REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

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

Table of Contents

7 Metabolism and residue data (KCA section 6).

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

The applicant has not provided new data. The report presents data already evaluated at EU peer review.

Storage stability

Mesotrione is considered to be stable under freezer storage for at least 42 months in corn grain and fodder and for 31 months in corn forage. Frozen storage stability of metabolite MNBA in corn grain, forage and fodder was demonstrated for at least 42 months. Degradation of residues during storage of the trial samples is not expected.

Metabolism in plants and animals

The metabolism of mesotrione was sufficiently investigated in cereals (maize) and oilseeds (peanuts). The residue definition for enforcement and risk assessment is proposed as mesotrione in cereals as well as in pulses and oilseeds. Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

The animal metabolism study is acceptable to derive a residue definition for enforcement and risk assessment in ruminant. AMBA is expected to be the predominant compound of the total residues in the major feed item (maize silage and grass). At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use.

Plant residue definition for risk assessment:

Food commodities: mesotrione (cereals and pulses/oilseeds only)

Feed commodities: mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds) – Provisional. - EFSA journal 2016;14(3):4419

Magnitude of residues in plants

Comparison of EU and intended GAP in maze:

Type of GAP	Method	Number of applications	Application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
GAP EU (EFSA, 2016)	Foliar spray	1	0.12 – 0.15	-	BBCH 12 – 18	-
Intended GAP	Foliar spray	1	0.1	-	BBCH 14 – 15	-

The proposed use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) 2017/626) will not be exceeded.

Magnitude of residues in livestock

Dietary burden calculation are not necessary, because magnitude of the residues in plants is below LOQ level.

Magnitude of residues in processed commodities

Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered

(Mesotrione residue levels in maize grain <0.01 mg/kg) (EFSA, 2016).

Magnitude of residues in representative succeeding crops

For the intended uses of mesotrione on maize, no residues are expected in rotational crops. No field rotational crop studies are considered necessary.

Other / special studies

Studies are not required.

Estimation of exposure through diet and other means

The calculation of the TMDI led to an utilisation of the ADI of 7.0 % based on NL toddler being the population group with the highest value. For this diet, the highest contributor is milk with 6% of the ADI. Chronic intakes for all consumer groups are below the ADI.

The highest International Estimated Short-Term Intake (IESTI) is at 6.0% and 2.0% of the ARfD for the consumption of milk by children and by adults.

The proposed uses of mesotrione in the product Mezi 100 SC do not represent unacceptable acute and chronic risks for the consumer.

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation MEZI 100 SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for Maize. A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for Mesotrione as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of Mesotrione residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS- PL agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are:
None

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Maize *Zea mays* ZEAMX	PL	MEZI 100 SC	F	Mono- and dicotyledonous weeds	SC	100 g/L	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	~~200-300~~ 0.1	n/a	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** 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 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation MEZI 100 SC is composed of Mesotrione.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Mesotrione

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesotrione					
ADI	EFSA Journal 2016;14(3):4419	2016	0.01 mg/kg bw/d	Mouse multi-generation	200
ARfD	EFSA Journal 2016;14(3):4419	2016	0.02 mg/kg bw/d	Mouse multi-generation	100

7.1.2.1 Summary for Mesotrione

Table 7.1-3: Summary for Mesotrione

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	Yes	Yes (grain: 15N, 19S, silage: 13N, 19S, forage: 13N, 15S)	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As residues of mesotrione do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

No new MRLs or mitigation measures have been proposed.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

7.1.2.2 Summary for MEZI 100 SC

Table 7.1-4: Information on MEZI 100 SC (KCA 6.8)

Crop	PHI for MEZI 100 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for MEZI 100 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mesotrione		
Maize	F	NR		

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for MEZI 100 SC
Crop group	Led by Mesotrione	
All crops	NR	

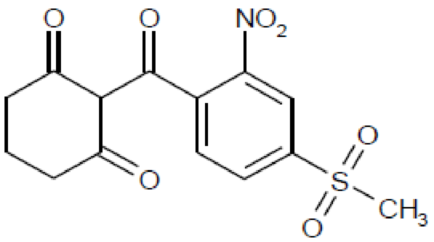
NR: not relevant

Assessment

7.2 Mesotrione

General data on Mesotrione are summarized in the table below (last updated 2017/03/23)

