	MEZI 100 SC	21 d Seedling emergence	ER50 (Emergence of plants)> 1000.00 ER50 (Survival of plant)> 1000.00 ER50 (Shoot length)>1000.00 ER50 (Shoot dry weight)>1000.00 ER50 (Plant damage)=413.64	Czarnynoga M.,(2023) Study code; G-51-23
Sunflower *Helianthus annuus*	MEZI 100 SC	21 d Vegetative vigour	ER50 (Emergence of plants)> 1000.00 ER50 (Shoot length)=99.83 ER50 (Shoot dry weight)=24.9 ER50 (Plant damage)=23.65	Czarnynoga M.,(2023) Study code; G-50-23
Lettuce *Lactuca sativa*	MEZI 100 SC	21 d Seedling emergence	ER50 (Emergence of plants)> 1000.00 ER50 (Survival of plant)> 204.77 ER50 (Shoot length)=74.95 ER50 (Shoot dry weight)=72.16 ER50 (Plant	Czarnynoga M.,(2023) Study code; G-51-23

Species	Substance	Exposure System	Results	Reference
			damage)=34.84	
Lettuce *Lactuca sativa*	MEZI 100 SC	21 d Vegetative vigour	ER50 (Plant number at the end of the experiment)=42.43 ER50 (Shoot length)=10.31 ER50 (Shoot dry weight)=3.49 ER50 (Plant damage)=11.04	Czarnynoga M.,(2023) Study code; G-50-23
Flax Linum usitatissimum	MEZI 100 SC	21 d Seedling emergence	ER50 (Emergence of plants)> 1000.00 ER50 (Survival of plant)> 1000.00 ER50 (Shoot length)>1000.00 ER50 (Shoot dry weight)=736.44 ER50 (Plant damage)=752.31	Czarnynoga M.,(2023) Study code; G-51-23
Flax Linum usitatissimum	MEZI 100 SC	21 d Vegetative vigour	ER50 (Plant number at the end of the experiment)> 1000.00 ER50 (Shoot length)>1000.00 ER50 (Shoot dry weight)=516.99 ER50 (Plant damage)=~~11.04~~ 957.50	Czarnynoga M.,(2023) Study code; G-50-23
Carrot Daucus carota	MEZI 100 SC	21 d Seedling emergence	ER50 (Emergence of plants)> 1000.00 ER50 (Survival of plant)=204.56 ER50 (Shoot length)=303.64 ER50 (Shoot dry weight)=76.58	Czarnynoga M.,(2023) Study code; G-51-23

Species	Substance	Exposure System	Results	Reference
			ER50 (Plant damage)=67.94	
Carrot Daucus carota	MEZI 100 SC	21 d Vegetative vigour	ER50 (Plant number at the end of the ex-periment)> 1000.00 ER50 (Shoot length)=568.22 ER50 (Shoot dry weight)=46.76 ER50 (Plant damage)=89.55	Czarnynoga M.,(2023) Study code; G-50-23
Oats Avena sativa	MEZI 100 SC	21 d Seedling emergence	ER50 (Emergence of plants)> 1000.00 ER50 (Survival of plant)> 1000.00 ER50 (Shoot length)>1000.00 ER50 (Shoot dry weight)>1000.00 ER50 (Plant damage)>1000.00	Czarnynoga M.,(2023) Study code; G-51-23
Oats Avena sativa	MEZI 100 SC	21 d Vegetative vigour	ER50 (Plant number at the end of the ex-periment)> 1000.00 ER50 (Shoot length)>1000.00 ER50 (Shoot dry weight)>1000.00 ER50 (Plant damage)>1000.00	Czarnynoga M.,(2023) Study code; G-50-23
Perennial ryegrass *Lolium perenne*	MEZI 100 SC	21 d Seedling emergence	ER50 (Emergence of plants)> 1000.00 ER50 (Survival of plant)> 1000.00 ER50 (Shoot length)>1000.00 ER50 (Shoot dry weight)>1000.00	Czarnynoga M.,(2023) Study code; G-51-23

Species	Substance	Exposure System	Results	Reference
			ER50 (Plant damage)>1000.00	
Perennial ryegrass Lolium perenne	MEZI 100 SC	21 d Vegetative vigour	ER50 (Emergence of plants)> 1000.00 ER50 (Shoot length)>1000.00 ER50 (Shoot dry weight)>1000.00 ER50 (Plant damage)>1000.00	Czarnynoga M.,(2023) Study code; G-50-23

m: monocotyledonous; d: dicotyledonous

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.
~~To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for non-target terrestrial plants from all other intended uses in groups~~ xxx (see 9.1.2).

Table 9.10-22: Assessment of the risk for non-target plants due to the use of MEZI 100 SC in Maize, based on study: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test

Intended use	Maize			
Product	MEZI 100 SC			
Application rate (g/ha)	1098 g/ha			
MAF	1			
Test species	**ER_{50} (ml test item/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**

Pea *Pisum sativum*	193.00 ml of test item /ha which is equivalent to 211.91g/ha	0.0277	30.41	~~6.35~~ 6.97
Sunflower Helianthus annuus	413.64 ml of test item /ha which is equivalent to 454.18g/ha	0.0277	30.41	14.94
Lettuce Lactuca sativa	34.84 ml of test item /ha which is equivalent to 38.25g/ha	0.0277	30.41	**1.26**
Flax Linum usitatissimum	736.44 ml of test item /ha which is equivalent to 808.61	0.0277	30.41	26.59
Carrot Daucus carota	67.94 ml of test item /ha which is equivalent to 74.6	0.0277	30.41	**2.45**
Oats Avena sativa	1000.00 ml of test item /ha which is equivalent to 1098g/ha	0.0277	30.41	36.1
Perennial ryegrass Lolium perenne	1000.00 ml of test item /ha which is equivalent to 1098g/ha	0.0277	30.41	36.1

Table 9.10-3: Assessment of the risk for non-target plants due to the use of MEZI 100 SC in Maize, based on study: Terrestrial Plant Test: Vegetative vigour test

Intended use	Maize
Product	MEZI 100 SC
Application rate (g/ha)	1098 g/ha
MAF	1

Test species	**ER_{50} (ml test item/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Pea *Pisum sativum*	17.35 ml of test item /ha which is equivalent to 19.05g/ha	0.0277	30.41	**0.63**
Sunflower Helianthus annuus	23.65 ml of test item /ha which is equivalent to 25.97g/ha	0.0277	30.41	**0.85**
Lettuce Lactuca sativa	3.49 ml of test item /ha which is equivalent to 3.83 g/ha	0.0277	30.41	**0.13**
Flax Linum usitatissimum	516.99 ml of test item /ha which is equivalent to 567.66	0.0277	30.41	~~18.96~~ 18.67

