FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 4300 A

Product name(s): MIGHTY

Chemical active substance:

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: December 2018

MS Finalisation date: 04/06/2024

Version history

When	What
02/2020	Dossier sent for evaluation
09/2023	zRMS finalised evaluation
11/2023	Updated by the Applicant
12/2023	Updated by the Applicant
02/2024	Updated by the Applicant
04/2024	Final version prepared by zRMS after Commenting period
June 2024	Final version prepared by zRMS after the second commenting period

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

This documentation has been prepared by the Applicant. All comments and changes introduced by zRMS are marked in gray.

All comments and changes introduced by zRMS after the comment period are marked in yellow.

GAP proposed for SHA 4300A: foliar spray, 1 application in BBCH 10-14 on maize, max application rate 0.15 kg as/ha.

GAP already evaluated at EU level (SANTE/11654/2016, 23 March 2017): 1 application per crop/season in BBCH 12-18 on maize, max application rate 0.15 kg as/ha.

The Applicant has not submitted any new studies for the purpose of this application. The use proposed in the GAP for SHA 4300A is covered by GAP already evaluated at EU level.

The crops under consideration can be grown in rotation. No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

The risk assessment performed using PRIMo 3.0 and applicable MRLs indicates that the chronic and the short-term intakes of mesotrione residues are unlikely to present a public health concern.

No additional data/studies are required.

As far as consumer health protection is concerned, the zRMS (PL) agrees with the authorisation of the intended use on maize.

During the commenting stage, the Applicant proposed lowering the application dose from 0.15 kg a.s./ha to 0.10 kg a.s./ha. It was accepted. The assessment covers a more critical scenario.

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 SHA4300A 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) 2017/626 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, Poland authorities agrees with the authorization of the intended use(s).

Data gaps

Noticed data gaps are:

- No data gaps

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
						Formulation		**Application**				**Application rate per treatment**				
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**	**Type**	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	~~**kg as/hL**~~ **min max** ~~kg or L product / ha a) max. rate per appl.~~ ~~b) max. total rate per crop/season~~ **kg as/hL** **min max**	**water L/ha min max**	**kg as/ha min max**	**PHI (days)**	**Conclusion**
1	Maize	CEU	SHA 4300	F	Broadleaved and grass weeds	SC	100	Foliar Spray	BBCH 10-14 (*)	a) 1 b) 1	N.A	~~a) 1.5~~ ~~b) 1.5~~ 0.017-0.05 (1.0 L prod/ha)	~~a) 150~~ ~~b) 150~~ 200-600	~~200-600~~ ~~0.150~~ 0.10	NA	(*)Weeds at early stages Only one application per season 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

(*) weeds at early stages

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 SHA 4300 A 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	Mouse multi-generation	200
ARfD	EFSA Journal 2016;14(3):4419	2016	0.02	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 (9 trials)	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 ~~2017/626~~ 283/2013, there is no need to investigate the effect of industrial and/or household processing.

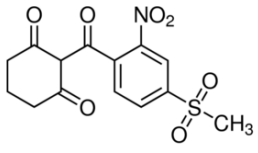
Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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.

7.2 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	$C_{14}H_{13}NO_7S$
Molar mass	339.3 g/mol
Chemical group	Triketone

Mode of action (if available)	HPPD inhibitor
Systemic	~~No~~ Yes
Company	Syngenta
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved Date of 01/10/2003 COMMISSION DIRECTIVE 03/68/EC Reg. (EU) 2017/725, date of approval 01/06/2017, Expiration of approval 31/05/2032
Restriction	~~None~~ Approval is restricted to uses as herbicide only.
Review Report	SANTE/11654/2016
Current MRL regulation	Regulation (EC) No 2017/626
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending, Reasoned opinion available only.
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	~~EFSA-Q-2008-585 (EMS)~~ ~~Maize~~ ~~Status: Reasoned opinion available (EFSA Journal 2015;13(1):3976)~~ None

* 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
		Mesotrione	MNBA	
Data relied on in EU				
Plant products				
Maize forage	High water content	31 months	42 months	EFSA, 2016
Maize grain	High starch content	42 months	42 months	EFSA, 2016

Conclusion on stability of residues during storage

Mesotrione is considered to be stable under freezer storage at -18°C ± 5°C for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at -18°C ± 5°C of MNBA in maize grain and forage was demonstrated for at least 42 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