Table 7.2-1: General information on Mesotrione

Active substance (ISO Common Name)	Mesotrione
IUPAC	2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione
Chemical structure	
Molecular formula	C14H13NO7S
Molar mass	339.3 g/mol
Chemical group	Triketone herbicide
Mode of action (if available)	Inhibition of HPPD (p-Hydroxyphenylpyruvate dioxy-genase)
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	BE (original RMS was UK)
Approval status	Approved Commission Implementing Regulation (EU) 2017/725 of 24 April 2017
Restriction (e.g. is restricted to use as "...")	Regulation (EU) 2017/~~755~~ 725 of 24/04/2017: ~~Restriction is not required~~ "The risk assessment for the renewal of the approval of mesotrione is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing mesotrione may be authorised. It is therefore appropriate not to maintain the restriction for use only as herbicide."
Review Report	SANTE/11654/2016 23 March 2017
Current MRL regulation	Reg. (EU) 2017/626
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes**(EFSA Journal 2016;14(3):4419)
EFSA Journal: conclusion on article 12	Yes **(EFSA Journal 2015;13(1):3976)
Current MRL applications on intended uses	Reg. (EU) 2017/626

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference	Source
Data relied on in EU				
Plant products				
Maize, forage	High water content	31 months (Mesotrione)	Wiebe L.A., 1997 Report No: RR 97-042B INT Wiebe L.A & Peyton C.S., 1999 Report No. RR 97-042B FIN	RAR Mesotrione 2015, 2015a
		42 months (MNBA)		
Maize, fodder	High water content	42 months (Mesotrione, MNBA)		
Radish, root	High water content	44 months		
Maize, grain	High starch content	42 months (mesotrione, MNBA)		
Soybean, seed	High protein content	40 months		
Animal Products				
Not required				

Conclusion on stability of residues during storage

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for mesotrione. Storage stability of mesotrione for high water, starch and protein commodities when frozen (approximately -18°C) was demonstrated as listed in the table above.
Sufficient stability has been demonstrated to support the residue data presented in the submission.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Conclusion on stability of residues in sample extracts

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of mesotrione in sample extracts and fully support the residue data presented in the submission.

zRMS comment: The stability was assessed in the framework of the peer review for the active substance mesotrione. Mesotrione is considered to be stable under freezer storage for at least 42 months in corn grain and fodder and for 31 months in corn forage. Frozen storage stability of metabolite MNBA in corn grain, forage and fodder was demonstrated for at least 42 months. Residues of mesotrione and MNBA were also stable for a period of 40 months in soy bean seed and 44 months in radish root under freezer storage. Degradation of residues during storage of the trial samples is not expected.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details				Reference	Source
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)		
EU data								
Pulses and oilseeds	Peanut	phenyl-(U)-^{14}C	Pre-emergence, F	305 g a.s./ha 796 g a.s./ha	1 (1d after planting)	Foliage: 90 Hay: 153 Hulls, nutmeat: 169	Brown K, 2003. Report No: 1286-01	RAR Mesotrione 2015, 2015a
		cyclohexane-(U)-^{14}C	Pre-emergence, F	327 g a.s./ha 836 g a.s/ha	1 (1d after planting)	Foliage: 90 Hay, hulls, nutmeat: 154	Brumback D., 2003 Report No: 1287-01	
	HT soybean	phenyl-(U)-14C	Pre-emergence, G	217.7 g a.s./ha	1 (1d after planting)	Forage: 28 Hay: 42 Seed: 123	Dohn D. & Chu J., 2012 Report No. NC 27419	RAR Mesotrione 2015, 2015a
			Pre-/post-emergence, G	345.5 g a.s./ha (217.7 g a.s./ha pre- plus 127.8 g a.s./ha post-emerge.)	2 (1 d, 34 d after planting)	Forage: 28/-- Hay: 42/9 Seed: 123/90		
			Post-emergence, G	224.2 g a.s./ha	1 (12 d after planting)	Forage: 22 Hay: 40 Seed: 110		
		cyclohexane-(U)-14C	Pre-emergence, G	225.8 g a.s./ha	1 (1d after planting)	Forage: 28 Hay: 42 Seed: 123		
			Pre-/post-emergence, G	356 g a.s./ha (225.8 g	2 (1 d, 34 d after	Forage: 28/-- Hay: 42/9 Seed: 123/90		

				a.s./ha pre-, plus 130.2 g a.s./ha post-emerge.)	planting)			
			Post-emergence, G	229.6 g a.s./ha	1 (12 d after planting)	Forage: 22 Hay: 40 Seed: 118		
Cereals	Maize	phenyl-(U)-14C	Pre-emergence, F	280 g a.s./ha	1 (at planting)	Forage: 27 Grain, fodder: 153	Tarr & van Neste, 1997 Report No: RR 96-007B	RAR Mesotrione 2015, 2015a
			Post-emergence, F	164 g a.s./ha	1 (28 d after planting)	Forage: 28 Grain, fodder: 125	Wei & Dohn, 1997 Report No: RR 96-026B	
		cyclohexane-(U)-14C	Pre-emergence, F	280 g a.s./ha	1 (at planting)	Forage: 27 Grain, fodder: 153	Tarr & van Neste, 1997 Report No: RR 96-007B	RAR Mesotrione 2015, 2015a
			Post-emergence, F	164 g a.s./ha	1 (28 d after planting)	Forage: 28 Grain, fodder: 125	Wei & Dohn, 1997 Report No: RR 96-026B	