Carrot Daucus carota	46.76 ml of test item /ha which is equivalent to 51.34	0.0277	30.41	**1.69**
Oats Avena sativa	1000.00 ml of test item /ha which is equivalent to 1098g/ha	0.0277	30.41	36.11
Perennial ryegrass Lolium perenne	1000.00 ml of test item /ha which is equivalent to 1098g/ha	0.0277	30.41	36.11

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5, 10, 15, 20, 30, 40 or ~~1~~50 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.10-23: Risk assessment for non-target terrestrial plants due to the use of formulation in crop (use/use group) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Maize			
Product		MEZI 100 SC			
Application rate (g/ha)		1x1098 (g/ha)			
MAF		1			
Buffer strip (m)	**Drift rate**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	0.0277	30.41	15.2	~~22.8~~ 7.60	~~27.36~~ 3.041
5	0.0057	6.26	3.13	1.56	0.626
10	0.0029	3.18	1.59	0.795	0.318
15	0.002	2.196			
20	0.0015	1.647			
30	0.001	1.098			
40	0.0007	0.7686			
50	0.0006	0.6588			

Toxicity value **Test species** **ER_{50}** **Criterion:**		TER=0.13 Lettuce *Lactuca sativa* 3.83-g test item/ha (the most sensitive endpoint) TER ≥ 5			
Buffer strip (m)	**Drift rate**	**TER**	**TER 50 % drift red.**	**TER 75% drift red.**	**TER 90 % drift red.**
1	0.0277	0.13	0.25	~~0.17~~ 0.50	~~0.14~~ 1.26
5	0.0057	0.612	1.22	2.45	**6.02**
10	0.0029	1.2	2.41	4.82	**12.04**
15	0.002	1.74			
20	0.0015	2.325			
30	0.001	3.49			
40	0.0007	4.99			
50	0.0006	5.81			

9.10.3 Overall conclusions

MEZI 100 SC pose a unacceptable risk for non-target terrestrial plants according to label. This product can be used on non-target terrestrial plants only with 50m buffer strip or 5m buffer strip and 90% nozzle reduction.

zRMS comments:
The risk assessment for non-target terrestrial plants was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The risk assessment was based on the results of studies for formulation presented in Appendix 2 (vegetative vigour and on seedling emergence). Lettuce was the most sensitive species in both tests.

The TER is above the trigger value of 5 when 50 m buffer strip or 5 m buffer strip and 90% drift reduction is applied.

Conclusion:
According to the performed risk assessment there is low risk to non-target terrestrial plants resulting from exposure to active substances following use of MEZI 100 SC in compliance with proposed GAP when:

- 50 m buffer strip or
- 5 m buffer strip and 90% drift reduction is applied.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Tests on other terrestrial species are not required.

9.12 Monitoring data (KCP 10.8)

There are no other relevant data for the active substance or product on organisms in the environment generated from monitoring schemes

9.13 Classification and Labelling

Based upon all the available aquatic endpoints for A12739A, the proposed classification and labelling of MEZI 100 SC is driven by effects on *Lemna* (E_rC_{50} = 0.117 mg A12739A/L for the acute classification, and the *Lemna* NOEC = 0.0114 mg A12739A/L for the chronic classification).

Acute Category 1

H400 'Very toxic to aquatic life'

Chronic Category 1

H410 'Very toxic to aquatic life with long lasting effects'

Hazard pictograms:	GHS09
Signal word:	Warning
Hazard statement(s):	H410 - Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P391: Collect spillage P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.3.1	Zaworska K	2023	Honey bee, chronic oral toxicity test of test item MEZI 100 SC Study code: 0038/0178/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Chemirol
KCP 10.3.1	Woźniak A.	2023	Honey bee larval toxicity test following repeated exposure of the test item MEZI 100 SC Study code: 0038/0176/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Chemirol
KCP 10.6.2	Czarnynoga M.	2023	MEZI 100 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-51-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group GLP Unpublished	N	Chemirol

List of data submitted by the applicant and relied on, but evaluated before in Callisto 100 SC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.1.2.2	North L.	2016	Mesotrione - Foliage Decline with A12739A on Maize in Northern France and the United Kingdom in 2015 Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services Ltd, Wilson, UK, S15-02057 GLP not published Syngenta File No A12739A_11065	N	SYN
KCP 10.1.2.2	Grimm T & Katzschner I	2019	Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, Germany Report No. R1740045 GLP, Unpublished Syngenta File No. NA_14950	N	SYN
KCP 10.1.2.2	Allen L.	2019	Mesotrione – Mesotrione – Foliage Decline Study on Clover in Hungary, Germany, United Kingdom, Northern France and Belgium in 2018. CEMAS, Imperial House, Oaklands Park, Wokingham, Berkshire, RG41 2FD, , UK Report No. CEMR-8397 GLP, Unpublished Syngenta File No. A12738A_10535	N	SYN
KCP 10.1.2.2	Murfitt R., Foudoulakis M., Ebeling M., Guth K., Brugger K.	2015	Measured residues on maize foliage for use in bird and mammal risk assessment' Syngenta, Bracknell, UK; and others. Poster presented at SETAC Barcelona, 2015 Not GLP published	N	-
KCP 10.2.	Hengsberger A., Wydra V. (report amendment 2; Kosak L., Wydra V.)	2015 (amend. 2 2016)	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a semi-static growth inhibition test with a subsequent recovery period Syngenta Crop Protection AG, Basel, Switzerland IBACON GmbH, Rossdorf, Germany, 105732240 GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			not published Syngenta File No ZA1296_10438		
KCP 10.2.	Gonsior G.	2017	Mesotrione - Growth inhibition of Myriophyllum spicatum in a water/sediment system Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S16-06273 GLP not published Syngenta File No ZA1296_10504	N	SYN
KCP 10.4.2.1	Dickinson R.	2015	R169649 - Collembola (Folsomia candida) Reproduction Test in Soil Syngenta Crop Protection AG, Basel, Switzerland AgroChemex Ltd, Manningtree, United Kingdom, ENV-14-015 GLP not published Syngenta File No CA3511_10011	N	SYN
KCP 10.4.2.1	Ramsden C.	2015	R169649 - Predatory Mite (Hypoaspis (Geolaelaps) aculeifer) Reproduction Test in Soil Syngenta Crop Protection AG, Basel, Switzerland AgroChemex Ltd, Manningtree, United Kingdom, ENV-14-012 GLP not published Syngenta File No CA3511_10010	N	SYN