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
			Method, F or G (a)	Rate (kg a.s./ha)	Sampling (DAT)	Remarks	
EU data							
Cereals	Maize	cyclohexane-2-^{14}C and phenyl-U-^{14}C	F	280–307 g a.s./ha (pre-emergence)	Forage: 27 Fodder: 154 Grain: 154	-	EFSA journal 2016;14(3):4419
				161–164 g a.s./ha (post- emergence)	Forage : 28 Fodder: 125 Grain : 125	-	EFSA journal 2016;14(3):4419

Summary of plant metabolism studies reported in the EU

The information provided in the EFSA Journal 2016;14(3):4419 is reported below:
Plant metabolism was studied in maize (pre- and post-emergence) with mesotrione labelled on cyclohexane-2-^{14}C and phenyl-U-^{14}C. In maize, parent mesotrione was hardly recovered (3% TRR in maize forage only) whilst the most pertinent metabolite 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. Further metabolites' identification was not conducted in maize grain due to the very low recovered total residues (0.014 mg/kg The unextracted radioactivity was further characterized as carbohydrates (maize) incorporated into the natural constituents of the plant. The metabolism of mesotrione in maize 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 maize.

Conclusion on metabolism in primary crops

According to the EFSA Journal 2016;14(3):4419 conclusions: "*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 needs to be addressed (see data gap in section 2). ***For risk assessment in feed commodities*** *and pending on the toxic logical 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.*** *For future uses on genetically modified crops and considering the significant proportions of 4/5-hydroxy mesotrione recovered in soya bean forage and hay, this compound may have to be included in the residue definition for risk assessment pending on its toxicological relevance".*

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
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Broad Leaves Endive	cyclohexane-2-^{14}C and phenyl-U-^{14}C	F	164 g a.s./ha	120	300	The 300 DAT crops were not harvested.	EFSA journal 2016;14(3):4419 DAR UK, 1999
Root and tuber vegetables	Radish	cyclohexane-2-^{14}C and phenyl-U-^{14}C	F	164 g a.s./ha	120	300	The 300 DAT crops were not harvested.	EFSA journal 2016;14(3):4419 DAR UK, 1999
Cereals	Wheat	cyclohexane-2-^{14}C and phenyl-U-^{14}C	F	164 g a.s./ha	120	300	The 300 DAT crops were not harvested.	EFSA journal 2016;14(3):4419 DAR UK, 1999

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

Summary of plant metabolism studies reported in the EU

The information provided in the EFSA Journal 2015;13(1):3976 is reported below:

The metabolism and distribution of ZA 1296 was investigated in the rotational crops wheat, endive and radish planted 120 and 300 days following soil application of [^{14}C] ZA 1296 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 ZA 1296 were <0.001-0.002 mg/kg. TRR in the crops grown in soil treated with [^{14}C]-phenyl labelled ZA 1296 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). ZA 1296 was not detected.
The metabolism of mesotrione is similar in rotational crops to that observed in primary crops.

Conclusion on metabolism in rotational crops

According to the EFSA Journal 2016;14(3):4419 conclusions: *"The metabolism of Mesotrione in rotational crops was found to be similar to the primary crops."*

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

According to the 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)".*

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

Residues in the Raw Agricultural Commodity are <0.01 mg/kg. Therefore, since no significant residues occur in any relevant commodity, no studies are required for the renewal of approval on the nature of residue.

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	Cereals / grass crops (maize)
Rotational crops covered	Root/tuber crops (Radish) Leafy crops (Broad leaves endive) Cerelas (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not relevant.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	Mesotrione (cereals and pulses/oilseeds only) EFSA journal 2016;14(3):4419
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 only – Conventional crops) – Provisional. EFSA journal 2016;14(3):4419
Conversion factor from enforcement to RA	Not applicable

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
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	phenyl-U-^{14}C AMBA	1	0.4	7	Milk	daily	EFSA journal 2016;14(3):4419
						Liver	at sacrifice	
						Kidney	at sacrifice	
						Subcutaneous fat	at sacrifice	
						Perirenal fat	at sacrifice	

Summary of plant metabolism studies reported in the EU

According to the EFSA Journal 2016;14(3):4419*: The total residues were below 0.01 mg/kg in all matrices except in kidney (0.053 mg/kg) and fat (0.018 mg/kg) with AMBA being the predominant compound that accounted for 79% TRR and 62% TRR, respectively. A fish metabolism study is also not requested. 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*.