Summary of plant metabolism studies reported in the EU

„Plant metabolism was studied in maize (pre- and post-emergence), peanuts (pre-emergence) and genetically modified soya bean (pre-, post-emergence and combined pre-/post-emergence) with mesotrione labelled on cyclohexane-2-14C and phenyl-U-14C. The metabolic pattern of Mesotrione was found to be quantitatively different in conventional crops (maize, peanut) compared to genetically modified soya bean. In maize and peanuts, parent mesotrione was hardly recovered (3% TRR in maize forage only) whilst the most pertinent metabolites identified in the feed items were MNBA (up to 20% TRR in maize forage leaves) and AMBA, free and conjugated (13% and 28% TRR respectively in maize forage leaves and fodder; 15% TRR in peanut meat). Further metabolites' identification was not conducted in maize grain due to the very low recovered total residues (0.014 mg/kg). In genetically modified herbicide tolerant soya bean, parent mesotrione was less extensively metabolised compared to conventional crops and occurred in forage at up to 18% TRR and in soya bean seed (10% TRR). The predominant compounds were identified as 4/5-hydroxy mesotrione (forage 19% TRR; hay 25% TRR; seed 8% TRR) and MNBA (forage 25% TRR; hay 20% TRR; seed 5% TRR). AMBA compound was never detected. The unextracted radioactivity was further characterized as polar compounds (soya bean), lipids (peanut meat) and carbohydrates (maize) incorporated into the natural constituents of the plant. The metabolism of mesotrione in maize, peanuts and soya bean proceeds by oxidation of the parent molecule to 4/5-hydroxy mesotrione and to MNBA with subsequent reduction to AMBA and its conjugates observed in conventional maize and peanuts only. The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

Since the absolute concentration of all metabolites was below 0.01 mg/kg in the seeds, the residue definition for enforcement and risk assessment was set as mesotrione only for food commodities.

For feed commodities, the potential inclusion of the predominant metabolites MNBA and AMBA (free and conjugated) besides mesotrione in the residue definition for risk assessment was envisaged. MNBA was characterized as non-genotoxic and of lower toxicity compared to the parent compound and was never detected in the GAP-compliant residue trials on maize (<0.01 mg/kg).

In contrast, a genotoxic potential in vivo could not be excluded for AMBA and repeated dose toxicity profile needed to be addressed (see data gap in Mammalian toxicity). For risk assessment in feed commodities and pending on the toxicological profile of AMBA conjugates, the residue definition is provisionally proposed as mesotrione and AMBA (including its conjugates).

If it can be demonstrated that the conjugates of AMBA are not genotoxic and of no toxicological relevance, additional residue trials on maize where AMBA is analysed for are not needed and only mesotrione has to be included in the residue definition. These residue definitions are valid for conventional crops (cereals, pulses and oilseeds) only."

Conclusion on metabolism in primary crops

Based on the available metabolism data on plants and the toxicological data on AMBA, it can be concluded that the residue definition for risk assessment in food and feed commodities should include Mesotrione parent compound only.

zRMS comment: According to EFSA (2015) The metabolism of mesotrione was considered as sufficiently investigated in cereals (maize) and oilseeds (peanuts). The residue definition for enforcement and risk assessment is proposed as mesotrione in cereals as well as in pulses and oilseeds.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				Reference	Source
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU data								
Leafy vegetables	Endive	phenyl-(U)-14C	Soil application, G	164	120, 300(b)	Maturity: 198	Gorder et al., 1997. Report No: RR 96-084B	RAR Mesotrione (2015, 2015a)
		cyclohexane-	Soil	164	120, 300(b)	Maturity:	Spillner et	

		(U)- 14C	application, G			198	al., 1997 Report No: RR 95-042B	
Root and tuber vegetables	Radish	phenyl-(U)-14C	Soil application, G	164	120, 300(b)	Maturity (tops and roots): 176	Gorder et al., 1997. Report No: RR 96-084B	
		cyclohexane-(U)- 14C	Soil application, G	164	120, 300(b)	Maturity (tops and roots): 176	Spillner et al., 1997 Report No: RR 95-042B	
Cereals	Wheat	phenyl-(U)-14C	Soil application, G	164	120, 300(b)	Forage: 142 Hay: 177 Grain, straw: 254	Gorder et al., 1997. Report No: RR 96-084B	
		cyclohexane-(U)- 14C	Soil application, G	164	120, 300(b)	Forage: 142 Hay: 177 Grain, straw: 254	Spillner et al., 1997 Report No: RR 95-042B	

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies on rotational crops reported in the EU

Reference: RAR Mesotrione 2015, 2015a

One confined rotational crop study investigating the nature of residues following different plant-back intervals is available.