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.1.2.2	Funkenhaus A, Giessing B	2010	Exposure of mammals in maize fields in France - Attractiveness of maize fields and relevant species Syngenta - Jealott's Hill, Bracknell, United Kingdom Rifcon, Heidelberg, Germany, R09012-2 GLP not published Syngenta File No NA_11991	N	SYN
KCP 10.1.2.2	[redacted]	2005	Generic field monitoring of birds and mammals on maize and beet fields in Austria [redacted] GLP not published [redacted]	Y	BCS (SYN access)
KCP 10.1.2.2	[redacted]	2014	Generic field study on small mammals - focal species and wood mouse (Apodemus sylvaticus) PT in maize fields in Germany [redacted] GLP not published [redacted]	Y	OXN (SYN access)
KCP 7.1.1	[redacted]	2005	Mesotrione 100 G/L SC Formulation (A12739A): Acute Oral Toxicity Study in the Rat (Up and Down Procedure) xxxxxxxxxxx GLP not published [redacted]	Y	SYN
KCP 10.2	[redacted]	2005	Mesotrione 100 g/L SC formulation (A12739A): Acute toxicity to carp (Cyprinus carpio) [redacted] GLP not published [redacted]	~~N~~Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.2	Ricketts D., Langridge G.	2005	Mesotrione 100 g/L SC (A12739A): Acute toxicity to the Cladoceran Daphnia magna under static conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3714B GLP not published Syngenta File No ZA1296/2042	N	SYN
KCP 10.2	Volz E.	2005	Mesotrione 100 SC Formulation (A12739A): Toxicity to Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum) in a 96-hour algal growth inhibition test Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, A18325 GLP not published Syngenta File No ZA1296/2049	N	SYN
KCP 10.2	Zawadsky C.	2013	Mesotrione SC (A12739A) - Assessment of Toxic Effects on the duckweed Lemna gibba in a 7 day Semi-Static Test and 14 day Recovery Period Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S12-03986 GLP not published Syngenta File No A12739A_10273	N	SYN
KCP 10.3.1	Kleebaum K.	2013	Mesotrione SC (A12739A) - Semi-chronic toxicity to the honeybee larvae Apis mellifera L. under laboratory conditions (in vitro) Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 073 B GLP not published Syngenta File No A12739A_10464	N	SYN
KCP 10.3.1	Kleebaum K.	2013a	Mesotrione SC (A12739A) - Chronic toxicity to the honeybee Apis mellifera L. in a 10 day continuous laboratory feeding study Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 074 B	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP not published Syngenta File No A12739A_10465		
KCP 10.2	Ricketts D., Langridge G.	2005	Mesotrione 100 g/L SC (A12739A): Acute toxicity to the Cladoceran Daphnia magna under static conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3714B GLP not published Syngenta File No ZA1296/2042	N	SYN
KCP 10.2	Volz E.	2005	Mesotrione 100 SC Formulation (A12739A): Toxicity to Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum) in a 96-hour algal growth inhibition test Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, A18325 GLP not published Syngenta File No ZA1296/2049	N	SYN
KCP 10.2	Zawadsky C.	2013	Mesotrione SC (A12739A) - Assessment of Toxic Effects on the duckweed Lemna gibba in a 7 day Semi-Static Test and 14 day Recovery Period Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S12-03986 GLP not published Syngenta File No A12739A_10273	N	SYN
KCP 10.3.1	Kleebaum K.	2013	Mesotrione SC (A12739A) - Semi-chronic toxicity to the honeybee larvae Apis mellifera L. under laboratory conditions (in vitro) Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 073 B GLP not published Syngenta File No A12739A_10464	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.3.1	Kleebaum K.	2013a	Mesotrione SC (A12739A) - Chronic toxicity to the honeybee Apis mellifera L. in a 10 day continuous laboratory feeding study Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 074 B GLP not published Syngenta File No A12739A_10465	N	SYN
KCP 10.3.1	Franke M.	2013	Mesotrione SC (A12739A) - Acute toxicity to the honeybee Apis mellifera L. under laboratory conditions Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 001 B GLP not published Syngenta File No A12739A_10015	N	SYN
KCP 10.3.2	Fallowfield L.	2012	Mesotrione SC (A12739A) - A rate-response laboratory bioassay of the effects of fresh residues on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-41 GLP not published Syngenta File No A12739A_10010	N	SYN
KCP 10.3.2	Stevens J.	2012	Mesotrione SC (A12739A) - A rate-response laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-42 GLP not published Syngenta File No A12739A_10008	N	SYN
KCP 10.3.2	Fallowfield L.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-4	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP not published Syngenta File No A12739A_10020		
KCP 10.3.2	Stevens J.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-5 GLP not published Syngenta File No A12739A_10276	N	SYN
KCP 10.3.1	Franke M.	2013	Mesotrione SC (A12739A) - Acute toxicity to the honeybee Apis mellifera L. under laboratory conditions Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 001 B GLP not published Syngenta File No A12739A_10015	N	SYN
KCP 10.3.2	Fallowfield L.	2012	Mesotrione SC (A12739A) - A rate-response laboratory bioassay of the effects of fresh residues on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-41 GLP not published Syngenta File No A12739A_10010	N	SYN
KCP 10.3.2	Stevens J.	2012	Mesotrione SC (A12739A) - A rate-response laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-42 GLP not published Syngenta File No A12739A_10008	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.3.2	Fallowfield L.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-4 GLP not published Syngenta File No A12739A_10020	N	SYN
KCP 10.3.2	Tew G.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory test to evaluate the effects of fresh residues on the rove beetle Aleochara bilineata (Coleoptera; Staphylinidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-6 GLP not published Syngenta File No A12739A_10275	N	SYN
KCP 10.3.2	Vaughan R.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory test to determine the effects of fresh residues on spiders of the genus Pardosa (Araneae, Lycosidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-7 GLP not published Syngenta File No A12739A_10388	N	SYN
KCP 10.4	Friedrich S.	2011	Mesotrione SC (A12739A) - Sublethal toxicity to the earthworm Eisenia fetida in artificial soil Syngenta - Jealott's Hill, Bracknell, United Kingdom BioChem Agrar, Gerichshain, Germany, 11 10 48 003 S GLP not published Syngenta File No A12739A_10000	N	SYN
KCP 10.4	Friedrich S.	2013	Mesotrione SC (A12739A) - Effects on the Reproduction of the Collembolan Folsomia candida Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 009 S GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			not published Syngenta File No A12739A_10013		
KCP 10.4 /	Schulz L.	2013	Mesotrione SC (A12739A) - Effects on the Reproduction of the Predatory Mite Hypoaspis aculeife Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 010 S GLP not published Syngenta File No A12739A_10014	N	SYN
KCP 10.3.2	Tew G.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory test to evaluate the effects of fresh residues on the rove beetle Aleochara bilineata (Coleoptera; Staphylinidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-6 GLP not published Syngenta File No A12739A_10275	N	SYN
KCP 10.3.2	Vaughan R.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory test to determine the effects of fresh residues on spiders of the genus Pardosa (Araneae, Lycosidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-7 GLP not published Syngenta File No A12739A_10388	N	SYN
KCP 10.5	Schulz L.	2014	Mesotrione SC (A12739A) - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 006 C/N GLP not published Syngenta File No A12739A_10024	N	SYN
KCP 10.6	Porch J., Martin K., Krueger H.	2003	ZA1296 (Mesotrione): The toxicity effects of a 100 g/litre SC formulation (A12739A) on the seedling emergence of ten species of plants Syngenta Crop Protection AG, Basel, Switzerland	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Wildlife International Ltd., Easton MD, USA, 528-152 GLP not published Syngenta File No ZA1296/1144		
KCP 10.6	Porch J., Martin K., Krueger H.	2003a	ZA1296 (Mesotrione): The toxicity effects of a 100 g/litre SC formulation (A12739A) on the vegetative vigour of ten species of plants Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton MD, USA, 528-153 GLP not published Syngenta File No ZA1296/1145	N	SYN
KCP 10.5	Schulz L.	2014	Mesotrione SC (A12739A) - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 006 C/N GLP not published Syngenta File No A12739A_10024	N	SYN
KCP 10.6	Porch J., Martin K., Krueger H.	2003	ZA1296 (Mesotrione): The toxicity effects of a 100 g/litre SC formulation (A12739A) on the seedling emergence of ten species of plants Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton MD, USA, 528-152 GLP not published Syngenta File No ZA1296/1144	N	SYN
KCP 10.6	Porch J., Martin K., Krueger H.	2003a	ZA1296 (Mesotrione): The toxicity effects of a 100 g/litre SC formulation (A12739A) on the vegetative vigour of ten species of plants Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton MD, USA, 528-153 GLP not published Syngenta File No ZA1296/1145	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.5	Schulz L.	2014	Mesotrione SC (A12739A) - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 006 C/N GLP not published Syngenta File No A12739A_10024	N	SYN