Conclusion on metabolism in livestock

According to the EFSA Journal 2016;14(3):4419*:* 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. A fish metabolism study is also not requested

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	Cow
Time needed to reach a plateau concentration	5 days in milk
Animal residue definition for monitoring	Not required for the representative use. EFSA journal 2016;14(3):4419
Animal residue definition for risk assessment	Not required for the representative use. 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.

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

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

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

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of SHA 4300 A 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	EFSA Journal 2016;14(3):4419 DAR Mesotrione 1999	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 16-18, outdoor Forage: ~~6~~ 5x < 0.01, PHI [30-63] Silage: ~~6~~ 5x < 0.01, PHI [68-801] Grain: ~~6~~ 5x < 0.01, PHI [78-120] Grain + cob: ~~6~~ 5x x < 0.01, PHI [78-120] Grain + cob + husk: ~~6~~ 5x x < 0.01, PHI [78-120] GAP on which MRL/EU a.s. assessment is based: 1 x 0.2 kg as/ha, BBCH 17-18, outdoor Forage: 4x < 0.01, PHI [14-56] Silage: 4x < 0.01, PHI [90-110] Grain: 4x < 0.01, PHI [109-135] Grain + cob: 4x < 0.01, PHI [109-135] Grain + cob + husk: 4x < 0.01, PHI [109-135]	N/A				
	Overall supporting data for cGAP	N-EU	Forage: 9x < 0.01 Silgae: 9x < 0.01 Grain: 9x < 0.01 Grain + cob: 9x < 0.01 Grain + cob + husk: 9x < 0.01	0.01	0.01		0.01	Yes

* Source of EU MRL: EU 2017/626

7.2.3.2 Conclusion on the magnitude of residues in plants

For the use of Maize, are available in the RAR (for details please refer to the point A 2.1.3) enough trials to cover the proposed GAP. 6 trials carried out with dose of 150 g ai/ha and 4 trials carried out with dose of 200 g ai/ha, and all results below LOQ (<0,01 mg/kg).

According to the available data, the intended uses on maize is considered acceptable, for outdoor uses.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1 Mesotrione				
Maize grain	0.01	Median residue	0.01	Median residue
Maize fodder	0.01	Median residue	0.01	Median residue
Maize forage	0.01	Median residue	0.01	Median residue
Rapeseed meal	0.01	Median residue	0.01	Median residue
Linseed meal	0.01	Median residue	0.01	Median residue
Risk assessment residue definition 2 AMBA metabolite (including its conjugates)				
Maize grain	0.014	-	0.014	Total residues from the metabolism data
Maize fodder	0.301 (provisional)	-	0.301 (provisional)	Maximum residues level for total AMBA (including its conjugates) recovered from the metabolism data. Pending clarification of the genotoxic potential of AMBA and of its toxicological profile GAP-compliantresidue trials for the determination of AMBA conjugates residues in maize fodder, forage may be needed and the livestock dietary burden to be revised accordingly
Maize forage	0.043 (provisional)	-	0.043 (provisional)	

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Trigger exceeded (Y/N)
Risk assessment residue definition 1 (Mesotrione)				
Cattle (all diets)	0,004	0,004	Maize	N
Cattle (dairy only)	0,004	0,004		N
Sheep (all diets)	0,001	0,001		N
Sheep (ewe only)	0,001	0,001		N
Swine (all diets)	0,002	0,002		N
Poultry (all diets)	0,003	0,003		N
Poultry (layer only)	0,003	0,003		N
Risk assessment residue definition 2 (AMBA)				
Cattle (all diets)	0,001	0,001	Maize	N
Cattle (dairy only)	0,001	0,001		N
Sheep (all diets)	0,001	0,001		N
Sheep (ewe only)	0,001	0,001		N
Swine (all diets)	0,001	0,001		N
Poultry (all diets)	0,002	0,002		N
Poultry (layer only)	0,002	0,002		N

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The maximum dietary burden of Mesotrione in all animal species assessed is shown to be below the intake limit in feed items. Therefore, livestock feeding studies have not been performed.