The metabolism and distribution of mesotrione[1] was investigated in the rotational crops wheat, endive and radish planted 120 and 300 days following soil application of [^{14}C] mesotrione to soil in pots at ca 1.2N. A replanting interval of 30 days was not investigated but is not of concern since replanting after this interval would not be anticipated for this crop.

TRR in the plants grown in the soil treated with [^{14}C]-cyclohexane labelled mesotrione were <0.001-0.002 mg/kg. TRR in the crops grown in soil treated with [^{14}C]-phenyl labelled mesotrione were 0.004 mg/kg in both radish roots and tops, 0.012 mg/kg in endive and 0.033, 0.018, 0.031 and 0.006 mg/kg in wheat forage, hay, straw and grain respectively. The 300 DAT crops were not harvested due to the low levels of radioactivity in the 120 DAT crops.

MNBA, AMBA sulphate and AMBA conjugate were present in all extracts of wheat forage, hay and straw, the only significant component was MNBA at 0.011 mg/kg in wheat forage (33% TRR). Mesotrione was not detected.

All of the plant metabolites have also been determined in mammalian metabolism studies.

Summary of new plant metabolism studies

There are no new plan metabolism studies.

Conclusion on metabolism in rotational crops

According to EFSA Mesotrione- EFSA Journal 2016;14(3):4419: The metabolism of Mesotrione is similar in rotational crops to that observed in primary crops

zRMS comment: Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. The magnitude of residues in rotational crops is not expected to exceed 0.01 mg/kg, provided that mesotrione is applied in compliance with the authorized European uses (EFSA, 2015).

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

According to EFSA Mesotrione- EFSA Journal 2016;14(3):4419: Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (Mesotrione residue levels in maize grain <0.01 mg/kg).

zRMS comment: as the residues in maze grain are <0.01 mg/kg, processing studies are not necessary.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Pulses and oilseeds (Peanut, HT soybean) Cereals (Maize)
Rotational crops covered	Leafy crops (endive), root vegetables (radish) and cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Mesotrione (parent only) (Cereals and pulses/oilseeds only)
Plant residue definition for risk assessment	Food commodities: Mesotrione (parent only) (cereals and pulses/oilseeds only) Feed commodities: Mesotrione (cereals, pulses and oilseeds only – conventional crops).
Conversion factor from enforcement to RA	Not applicable (EFSA Journal 2016;14(3):4419)

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference	Source
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of samp-ling		
EU data									
Lactating ruminants(a)	Cow	phenyl-(U)-14C AMBA	1	0.389 mg/kg bw/day AMBA	7	Milk	Twice daily	[redacted] 1997	RAR Mes-otrione (2015, 2015a)
						Liver	23h after sacrifice		
						Kidney	23h after sacrifice		
						Subcutaneous fat	23h after sacrifice		
						Perirenal fat	23h after sacrifice		
Laying poultry(a)	--	----	---	---	---	---	---	None	
Fish(b)	---	---	---	---	---	---	---	None	

a) “Since animal intakes are less than 0.004 mg/kg bw/day the need for metabolism studies is not triggered” (UK, 2015, 2015a).
(b) “No guideline is available for possible design of fish metabolism studies or for estimation of dietary burden for farmed fish diet. However, from the uses of mesotrione and the magnitude of residues (all <0.01 mg/kg) it can be expected that there is no potential for residues in commercial fish diet.” (UK, 2015, 2015a)

Summary of animal metabolism studies reported in the EU

Livestock metabolism studies are not triggered considering the estimated dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data. This assessment has to be reconsidered pending the outcome of data gap set for clarification of the genotoxic potential of AMBA and of its toxicological profile.
A fish metabolism study is also not requested.

Conclusion on metabolism in livestock

A residue definition for animal commodities is not considered necessary.

zRMS comment: EFSA is of the opinion that the available metabolism study is acceptable to derive a residue definition for enforcement and risk assessment in ruminant. AMBA is expected to be the predominant compound of the total residues in the major feed item (maize silage and grass) to which ruminants are expected to be exposed to. At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use (EFSA, 2016).