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.2.1 Study 1

Comments of zRMS:	The study was conducted in accordance with OECD 245. All validity criteria for the study were met. After 10 days of continuous exposure, mortality in the control was 0 % and thus below the threshold of 15 %. Mortality in the reference treatment group was 100 % and thus above the threshold of 50 %. There were deviations from guideline, temperature as well as humidity deviated from the range of values specified in the guidelines. According to study director deviations did not affect the course of the study and the reliability of the study. Study is acceptable.

Reference:	KCP 10.3.1.2
Report	Honey bee, chronic oral toxicity test of test item MEZI 100 SC K.Zaworska, 2023, Study code: 0038/0178/E
Guideline(s):	OECD 245
Deviations:	Yes Deviations from Guideline / Study plan Deviations from the Study plan and OECD 245 Guideline were found: 1. During the definitive test, the temperature increased to maximum 35.1°C with average temperature 33.3°C and the humidity increased to maximum 74.9% with average humidity 63.4% (requirements: temperature 33±2°C; humidity 50-70%). 2. During the stability test under test conditions (33±2°C), the temperature increased to 35.5°C with average temperature of 33.0°C and the increased to maximum 74.9% with average humidity 68.8% (requirements: temperature 33±2°C; humidity 50-70%). 3. During the acclimatization for the definitive test, the temperature lowered to minimum 30.6°C and increased to maximum 37.7°C with average temperature 35.5°C and the humidity lowered to minimum 48.6% and increased to maximum 73.2% with average humidity 64.7% (requirements: temperature 33±2°C, humidity 50-70%). Above deviations did not affect the course of the study and the reliability of the study.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Summary

Chronic oral toxicity test of the test item MEZI 100 SC on honey bee (*Apis mellifera* L.) was conducted. The aim of the test was to determine the concentration causing 50% mortality of population (LC50 value), the dose causing mortality of 50% of population after 10 days (LDD50 value), NOEC/NOEDD and LOEC/LOEDD values.

The study was conducted according to OECD 245 Guideline.

The definitive test: Test design	tested concentrations, reference item concentration and control in three replicates, 10 bees per replicate
Test cages	well-ventilated, plastic cages, size 18 cm × 12 cm × 7.5 cm with food dispensers
Duration time	10 days
Tested concentrations	• control (0 mg of the test item/kg of food) • 64 mg of the test item/kg of food (average test item intake dose: 2.82 µg/bee/day) • 160 mg of the test item/kg of food (average test item intake dose: 7.30 µg/bee/day) • 400 mg of the test item/kg of food (average test item intake dose: 18.81 µg/bee/day) • 1000 mg of the test item/kg of food (average test item intake dose: 45.44 µg/bee/day) • 2500 mg of the test item/kg of food (average test item intake dose: 110.06 µg/bee/day) • dimethoate (0.75 mg of the reference item/kg of food)
Study conditions	average temperature 33.3°C (minimum 31.7°C; maximum 35.1°C)1 average humidity: 63.4% (minimum 57.3%; maximum 74.9%)1 darkness

[1] Deviation from the Study plan and OECD Guideline 245 were found and are described in point 6.

Final results

The test item in the course of this test did not show any apitoxic effect on the mortality of honey bees after 10 days of the study.
Based on the analysis of the results, the LC10/LDD10, LC20/LDD20, LC50/LDD50, LOEC/LOEDD and NOEC/NOEDD values were determined.
Bee mortality in the reference item treatment after 10 days was 100.0% (required: ≥50%).
The final results of the study are presented in Table 1.