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

7.2.5.1 Available data for all crops under consideration

Processing studies are not necessary since no significant or analytically determinable residues greater than the limit of quantification occur in the crops considered in this submission, and the theoretical maximum daily intake is calculated to be <10% of the ADI.

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

7.2.5.2 Conclusion on processing studies

Intended uses are safe concerning distribution of residues and their level in processed commodities because no residues are found above the appropriate LOQ.

7.2.6 Magnitude of residues in representative succeeding crops

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

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 7.2-11: 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 (DAR UK, 1999)					
Maize	0.340	Leafy vegetables	Soybean forage	30	EFSA Journal 2016;14(3):4419
			Soybean hay	30	EFSA Journal 2016;14(3):4419
			Soybean seed	30	EFSA Journal 2016;14(3):4419
		Root and tuber vegetables	Radish tops	30	EFSA Journal 2016;14(3):4419
			Radish roots	30	EFSA Journal 2016;14(3):4419
		Small Grain	Millet forage	30	EFSA Journal 2016;14(3):4419
			Sorghum forage	30	EFSA Journal 2016;14(3):4419
			Millet hay	30	EFSA Journal 2016;14(3):4419
			Millet straw	30	EFSA Journal 2016;14(3):4419
			Millet grain	30	EFSA Journal 2016;14(3):4419
	0.34 + 0.22 (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)	Leafy vegetables	Endive leaves	74	EFSA Journal 2016;14(3):4419
		Root and tuber vegetables	Radish tops	85	EFSA Journal 2016;14(3):4419
			Radish roots	85	EFSA Journal 2016;14(3):4419
		Small grain	Wheat forage	100	EFSA Journal 2016;14(3):4419
			Wheat hay	100	EFSA Journal 2016;14(3):4419
			Wheat straw	100	EFSA Journal 2016;14(3):4419
			Wheat grain	100	EFSA Journal

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
					2016;14(3):4419
Maize	0.340	Leafy vegetables	Soybean forage	29	EFSA Journal 2016;14(3):4419
			Soybean hay	29	EFSA Journal 2016;14(3):4419
			Soybean seed	29	EFSA Journal 2016;14(3):4419
		Root and tuber vegetables	Radish tops	29	EFSA Journal 2016;14(3):4419
			Radish roots	29	EFSA Journal 2016;14(3):4419
		Small grain	Millet forage	29	EFSA Journal 2016;14(3):4419
			Sorghum forage	29	EFSA Journal 2016;14(3):4419
			Millet hay	29	EFSA Journal 2016;14(3):4419
			Millet straw	29	EFSA Journal 2016;14(3):4419
			Millet grain	29	EFSA Journal 2016;14(3):4419
	0.34 + 0.22 (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)	Leafy vegetables	Endive leaves	98	EFSA Journal 2016;14(3):4419
		Root and tuber vegetables	Radish tops	98	EFSA Journal 2016;14(3):4419
			Radish roots	98	EFSA Journal 2016;14(3):4419
		Small grain	Wheat forage	98	EFSA Journal 2016;14(3):4419
			Wheat hay	98	EFSA Journal 2016;14(3):4419
			Wheat straw	98	EFSA Journal 2016;14(3):4419
			Wheat grain	98	EFSA Journal 2016;14(3):4419

In the two trials presented above, residues of Mesotrione and MNBA metabolite were determined in a range of rotational crops planted after ageing periods of 29 to 100 days, following applications of Mesotrione to both soil and soil + crop. The soil and crop application rates were approximately 2x and 3x the GAP post-emergence application rate, respectively, and no residues of Mesotrione or MNBA were present in the succession/rotational crops at harvest, with a limit of quantification of 0.01 mg/kg.

Conclusion on rotational crops studies

Metabolism studies in rotational crops showed that the metabolic pathway in primary and succeeding crops is essentially the same: Mesotrione was metabolised in MNBA, which is further reduced to AMBA. Under field conditions, no significant residues of Mesotrione or MNBA were found in rotated crops even after application at levels at least twice the proposed EU GAP. These results are consistent with the conclusions that additional field studies in succeeding crops are not required due to the rapid decline of Mesotrione observed in crop residue field studies.

zRMS comments:

According to EFSA Journal 2016;14(3):4419:

Confined rotational crop study: Bare soil application of mesotrione labelled respectively on cyclohexane-2-^{14}C and phenyl-U^{14}C at a dose rate of 164 g a.s./ha (1N). At 120 day plant back interval (PBI), TRRs are very low in all crop parts: <0.01 mg/kg in wheat grain and radish root, 0.012 mg/kg in broad-leaves endive and up to 0.033 mg/kg in wheat forage and straw. Metabolites' identification at 300 d PBI not further investigated.