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating ruminants
Time needed to reach a plateau concentration	5 days in milk
	5 days in eggs
Animal residue definition for monitoring	Not required for the representative use (provisional) (EFSA Journal 2016;14(3):4419)
Animal residue definition for risk assessment	Not required for the representative use (provisional) (EFSA Journal 2016;14(3):4419)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	AMBA residues in muscle (<0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat soluble.

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-8: Summary of EU reported supporting the intended uses of MEZI 100 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize grain	RAR Mesotrione (2015, 2015a)	N-EU	GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A(b) 15x <0.01(a)	<0.01	<0.01	0.01	0.01	Yes
Maize cob Harvest at BBCH 75-84	RAR Mesotrione (2015, 2015a)	N-EU	GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A(b) 8x <0.01(a)	<0.01	<0.01	0.01	0.01	Yes
Maize stover	RAR Mesotrione (2015, 2015a)	N-EU	GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A(b) 10x <0.01(c)	<0.01	<0.01	N/A	--	---
Maize	**Overall supporting data for cGAP**	N-EU	GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A(b) 33x <0.01(c)	<0.01	<0.01	0.01	0.01	Yes

* Source of EU MRL: Reg. (EU) 2017/626

N/A – not applicable
(a) Definition of residue for enforcement and risk assessment are the same: Mesotrione
(b) PHI is determined by crop maturity
(c) Definition of residue for enforcement is not relevant for feed items since no MRL is set.

7.2.3.2 Conclusion on the magnitude of residues in plants

The trials evaluated at the EU level in the original RAR (United Kingdom, 2015, 2015a) correspond to the proposed uses and demonstrate the zero residue situation.
The data submitted show that no detectable residues are expected in treated crops and no exceedance of the MRL will occur. The proposed uses are considered acceptable.

zRMS comment: Comparison of EU and intended GAP in maze:

Type of GAP	Method	Number of applications	Application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
GAP EU (EFSA, 2016)	Foliar spray	1	0.12 – 0.15	-	BBCH 12 – 18	-
Intended GAP	Foliar spray	1	0.1	-	BBCH 14 – 15	-

Maize is a major crop in Northern Europe.. The applicant relied upon 15 NEU trials that have been previously evaluated at EU level, with application rates higher than those proposed GAP. The proposed use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) 2017/626) will not be exceeded. Therefore the proposed uses of the product can be considered as supported on maize in Central Europe.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Dietary burden calculation are not necessary, because magnitude of the residues in plants is below LOQ level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Livestock animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009. Feeding studies are therefore not required.

Considering the low levels of residues expected in livestock feed commodities from the crops and associated GAP supported in this submission along with extrapolation of residue results from the livestock nature or residue studies in goats and hens, residues of mesotrione in edible tissues, milk or eggs are not expected to be quantifiable above 0.01 mg/kg.

No new data were submitted in the framework of this application.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

As quantifiable residues of Mesotrione are not expected in the treated crops and the TMDI is <10% (see also 7.2.8), there is no need to investigate the effect of industrial and/or household processing.

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

7.2.5.2 Conclusion on processing studies

Processing studies are not required to support the proposed uses of Mesotrione in this submission.

zRMS comment: According to Commission Regulation (EU) No. 283/2013, no processing studies are required if the level of residue in the plant or plant product to be processed is less than 0,1 mg/kg.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.2-9: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
None/bare soil	340	Oilseeds/pulses	Soyabean	30	Barnes & Wiebe, 1997 Report: RR 97-044B RAR Mesotrione 2015, 2015a
				29	
Maize	340+220	Leafy	Endive	74	
				98	
None/bare soil	340	Root and tuber vegetables	Radish	30	
				29	
Maize	340+220[(a)]			85	
				98	
None/bare soil	340[(a)]	Cereals	Millet	30	
				29	
	340[(a)]		Sorghum	30	

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
None/bare soil				29	
Maize	340+220[(a)]		Wheat	100	
				98	

(a) 0.34 kg as/ha incorporated into soil before the maize crop was planted, and the 0.22 kg a.s./ha applied post-emergent to the maize. The maize crop was removed prior to the planting of the succession crops.