Table 1. Final results of the study

Final results			
Parameter	**Concentration [mg of the test item/ kg of food]**	**Parameter**	**Dose [µg of the test item/ bee/day]**
LC_{10}	1267.10	**LDD_{10}**	56.94
LC_{20}	>2500.00*	**LDD_{20}**	>110.06*
LC_{50}	>2500.00*	**LDD_{50}**	>110.06*
NOEC	1000.00	**NOEDD**	45.44
LOEC	2500.00	**LOEDD**	110.06
Reference item treatment			
Concentration [mg of the reference item/kg of food]		**Mortality [%]**	
0.75		100.0	

n.d. impossible to determine for mathematical reasons
LC_{10} test item concentration causing mortality of 10% population
LC_{20} test item concentration causing mortality of 20% population
LC_{50} test item concentration causing mortality of 50% population
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
LDD_{10} test item dose causing mortality of 10% population
LDD_{20} test item dose causing mortality of 20% population
LDD_{50} test item dose causing mortality of 50% population
NOEDD the highest test item dose not causing statistically significant differences in relations to the control
LOEDD the lowest test item dose causing statistically significant differences in relations to the control
* values determined based on the analysis of the results

Validity criteria

The test met the validity criteria of the study according to OECD 245 guideline:

- bee mortality in control after 10 days was 0.0% (required: ≤15%), Table 8
- bee mortality in the reference item treatment after 10 days was 100.0% (required: ≥50%),

Final conclusions

The test item in the course of this test did not show any apitoxic effect on the mortality of honey bees after 10 days of the study.
Based on the analysis of the results, the LC10/LDD10, LC20/LDD20, LC50/LDD50, LOEC/LOEDD and NOEC/NOEDD values were determined.
Bee mortality in the reference item treatment after 10 days was 100.0% (required: ≥50%).
The final results of the study are presented in Table 1.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A 2.3.1.3.1 Study 2

Comments of zRMS:	The study was conducted in accordance with OECD 239. The validity criteria with regards to control larval mortality on D8, control adult emergence on D22 and toxicity of the reference item were met. Study is acceptable. There were deviations from guideline, temperature as well as humidity deviated from the range of values specified in the guidelines. According to study director deviations did not affect the course of the study and the reliability of the study. Study is acceptable.

Reference:	KCP 10.3.1.3
Report	Honey bee larval toxicity test following repeated exposure of the test item MEZI 100 SC 2023, Study code: 0038/0176/E
Guideline(s):	OECD GD 239 ENV/JM/MONO(2016)34
Deviations:	Yes Deviation from the Study plan and OECD GD 239 ENV/JM/MONO(2016)34 guideline was found: 1. During the definitive test the decrease in temperature during larval stage to 33.5°C and pre-pupal stage to 33.9°C was observed. Additionally increase in average humidity 86.2%RH in larval stage and 85.7% during pre-pupal stage was observed. Requirements: temperature: 34.5±0.5°C, humidity: larvae 95±5% RH, pre-pupae 80±5% RH, pupae/imago 50-80% RH. The above deviations did not affect the test result. The study met the validity criteria
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

SUMMARRY

The assessment test of the test item MEZI 100 SC toxicity on honey bee larvae (*Apis mellifera* L.) was conducted in accordance with the OECD GD 239 ENV/JM/MONO(2016)34 Guideline.
During the test, the impact on the successive stages of development of the honey bee, resulting from the repeated exposure of the larval stage to the test item, were determined. The aim of the study was to determine the concentration of the test item causing the mortality of 50% of the population in the test (EC50 value) and the dose of the test item causing the mortality of 50% of the population after 22 days (ED50 value). The values of NOEC and NOED, EC10/ED10 and EC20/ED20 were determined for emerged adults (survival) on the 22nd day of the study.

The definitive test:	
Test design	tested concentrations and control groups consisted of 36 larvae i.e. 12 larvae from 3 different colonies (breedings) located on the same plate
Test equipment	48-well breeding plates with queen-cell cups placed in the dissector and placed in incubator; from day 15 of the test – transparent plastic boxes placed in test room
Exposition time	4 days (from day 3 to day 6)
Duration of the test	22 days
Tested concentrations (doses)	□ control (0.00 mg of test item/kg of diet), corresponding to 0.00 µg of test item/larva (0.00 g of test item/L of deionized water) □ 8.02 mg of test item/kg of diet, corresponding to 1.23 µg of test item/larva (0.62 g of test item/L of deionized water) □ 24.07 mg of test item/kg of diet, corresponding to 3.70 µg of test item/larva (1.85 g of test item/L of deionized water) □ 72.22 mg of test item/kg of diet, corresponding to 11.11 µg of test item/larva (5.56 g of test item/L of deionized water) □ 216.67 mg of test item/kg of diet, corresponding to 33.33 µg of test item/larva (16.67 g of test item/L of deionized water) □ 650.00 mg of test item/kg of diet, corresponding to 100.00 µg of test item/larva (50.00 g of test item/L of deionized water) □ 48.00 mg of reference item (dimethoate)/kg of diet, corresponding to 7.39 µg of reference item/larva (0.528 g of reference item/L of deionized water)
Test conditions[1]	□ for larval stage (day 1-8): average temperature 34.3°C (min. 33.5°C, max. 34.9°C) average relative humidity 99.8% (min. 92.0%, max. 99.9%) darkness for pre-pupal stage (day 8-15): average temperature 34.2°C (min. 33.9°C, max. 34.7°C) average relative humidity 86.2% (min. 85.2%, max. 94.3%) darkness □ for pupal/imago stage (day 15-22): average temperature 34.3°C (min. 34.0°C, max. 34.3°C), average relative humidity 85.7% (min. 84.9%, max. 86.1%) darkness 1 The deviations from Study plan and OECD GD 239 ENV/JM/MONO(2016)34 guideline were found. The deviations are described in details in point 6.

Final results

During definitive test, no statistically significant effect on larval mortality was observed on day 8 at a concentration range 8.02 mg test item/kg of diet - 650.00 mg test item/kg of diet.
The test item showed no statistically significant effect on the mortality of pupae on day 22 at a concentration range 8.02 mg test item/kg of diet - 650.00 mg test item/kg of diet.
For emerged adults, no statistically significant effect was observed at the range 8.02 mg test item/kg of diet - 650.00 mg test item/kg of diet.

The final results of the study are presented in Table 1.