Field rotational crop study: Not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate 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 of MNBA were < 0.01 mg/kg in all crop parts.

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 SHA 4300 A. 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 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1 (Mesotrione)				
Input vales are based on MRL's from the Reg. (EU) Reg. (EU) 2017/626				

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	12 % (based on NL toddler) 7 % (NL child)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	**Raw commodities** Maize/corn: 0,3% (based on acute risk assessment – children) Maize/corn: 0,1% (based on acute risk assessment –adult) **Processed commodities** Maize/oil: 1 % (based on acute risk assessment – children)

	Maize/processed: 0,1 % (based on acute risk assessment – children) Maize/oil: 0,6 % (based on acute risk assessment –adult)
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

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

The proposed uses of Mesotrione in the formulation MIGHTY (MESOTRIONE 10% SC) do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

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 396/20051. EFSA Journal 2015;13(1):3976.

European Commission, 2003. Review report for the active substance mesotrione. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 11 April 2003 in view of the inclusion of mesotrione in Annex I of Directive 91/414/EEC. SANCO 1416/2001.

EFSA (European Food Safety Authority), 2016. Peer review of the pesticide risk assessment of the active substance mesotrione. EFSA Journal 2016;14(3):4419

United Kingdom, 1999. Initial risk assessment provided by the Rapporteur Member State United Kingdom for the active substance Mesotrione (ZA1296) as referred to in Article 8(1) of Council Directive 91/414/EEC. December 1999.

Appendix 1 Lists of data considered in support of the evaluation

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
KCP 8.3.1	Barnes J.P. et al.	1995-1996	Residue Levels in Maize from Trials Carried out in Germany and France (59806, 59808, 59810, 59812) Zeneca Agrochemicals, Jealott's Hill, United Kingdom Yes Published	N	SYN
KCP 7.2.1.1	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, published Syngenta File No ZA1296/0125	N	SYN
KCP 7.2.2.1	Wei, Y. et al	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B Yes Published	N	SYN
KCP 7.2.2.1	Tarr, J.B. et al	1997	[Phenyl-U-14C]ZA 1296: nature of the residues in corn Yes Published	N	SYN
KCP 7.2.2.2	Gorder, G.W. et al	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate Yes Published	N	SYN
KCP 7.2.2.5	Hand, L.H.	1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow Yes Published	N	SYN
KCP 7.2.6.1	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	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
			Report No:RR 97-044B Yes Published		

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Mesotrione

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new data provided.

A 2.1.1.1.2 Storage stability of residues in animal products

No new data provided.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new data provided.

A 2.1.2.1.2 Nature of residue in rotational crops

No new data provided.

A 2.1.2.1.3 Nature of residues in processed commodities

No new data provided.

A 2.1.2.2 Nature of residues in livestock

No new data provided.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Maize

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (1)	1	0,15-0,2 kg sa/ha	-	BBCH 16-18	N/A

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

A 2.1.3.1.1 Study 1

Reference: EU data

Report: ZA1296. Residue Levels in Maize from Trials Carried out in Germany and France (59806, 59808, 59810, 59812)
Zeneca Agrochemicals, Jealott's Hill, United Kingdom

Guideline(s): -

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing seasons of 1995-1996, a total of ten trials were conducted in maize in Northern Europe to determine the magnitude and decline of residues of Mesotrione and its metabolites in or on raw agricultural commodities (RAC).