Conclusion on rotational crops studies

Field rotational crop studies are not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate (see Table 7.2-4) and considering also the low to moderate persistence of Mesotrione, MNBA and AMBA.
US rotational crop field trials were conducted on pulses/oilseeds (soya bean), leafy vegetables (endive), root vegetables (radish) and cereals (small grains (wheat)) after bare soil application at 0.34 kg a.s./ha or after bare soil application (0.34 kg a.s./ha) followed by a post-emergence application (0.22 kg a.s./ha). Residues of Mesotrione and MNBA were < 0.01 mg/kg in all crop parts (EFSA, 2016).

zRMS comment: The available rotational crop field trials demonstrated the absence of residues in rotational crops. For the intended uses of mesotrione on maize, no residues are expected in rotational crops. No field rotational crop studies are considered necessary.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of MEZI 100 SC. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see Table 7.1-2).

7.2.8.1 Input values for the consumer risk assessment

The TMDI was undertaken with all MRLs listed below (see Table 7.2-12) and all other non-default MRLs listed in Regulation (EU) 2017/626 IESTI was calculated using HR values from residue trials for the crops relevant for this submission.

Table 7.2-10: Input values for the consumer risk assessment

Commodity Code	Commodity	Chronic risk assessment TMDI		Acute risk assessment IESTI	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition : mesotrione					
234000	Sweetcorn	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	HR from maize trials presented(a) = LOQ
401060	Oilseed rape	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	Not relevant for this submission
500030	Maize	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	HR from maize trials presented(a) = LOQ
500080	Sorghum	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	Not relevant for this submission
900020	Sugarcane	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	Not relevant for this submission
1011010	Swine meat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1011020	Swine fat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1011030	Swine liver	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1011040	Swine kidney	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1012010	Bovine meat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1012020	Bovine fat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1012030	Bovine liver	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1012040	Bovine kidney	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1013010	Sheep meat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1013020	Sheep fat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)

Commodity Code	Commodity	Chronic risk assessment TMDI		Acute risk assessment IESTI	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
1013030	Sheep liver	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1013040	Sheep kidney	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1014010	Goat meat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1014020	Goat fat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1013020	Sheep fat	0.01	MRL = LOQ Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1013030	Sheep liver	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1013040	Sheep kidney	0.01	MRL = LOQ (SANTE/11707/2016)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1014010	Goat meat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1014020	Goat fat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1014030	Goat liver	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1014040	Goat kidney	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1015010	Horse meat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1015020	Horse fat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1015030	Horse liver	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1015040	Horse kidney	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)

Commodity Code	Commodity	Chronic risk assessment TMDI		Acute risk assessment IESTI	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
1016010	Poultry meat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1016020	Poultry fat	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1016030	Poultry liver	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1020010	Bovine milk	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1020020	Sheep milk	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1020030	Goat milk	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1020040	Horse milk	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1020990	Milk (others)	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1030010	Chicken eggs	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1030020	Duck eggs	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1030030	Goose eggs	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1030040	Quail eggs	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)
1030990	Other eggs	0.01	MRL = LOQ (Reg. (EU) 2017/626)	0.01	MRL = LOQ (Reg. (EU) 2017/626)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo ver 3.1	7 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo ver 3.1	Not required
IESTI (% ARfD) according to EFSA PRIMo* ver 3.1	Maize (unprocessed commodities) Adult:0.1 % ARfD Children:: 0.3% ARfD
	Maize oil (processed commodities) Adult:0.6% ARfD Children: 1% ARfD
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of Mesotrione in the MEZI 100 SC do not represent unacceptable acute and chronic risks for the consumer.

zRMS comment: The calculation of the TMDI led to an utilisation of the ADI of 7.0 % based on NL toddler being the population group with the highest value. For this diet, the highest contributor is milk with 6% of the ADI. Chronic intakes for all consumer groups are below the ADI.
The highest International Estimated Short-Term Intake (IESTI) is at 6.0% and 2.0% of the ARfD for the consumption of milk by children and by adults.
The proposed uses of mesotrione in the product Mezi 100 SC do not represent unacceptable acute and chronic risks for the consumer.
No further studies are required to support the proposed uses.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EC European Commission, 2017 Review report for the active substance mesotrione. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on in 23 March 2017 view of. the renewal of the approval of mesotrione as active substance in accordance with Regulation (EC) No 1107/2009

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mesotrione according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3976, 36 pp. doi:10.2903/j.efsa.2015.3976

EFSA (European Food Safety Authority), 2016. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance mesotrione. EFSA Journal 2016;14(3):4419, [103 pp.] doi:10.2903/j.efsa.2016.4419.

FAO (Food and Agriculture Organisation of the United Nations), 2015. Mesotrione. In: Pesticide residues in food – 2014. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 221.

United Kingdom, 2015. Renewal assessment report (RAR) on the active substance Mesotrione prepared by the rapporteur Member State, the United Kingdom, in the framework of Commission Implementing Regulation (EU) No 844/2012, February 2015.