Table 1. Final results of the study

Larval mortality results				
Concentration [mg of test item/kg of diet]	Time [day]			
	8			
	Mortality [%]	Statistical significance*)	LOEC	NOEC
			[mg of test item/kg of diet]	
Control	5.56	-	>650.00	≥650.00
8.02	5.56	-		
24.07	8.33	-		
72.22	11.11	-		
216.67	5.56	-		
650.00	11.11	-		
Concentration [mg of reference item/kg of diet]	Time [day]			
	8			
	Mortality [%]	Statistical significance*)	LOEC	NOEC
			[mg of reference item/kg of diet]	
48.00	100.00	+	not applicable	

- statistically insignificant
+ statistically significant
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
*) values calculated using ToxRat Professional using Fisher's Test after Bonferroni-Holm correction with significance level p=0.05

Pupal mortality results						
Concentration [mg of test item/kg of diet]	Time [day]					
	15		22			
	Mortality [%]	Statistical significance*)	Mortality [%]	Statistical significance*)	LOEC	NOEC
					[mg of test item/kg of diet]	
Control	8.82	not applicable	11.76	not applicable	>650.00	≥650.00
8.02	8.82	-	17.65	-		
24.07	6.06	-	18.18	-		
72.22	9.38	-	12.50	-		
216.67	5.88	-	14.71	-		
650.00	12.50	-	21.88	-		

- statistically insignificant
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
*) values calculated using ToxRat Professional using Chi2 2x2 Table with Bonferroni correction test after Bonferroni-Holm correction with significance level p=0.05

Emergence results							
Concentration [mg of test item/kg of diet]	Dose [µg of test item/larva]	Time [day]					
		22					
		Mortality [%]	Statistical significance*)	LOED	NOED	LOEC	NOEC
				[µg of test item/larva]		[mg of test item/kg of diet]	
Control	Control	16.67	not applicable	>100.00**	≥100.00	>650.00**	≥650.00
8.02	1.23	22.22	-				
24.07	3.70	22.22	-				
72.22	11.11	25.00	-				
216.67	33.33	19.44	-				
650.00	100.00	30.56	-				

- statistically insignificant
*) values calculated using ToxRat Professional using Chi2 2x2 Table with Bonferroni correction test after Bonferroni-Holm correction with significance level p=0.05
** values determined based on the analysis of the results
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
NOED the highest test item dose not causing statistically significant differences in relations to the control
LOED the lowest test item dose causing statistically significant differences in relations to the control

Emergence results			
Parameter	Concentration [mg of test item/kg of diet]	Parameter	Dose [µg of test item/larva]
EC_{10}	195.87	ED_{10}	30.13
EC_{20}	not determined	ED_{20}	not determined
EC_{50}	>650.00*	ED_{50}	>100.00*

EC_{10} test item concentration causing effect on 10% population
EC_{20} test item concentration causing effect on 20% population
EC_{50} test item concentration causing effect on 50% population
ED_{10} test item dose causing effect on 10% population
ED_{20} test item dose causing effect on 20% population
ED_{50} test item dose causing effect on 50% population
* values determined based on the analysis of the results

Validity criteria

The study met the validity criteria (acc. to OECD GD 239 ENV/JM/MONO(2016)34):

- larval mortality in control on days 3-8 was 8.33% in replicate 1 and 3 and 0.00%in replicate 2, required: ≤15%),
- the adults emergence rate in control on day 22 was 83.33% in all replicates 1 (required: ≥70%),
- for dimethoate as reference item, the larval mortality on day 8 was 100.00% (required: ≥50%).

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study was conducted to OECD guideline 227 and with accordance to the principles of GLP. All the validity criterions are met. The seedling emergence: ≥ 70 % (actual 100%). For control group: mean plant survival for duration of the study ≥ 90 % (acual 100%), plants did not exhibit any visible phytotoxic symptoms, environmental conditions for all plants belonging to the same species were identical. One deviation from OECD Guideline No. 227 was recorded: according to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 200.9 – 250.0 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviations did not affect the results of the experiment. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.6.2
Report	Terrestial Plant Test: Vegetative Vigour Test, Czarnynoga M., 2024, Study code G-50-23
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	Yes Deviation from OECD Guideline No. 227: According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 200.9 – 250.0 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

SUMMARY

The aims of this study were to assess the impact of the test item i.e. MEZI 100 SC on vegetative vigour of selected terrestrial plant species and to determine ER10, ER25, ER50 and NOER for chosen parameters of

the test.

MATERIAL AND METHODS

The study coded as G-50-23 [SOP/OG/2] was performed according to the OECD Guideline for the Testing of Chemicals No. 227 (2006): "Terrestrial Plant Test: Vegetative Vigour Test", the Standard Operating Procedure SOP/G/70: "Terrestrial Plant Test: Vegetative Vigour Test" and the Study Plan.

Test item:

Name:	MEZI 100 SC
Batch number:	CHR/12
Active substance and CAS number:	mesotrione: 104206-82-8
Production date:	09.2020
Expiry date:	09.2024
Appearance:	liquid
Formulation:	SC (suspension concentrate)
Active substances:	mesotrione – 9.6% (w/w) 104.8 g/L
Density (20 °C)	1.092 g/mL
Storage conditions:	19.2 – 20.2°C [SOP/OG/1, SOP/PB/1, SOP/G/114]
Certificate of Analysis:	no. N/0038/0009/FA from 20.09.2023 (Appendix No. 1)

Test species:
pea (Pisum sativum), sunflower (Helianthus annuus), lettuce (Lactuca sativa), flax (Linum usitatissimum), carrot (Daucus carota), oats (Avena sativa), perennial ryegrass (Lolium perenne)

Soil: Sandy loam

STUDY DESIGN:

Plant species	Number of replicates per rate	Number of plants per replicate	Total number of plants per rate
pea	7	3	21
sunflower	7	3	21
lettuce	7	3	21
flax	4	5	20
carrot	4	5	20
oats	4	5	20
perennial ryegrass	4	5	20

Exposure termination: 21 days after spraying

Application rates:
- a control,
- 0.2 mL of the test item /ha;
- 0.5 mL of the test item /ha;
- 1.4 mL of the test item /ha;
- 4.1 mL of the test item /ha;

- 12.3 mL of the test item /ha;
- 37.0 mL of the test item /ha;
- 111.1 mL of the test item /ha;
- 333.3 mL of the test item /ha;

Test conditions:
temperature: 19.4 – 24.1°C, humidity: 51.3 – 76.4%,
lighting: 16 h light : 8 h dark; light intensity: 200.9 – 250.0 µE/m2/s; carbon dioxide concentration: 328 – 347 ppm;

Statistical analysis:

Because no change in mortality of plants was to be observed, no computations in plant number have been performed for pea, flax, carrot, oats and perennial ryegrass.

In order to determine ER10, ER25, ER50 the following tests were used:

Plant number:
Weibull analysis using linear max. likelihood regression, probit analysis using linear max. likelihood regression.