Residues of ZA 1296 and MNBA were <0.01 mg/kg (the limit of quantification) in immature maize sampled at 12-15 days PHI. The analytical results in mg of metribuzin per kg are summarized in Table A.2:

Results:

Table A 2: Summary of the EU data

Trial No./ Location/ EU zone/ Year	Commodi-ty/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treat-ment or date	Portion ana-lyzed	Residues (mg/kg)		PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				ZA 1296	MNBA		
	(a)	(b)				(c)					(d)	(e)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				ZA 1296	MNBA		
	(a)	(b)				(c)					(d)	(e)
DP 59806/ NORTH FRANCE / NEU / 1995	Maize/ Bangy	n.a.	0.15	300	0.05	1	6-8 leaves (16-18 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	4.58 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.15 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 14 63 80 120 120 120	Limited weather and crop maintenance data. Different 100g/l SC used to that specified in the Submission. Barnes, J.P et al., 1997a
DP 59808/ NORTH FRANCE / NEU / 1996	Maize/ Cecilia	n.a.	0.20	300	0.07	1	6 leaves (16 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	14.4 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.12 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 14 61 92 146 146 146	Limited weather and crop maintenance data. Barnes, J.P et al., 1997b
DP 59810/ GERMANY / NEU / 1995	Maize/ Diamant	n.a.	0.15	300	0.05	1	7 leaves (17 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	9.23 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.08 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 13 32 68 78 78 78	Barnes, J.P et al., 1997c
DP 59810/ GERMANY / NEU / 1995	Maize/ General	n.a.	0.15	300	0.05	1	7 leaves (17 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	10.31 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.08 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 14 32 73 114 114 114	Barnes, J.P et al., 1997c
DP 59810/ GERMANY / NEU / 1995	Maize/ Graf	n.a.	0.15	300	0.05	1	6-7 leaves (16-17 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob +	11.56 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.08 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 14 32 78 114 114 114	Barnes, J.P et al., 1997c

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				ZA 1296	MNBA		
								Husk				
DP 59810/ GERMANY / NEU / 1995	Maize/ Anjou 207	n.a.	0.15	300	0.05	1	6-7 leaves (16-17 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	5.98 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.20 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 15 30 70 112 112 112	Barnes, J.P et al., 1997c
DP 59812/ GERMANY / NEU / 1996	Maize/ Janna	n.a.	0.20	200	0.10	1	6 leaves (16 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	23.2 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.10 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 14 44 86 109 109 109	Samples were received thawed after 9 days in transit. Barnes, J.P et al., 1997d
DP 59812/ GERMANY / NEU / 1996	Maize/ Ilias	n.a.	0.20	200	0.10	1	7 leaves (17 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	10.9 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.10 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 14 35 110 135 135 135	Barnes, J.P et al., 1997d
DP 59812/ GERMANY / NEU / 1996	Maize/ Helix	n.a.	0.20	200	0.10	1	8 leaves (18 BBCH)	Immature Immature Forage Silage Grain Grain + Cob Grain + Cob + Husk	9.21 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.08 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0 14 36 88 126 126 126	Barnes, J.P et al., 1997d
DP 59812/ GERMANY / NEU / 1995	Maize/ Samantha	n.a.	0.15	300	0.05	1	7-8 leaves (17-18 BBCH)	Silage Grain Grain + Cob Grain + Cob + Husk	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01	76 121 121 121	Barnes, J.P et al., 1997d

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method an

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

A 2.1.4.1.1 Livestock feeding study 1

No new data provided.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new data provided.

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Study 1

No new data provided.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data provided.