United Kingdom, 2015a. Revised renewal assessment report (RAR) on Mesotrione, compiled by EFSA, December 2015.

EFSA (European Food Safety Authority), 2018. Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mesotrione in light of confirmatory data. EFSA Supporting publication 2018:EN-1527

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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	Vertebrate study Y/N	Owner
KCA 6.1	Wiebe, L.A.	1997	ZA 1296: Stability of ZA 1296 and the Metabolite MNBA in Frozen Crops (Interim Report). Zeneca Report No:RR 97-042B INT GLP, not published	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Wiebe LA, Peyton CS	1999	ZA1296: Stability of ZA1296 & the Metabolite MNBA in Frozen Crops Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-042B FIN GLP, not published Syngenta File No ZA1296/0125	N	SYN
KCA 6.2.1	Brumback D.	2003	Cyclohexane-2-14C] Mesotrione: Nature of the Residue in Peanuts Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001287-01 1287-01 GLP, not published Syngenta File No ZA1296/1350	N	SYN
KCA 6.2.1	Brown K.	2003	[Phenyl-U-14C] Mesotrione: Nature of the Residue in Peanuts Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001286-01 1286-01 GLP, not published Syngenta File No ZA1296/1349	N	SYN
KCA 6.2.1	Dohn D., Chu J.	2012	14C-Mesotrione - Nature of the Residue in Herbicide Tolerant (HT) Soybeans Syngenta PTRL West, Hercules CA, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA, Landis International, Valdosta, USA, Agvise Laboratories, Northwood, ND, USA, 1943W, 860.1300-09-433-07B-03 GLP, not published Syngenta File No ZA1296_50531	N	SYN
KCA 6.2.1	Tarr, J.B. *et al*	1997	[Phenyl-U-14C]ZA 1296: nature of the residues in corn	N	SYN
KCA 6.2.1	Wei, Y. *et al*	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1					
KCA 6.3	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96-114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom RR 96-078B GLP not published Syngenta File No ZA1296/0409	N	SYN
KCA 6.3	Heillaut C	2009	Glyphosate (ASF71), Mesotrione (ZA1296) and S-Metolachlor (CGA77102) - Residue Study on GA21 (MON----21-9) Corn in France (North) and Czech Republic in 2007 Syngenta Crop protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, T011085-06 GLP not published Syngenta File No A15189G_10009	N	SYN
KCA 6.3	Heillaut C	2009a	Glyphosate, Mesotrione and S-Metolachlor - Residue Study on GA21 (MON-00021-9) Corn in Denmark and Sweden in 2008 Syngenta Crop protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, T009533-07-REG GLP not published Syngenta File No A15189G_10014	N	SYN
KCA 6.3	Meyer M	2011	Mesotrione - Residue Study on Field Corn in Germany and the United Kingdom in 2009 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T000920-09-REG GLP not published Syngenta File No A14203B_10105	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3	Klimmek S., Gizler A.	2008	MESOTRIONE AND NICOSULFURON: RESIDUE STUDY ON MAIZE IN NORTHERN FRANCE IN 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, T011368-07 GLP not published Syngenta File No A14351BX_10205	N	SYN
KCA 6.3	Schulz H	2010	Mesotrione and Nicosulfuron - Residue Study on Maize in France (North) in 2008 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T009530-07-REG GLP not published Syngenta File No ZA1296_10049	N	SYN
KCA 6.6.1	Gorder, G.W. et al	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	SYN
KCA 6.6.1	Spillner, C. et al	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	SYN
KCA 6.6.2	Barnes, J.P., Wiebe, L.A	1997	ZA 1296: Residue Levels on Rotated Crops from Trials Carried Out in the United States During 1995-1996. Zeneca Report No:RR 97-044B	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	Vertebrate study Y/N	Owner

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

Not required

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Mesotrione

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.02
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : –

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
7%	NL toddler	0.70	6%	Milk: Cattle	0.7%	Maize/corn	0.1%	Bovine: Muscle/meat		
4%	UK infant	0.43	4%	Milk: Cattle	0.1%	Eggs: Chicken	0.1%	Bovine: Muscle/meat		
3%	FR toddler 2 3 yr	0.33	3%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		
3%	FR child 3 15 yr	0.29	2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		
3%	NL child	0.28	2%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
2%	UK toddler	0.23	2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Eggs: Chicken		
2%	DE child	0.23	2%	Milk: Cattle	0.1%	Eggs: Chicken	0.1%	Poultry: Muscle/meat		
2%	FR infant	0.18	2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
2%	ES child	0.18	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Poultry: Muscle/meat		
2%	DK child	0.18	1%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
2%	SE general	0.18	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.1%	Eggs: Chicken		
2%	RO general	0.16	1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Maize/corn		
1%	DE general	0.15	1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
1%	DE women 14-50 yr	0.15	1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
1%	GEMS/Food G15	0.11	0.7%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Poultry: Muscle/meat		
1%	GEMS/Food G11	0.11	0.8%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Poultry: Muscle/meat		
1%	NL general	0.11	0.8%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
1%	GEMS/Food G07	0.11	0.6%	Milk: Cattle	0.1%	Poultry: Muscle/meat	0.1%	Swine: Muscle/meat		
1.0%	GEMS/Food G08	0.10	0.6%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Poultry: Muscle/meat		
1.0%	GEMS/Food G10	0.10	0.5%	Milk: Cattle	0.1%	Poultry: Muscle/meat	0.1%	Bovine: Muscle/meat		
0.8%	ES adult	0.08	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		
0.8%	DK adult	0.08	0.5%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
0.7%	FR adult	0.07	0.4%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
0.7%	IE adult	0.07	0.4%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
0.6%	LT adult	0.06	0.4%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.5%	GEMS/Food G06	0.05	0.2%	Milk: Cattle	0.1%	Maize/corn	0.1%	Poultry: Muscle/meat		
0.4%	UK adult	0.04	0.3%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Poultry: Muscle/meat		
0.4%	IE child	0.04	0.4%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.4%	UK vegetarian	0.04	0.3%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.0%	PT general	0.00	0.0%	Maize/corn		Grapefruits				
0.0%	IT toddler	0.00	0.0%	Maize/corn		Grapefruits				
0.0%	FI 6 yr	0.00	0.0%	Maize/corn		Grapefruits				
0.0%	IT adult	0.00	0.0%	Maize/corn		Grapefruits				
0.0%	FI 3 yr	0.00	0.0%	Maize/corn		Grapefruits				
0.0%	FI adult	0.00	0.0%	Maize/corn		Grapefruits				
0.0%	PL general	0.00	0.0%	Maize/corn		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Mesotrione is unlikely to present a public health concern.

A 3.2 IEDI calculations

Not required.

A 3.3 IESTI calculations- unprocessed commodities

Unprocessed commodities

Results for children				Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				IESTI			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Milk: Cattle	0.01 / 0.01	1.2	2%	Milk: Cattle	0.01 / 0.01	0.39
1%	Milk: Goat	0.01 / 0.01	0.24	0.9%	Milk: Goat	0.01 / 0.01	0.18
0.8%	Poultry: Muscle/meat	0.01 / 0.01	0.17	0.8%	Milk: Sheep	0.01 / 0.01	0.15
0.6%	Eggs: Chicken	0.01 / 0.01	0.12	0.6%	Poultry: Muscle	0.01 / 0.01	0.12
0.6%	Swine: Muscle/meat	0.01 / 0.01	0.12	0.3%	Bovine: Muscle	0.01 / 0.01	0.06
0.4%	Bovine: Liver	0.01 / 0.01	0.08	0.2%	Swine: Muscle/meat	0.01 / 0.01	0.05
0.4%	Bovine: Muscle/meat	0.01 / 0.01	0.07	0.2%	Equine: Muscle/meat	0.01 / 0.01	0.05
0.3%	Maize/corn	0.01 / 0.01	0.07	0.2%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.3%	Equine: Muscle/meat	0.01 / 0.01	0.06	0.2%	Poultry: Liver	0.01 / 0.01	0.05
0.3%	Sheep: Muscle/meat	0.01 / 0.01	0.05	0.2%	Eggs: Chicken	0.01 / 0.01	0.04
0.2%	Bovine: Kidney	0.01 / 0.01	0.04	0.2%	Bovine: Liver	0.01 / 0.01	0.04
0.2%	Milk: Sheep	0.01 / 0.01	0.04	0.1%	Sheep: Liver	0.01 / 0.01	0.03
0.1%	Bovine: Fat tissue	0.01 / 0.01	0.02	0.1%	Swine: Kidney	0.01 / 0.01	0.02
0.09%	Swine: Fat tissue	0.01 / 0.01	0.02	0.1%	Maize/corn	0.01 / 0.01	0.02
0.06%	Swine: Kidney	0.01 / 0.01	0.01	0.1%	Bovine: Kidney	0.01 / 0.01	0.02
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.4 IESTI calculations -processed commodities

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Maize / oil	0.01 / 0.25	0.23	0.6%	Maize / oil	0.01 / 0.25	0.13
0.1%	Maize / processed (not sp	0.01 / 0.01	0.02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list							

Appendix 4 Additional information provided by the applicant

Not required