Shoot length:
probit analysis using linear max. likelihood regression, logit analysis using linear max. likelihood regression.

Shoot dry weight:
probit analysis using linear max. likelihood regression, logit analysis using linear max. likelihood regression, 4-param. Normal CDF.

Plant damages:
probit analysis using linear max. likelihood regression, logit analysis using linear max. likelihood regression.

In order to determine the NOER values, the following tests were used:

- for the plant number: Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Tarone´s Test Procedure, Ch2 2x2 Table Test with Bonferroni Correction, Step-down Cochran-Armitage Test Procedure.

- for the shoot length: Shapiro-Wilk´s Test on Normal Distribution, Levene´s Test on Variance Homogeneity (with Residuals), Cochran's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure, Trend analysis by Contrasts (Monotonicity of Rate/Response), Dunnett`s Multiple t-test Procedure, Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm.

- for the plant shoot dry weight: Shapiro-Wilk´s Test on Normal Distribution, Levene´s Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure, Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm.

- for plant damages: Shapiro-Wilk´s Test on Normal Distribution, Levene´s Test on Variance Homogeneity (with Residuals), Dunnett`s Multiple t-test Procedure.

The ER10, ER25, ER50 and NOER values were determined using the ToxRat Professional 3.3.0 computer

software [11], [SOP/G/80, SOP/OG/7].

The all ER10, ER25, ER50 and NOER values were expressed in mL of the test item/ha and g of the active substance/ha.

RESULTS:

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements and ER50 values for plant damages at the end of the exposure period expressed as mL of the test item/ha for all test species are given below.

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Lettuce** *Lactuca sativa*	**Flax** *Linum usitatissimum*	**Carrot** *Daucus carota*	**Oats** *Avena sativa*	**Perennial ryegrass** *Lolium perenne*
Plant number at the end of the experiment							
ER_{50}	>1000.00	>1000.00	42.43 (33.96 – 59.52)	>1000.00	>1000.00	>1000.00	>1000.00
NOER	≥1000.00	≥1000.00	12.30	≥1000.00	≥1000.00	≥1000.00	≥1000.00
Shoot length							
ER_{50}	85.21 (61.33 – 118.39)	99.83 (41.85 – 238.11)	10.31 (6.38 – 16.66)	>1000.00	568.22 (368.59 – 875.96)	>1000.00	>1000.00
NOER	4.10	4.10	1.40	37.00	4.10	111.10	≥1000.00
Shoot dry weight							
ER_{50}	59.90 (26.45 – 135.68)	24.90 (12.13 – 51.13)	3.49 (1.46 – 8.01)	516.99 (358.75 – 745.02)	46.76 (38.60 – 56.65)	>1000.00	>1000.00
NOER	4.10	4.10	1.40	37.00	12.30	333.30	≥1000.00
Plant damages							
ER_{50}	17.35 (13.99 – 21.52)	23.65 (13.08 – 42.77)	11.04 (10.01 – 12.18)	957.50 (842.78 – >1000.00)	89.55 (78.88 – 101.68)	>1000.00	>1000.00
NOER	n.d.	1.40	1.40	n.d.	n.d.	n.d.	n.d.

CONCLUSIONS:
The test item, i.e. MEZI 100 SC, had a varied impact on vegetative vigour of pea, sunflower, lettuce, flax, carrot ond oats. The test item had no impact on vegetative vigour of perennial ryegrass.
The test item caused mortality of sunflower and lettuce. Mortality of pea, flax, carrot, oats and perennial ryegrass was not observed.
On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item inhibited the process of growth of pea, sunflower, lettuce, flax, carrot ond oats.
On the basis of NOER, ER10, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item inhibited the process of growth of pea, sunflower, lettuce, flax, carrot ond oats.
During the experiment, the phytotoxic symptoms of the test item were noticed in cultivation of pea, sunflower, lettuce, flax, carrot ond oats. In case of perennial ryegrass, the phytotoxic symptoms was not observed.

VALIDITY CRITERIA
On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of MEZI 100 SC on vegetative vigour of terrestrial plants were met:
- the seedling emergence of plants (validity criterion: at least 70%) was as follows:
92.9 – 100.0% – pea,
90.5 – 100.0% – sunflower,
88.1 – 100.0% – lettuce,
92.5 – 100.0% – flax,
95.0 – 100.0% – carrot,

97.5 – 100.0% – oats,
95.0 – 100.0% – perennial ryegrass.
- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%),
- the control plants did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

Comments of zRMS:	The study was conducted to OECD guideline 208 and with accordance to the principles of GLP. All validity criterions are met. For control group the seedling emergence: ≥ 70 % (actual 95 – 100), the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%); the control seedlings did not exhibit any visible phytotoxic effects and environmental conditions for all plants of the same species were identical. One deviation from OECD Guideline No. 227 was recorded: According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 200.4 and 250.1 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviations did not affect the results of the experiment. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.6.2
Report	MEZI 100 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Czarnynoga M., 2023, Study code
Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	Yes Deviation from OECD Guideline No. 208: According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 200.4 and 250.1 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affects the results of the study.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

SUMMARY

The study, aimed at evaluating the effect of MEZI 100 SC on seedling emergence and seedling growth of 7 terrestrial plants. The study was conducted on 5 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the soil surface. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 3 (pea, sunflower, lettuce) or 5 (flax, carrot, oats, perennial ryegrass) seeds/pot. The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence (every day to the emergence of 50% of the control seedlings and after then every 1 – 3 days)

and visual phytotoxicity (after 7 and 14 days after the emergence of 50% of the control seedlings). The exposure period finished 14 days after the emergence of 50% of the control seedlings. At the end of the exposure, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed.
The results concerning the emergence, survival, the shoot length, the dry weight and visual phytotoxic effects were statistically analyzed in order to determine the ER10, ER25, ER50, and NOER.

MATERIAL AND METHODS

Test item:	MEZI 100 SC batch number: CHR/12 active substance: mesotrione – 9.6% (w/w) 104.8 g/L
Test species:	pea (*Pisum sativum*), sunflower (*Helianthus annuus*), lettuce (*Lactuca sativa*), flax *(Linum usitatissimum),* carrot *(Daucus carota)*, oats *(Avena sativa),* perennial ryegrass *(Lolium perenne)*
Soil:	Sandy loam

STUDY DESIGN:

Plant species	Number of replicates per rate	Number of seeds per replicate	Total number of seeds per rate
pea	7	3	21
sunflower	7	3	21
lettuce	7	3	21
flax	4	5	20
carrot	4	5	20
oats	4	5	20
perennial ryegrass	4	5	20

Application rates:
- a control,
- 0.2 mL of the test item /ha;
- 0.5 mL of the test item /ha;
- 1.4 mL of the test item /ha;
- 4.1 mL of the test item /ha;
- 12.3 mL of the test item /ha;
- 37.0 mL of the test item /ha;
- 111.1 mL of the test item /ha;
- 333.3 mL of the test item /ha;
- 1000.0 mL of the test item /ha.