A 2.1.7 Other/Special Studies

No new data provided.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

MESOTRIONE

LOQs (mg/kg) range from: **0,01** to: **0,05**

Toxicological reference values

ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,02**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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 : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	12%	NL toddler	1,24	6%	Milk: Cattle	1%	Apples	0,7%	Maize/corn	12%	12%
	7%	NL child	0,67	2%	Milk: Cattle	0,8%	Sugar beet roots	0,6%	Apples	7%	7%
	6%	DE child	0,64	2%	Milk: Cattle	1%	Apples	0,4%	Wheat	6%	6%
	6%	UK infant	0,61	4%	Milk: Cattle	0,3%	Potatoes	0,3%	Wheat	6%	6%
	6%	FR toddler 2 3 yr	0,56	3%	Milk: Cattle	0,3%	Apples	0,3%	Wheat	6%	6%
	6%	FR child 3 15 yr	0,55	2%	Milk: Cattle	0,5%	Wheat	0,4%	Sugar beet roots	6%	6%
	5%	GEMS/Food G11	0,49	1%	Soyabeans	0,8%	Milk: Cattle	0,4%	Potatoes	4%	5%
	4%	UK toddler	0,45	2%	Milk: Cattle	0,4%	Wheat	0,3%	Potatoes	4%	4%
	4%	GEMS/Food G10	0,43	1,0%	Soyabeans	0,5%	Milk: Cattle	0,4%	Wheat	3%	4%
	4%	GEMS/Food G07	0,42	0,6%	Milk: Cattle	0,5%	Soyabeans	0,4%	Wheat	4%	4%
	4%	GEMS/Food G08	0,42	0,6%	Soyabeans	0,6%	Milk: Cattle	0,4%	Wheat	4%	4%
	4%	GEMS/Food G15	0,42	0,7%	Milk: Cattle	0,5%	Soyabeans	0,5%	Wheat	4%	4%
	4%	DK child	0,41	1%	Milk: Cattle	0,6%	Rye	0,4%	Wheat	4%	4%
	4%	GEMS/Food G06	0,41	0,7%	Wheat	0,4%	Soyabeans	0,4%	Tomatoes	4%	4%
	4%	RO general	0,38	1%	Milk: Cattle	0,5%	Wheat	0,4%	Potatoes	4%	4%
	4%	ES child	0,38	1%	Milk: Cattle	0,4%	Wheat	0,3%	Cocoa beans	4%	4%
	4%	SE general	0,37	1%	Milk: Cattle	0,4%	Bovine: Muscle/meat	0,4%	Potatoes	4%	4%
	4%	DE women 14-50 yr	0,37	1%	Milk: Cattle	0,5%	Sugar beet roots	0,3%	Apples	4%	4%
	4%	DE general	0,36	1%	Milk: Cattle	0,4%	Sugar beet roots	0,2%	Apples	4%	4%
	4%	FI adult	0,35	3%	Coffee beans	0,1%	Potatoes	0,1%	Rye	4%	4%
	3%	IE adult	0,33	0,4%	Milk: Cattle	0,4%	Sweet potatoes	0,2%	Wheat	3%	3%
	3%	NL general	0,30	0,8%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Potatoes	3%	3%
	3%	FR infant	0,29	2%	Milk: Cattle	0,2%	Potatoes	0,2%	Apples	3%	3%
	2%	FR adult	0,22	0,4%	Milk: Cattle	0,2%	Wine grapes	0,2%	Wheat	2%	2%
	2%	PT general	0,21	0,5%	Potatoes	0,4%	Wheat	0,2%	Wine grapes	2%	2%
	2%	ES adult	0,21	0,5%	Milk: Cattle	0,2%	Wheat	0,1%	Oranges	2%	2%
	2%	FI 3 yr	0,18	0,5%	Potatoes	0,1%	Bananas	0,1%	Wheat	2%	2%
	2%	IT toddler	0,16	0,7%	Wheat	0,2%	Other cereals	0,1%	Tomatoes	2%	2%
	2%	DK adult	0,16	0,5%	Milk: Cattle	0,1%	Potatoes	0,1%	Wheat	2%	2%
	2%	LT adult	0,16	0,4%	Milk: Cattle	0,3%	Potatoes	0,2%	Apples	2%	2%
	1%	UK vegetarian	0,15	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	1%	1%
	1%	FI 6 yr	0,14	0,4%	Potatoes	0,1%	Cocoa beans	0,1%	Wheat	1%	1%
	1%	UK adult	0,14	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	1%	1%
	1%	IT adult	0,12	0,4%	Wheat	0,1%	Tomatoes	0,1%	Apples	1%	1%
	1,0%	PL general	0,10	0,3%	Potatoes	0,2%	Apples	0,1%	Tomatoes	1,0%	1,0%
	0,8%	IE child	0,08	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,8%	0,8%

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 since TMDI does not exceed ADI

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**IESTI new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
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)	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)
0,3%	Maize/corn	0,01 / 0,01	0,07	0,1%	Maize/corn	0,01 / 0,01	0,02	0,3%	Maize/corn	0,01 / 0,01	0,07	0,1%	Maize/corn	0,01 / 0,01	0,02
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**							

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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 spe	0,01 / 0,01	0,01												
Expand/collapse list															

Appendix 4 Additional information provided by the applicant

Not needed.