Exposure termination:
14 days after the emergence of 50% of the control seedlings;

Test conditions:
temperature: ~~21.1 – 24.8~~ 19.3 – 24.1°C, humidity: ~~47.5 – 58.0~~ 51.3 – 74.7%,
lighting: 16 h light : 8 h dark; light intensity: 200.4 – 250.1 µE/m2/s; carbon dioxide concentration: 327 – 362 ppm;

Statistical analysis:

In order to determine the ER10, ER25 and ER50 values, the following tests were used:

The emergence of plants:
logit analysis using linear max. likelihood regression, probit analysis using linear max. likelihood regression

Because no change in emergence of plants was observed in cultivation of pea, no computations have been performed.

The survival of plants:
logit analysis using linear max. likelihood regression.
Because no change in survival of plants was observed in cultivation of pea, sunflower, flax, perennial ryegrass and oats, no computations have been performed.

The shoot length:

probit analysis using linear max. likelihood regression, logit analysis using linear max. likelihood regression, 3-param. normal CDF.

The shoot dry weight: probit analysis using linear max. likelihood regression, logit analysis using linear max. likelihood regression.

The visual phytotoxicity effects: probit analysis using linear max. likelihood regression, logit analysis using linear max. likelihood regression.

In order to determine the NOER values, the following tests were used:

The emergence of plants:

Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Fisher`s Exact Binomial Test with Bonferroni Correction, Tarone´s Test Procedure, Multiple Sequentially-rejective Fisher Test After

Bonferroni-Holm, Chi2 2x2 Table Test with Bonferroni Correction.

The survival of plants:

Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Tarone´s Test Procedure, Step-down Cochran-Armitage Test Procedure.

The shoot length:

Shapiro-Wilk´s Test on Normal Distribution, Levene´s Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Dunnett's Multiple t-test Procedure, Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm.

The plant dry weight:

Shapiro-Wilk´s Test on Normal Distribution, Levene´s Test on Variance Homogeneity (with Residuals), Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure, Dunnett's Multiple t-test Procedure.

Visual phytotoxic effects:

Shapiro-Wilk´s Test on Normal Distribution, Levene´s Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Jonckheere-Terpstra Test Procedure, Bartlett's Test Procedure on Variance Homogeneity, Dunnett's Multiple t-test Procedure.

The ER10, ER25, ER50 and NOER values were determined using the ToxRat Professional 3.3.0 computer software.

The all ER10, ER25, ER50 and NOER values were expressed in mL of the test item/ha and g of mesotrione/ha.

RESULTS

The ER50 and NOER values determined on the basis of emergence of plants, survival of plants, shoot length and shoot dry weight measurements and ER50 values for plant damages at the end of the exposure period expressed as mL of the test item/ha for all test species are given below.

	Pea *Pisum sativum*	Sunflower *Helianthus annuus*	Lettuce *Lactuca sativa*	Flax *Linum usitatissimum*	Carrot *Daucus carota*	Oats *Avena sativa*	Perennial ryegrass *Lolium perenne*
Emergence of plants							
ER_{50}	>1000.00	>1000.00	>1000.00	>1000.00	>1000.00	>1000.00	>1000.00
NOER	≥1000.00	≥1000.00	≥1000.00	≥1000.00	≥1000.00	≥1000.00	≥1000.00
Survival of plants							
ER_{50}	>1000.00	>1000.00	204.77 (147.93 – 284.03)	>1000.00	204.56 (144.11 – 293.46)	>1000.00	>1000.00
NOER	≥1000.00	≥1000.00	37.00	≥1000.00	37.00	≥1000.00	≥1000.00
Shoot length							
ER_{50}	603.85 (465.85 – 822.75)	>1000.00	74.95 (28.95 – 187.63)	>1000.00	303.64 (195.77 – 738.75)	>1000.00	>1000.00
NOER	111.10	12.30	12.30	111.10	37.00	≥1000.00	≥1000.00
Shoot dry weight							
ER_{50}	617.37 (403.18 – >1000.00)	>1000.00	72.16 (62.65 – 83.19)	736.44 (561.86 – >1000.00)	76.58 (55.43 – 106.57)	>1000.00	>1000.00
NOER	12.30	37.00	12.30	111.10	12.30	≥1000.00	≥1000.00
Plant damages							
ER_{50}	193.00 (179.30 – 207.76)	413.64 (386.03 – 443.23)	34.84 (31.90 – 38.04)	752.31 (691.89 – 823.64)	67.94 (64.05 – 72.07)	>1000.00	>1000.00
NOER	12.30	n.d.	4.10	111.10	12.30	≥1000.00	≥1000.00

n.d. – not determined

CONCLUSIONS:

On the basis of the obtained results it was proved that the test item i.e. MEZI 100 SC had a varied impact on the process of growth of pea, sunflower, lettuce, flax and carrot.
In cultivation of oats and perennial ryegrass no impact on the process of growth was observed.
Mortality of plants was observed in cultivation of lettuce and carrot.
Delayed emergence of plants in comparison to the cotrol group was noticed in cultivation of carrot.
On the basis of NOER, ER10, ER25 and ER50 values determined from the plant emergence during exposure period it was proved that the test item had no impact on seedling emergence of all tested species.
On the basis of NOER, ER10, ER25 and ER50 values determined from the survival of plants it was proved that the test item inhibited process of growth of lettuce and carrot.
On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length and shoot dry weight it was proved that the test item inhibited process of the growth of pea, sunflower, lettuce, flax and carrot.
During the exposure period, the phytotoxic symptoms of the test item were observed in cultivation of pea, sunflower, lettuce, flax and carrot.\

VALIDITY CRITERIA

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of MEZI 100 SC on seedling emergence and seedling growth of terrestrial plants were met:
- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
100.0% – pea,
95.2% – sunflower,
100.0% – lettuce,
95.0% – flax,
100.0% – carrot,
100.0% – oats,
95.0% – perennial ryegrass,
- the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data