

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

Detailed summary of the risk assessment

Product code: MEZOT 100 SC

Product name(s): Mezot 100 SC

Chemical active substance:

Mesotrione, 100 g/L

Central

Zonal Rapporteur Member State: POLAND

#### **CORE ASSESSMENT**

(authorization)

Applicant: Elvita Sp. z o.o.

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## Version history

When	What
02.02.2023	Point 7.1 – Completion of data and information.
02.02.2023	Point 7.2.3 – Correction of content.
02.02.2023	Point 7.2.4 – Correction of content.
02.02.2023	Appendix 1 – Completion of data and information.
08.2023	ZRMs evaluated dRR submitted by Applicant
12.2023	The final Registration Report

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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

The plant protection product Mezot 100 SC, registered only in Poland, contains one active substance:  
- Mesotrione (CAS number: 104206-82-8), for which after the renewal of the approval (01/06/2017), the data protection period in Poland expired on 02/07/2020,  
on the basis of renewal of certain authorisation of plant protection products registered in Poland.

#### Storage stability

The stability of residues during storage of samples was reviewed during the Annex I inclusion process and no further data is required.

Mesotrione is considered to be stable under freezer storage at  $-18^{\circ}\text{C}\pm 5^{\circ}\text{C}$  for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at  $-18^{\circ}\text{C}\pm 5^{\circ}\text{C}$  of MNBA in maize grain and forage was demonstrated for at least 42 months.

#### Metabolism in plants and animals

Metabolism in plants and livestock data was provided during the EU review of mesotrione.

Plant residue definition for monitoring Mesotrione (cereals and pulses/oilseeds only) - EFSA journal 2016;14(3):4419, Reg. (EU) 2017/626

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

#### Magnitude of residues in plants

Proposed GAP for maize is within the EU GAP (SANTE/11654/2016, 23 March 2017).

Sufficient unprotected data were submitted and evaluated in DAR and RAR, and considered enough to support the intended use in maize in NEU. Unprotected data are accepted in RAR.

An exceedance of the current MRL of 0.01 mg/kg for mesotrione on maize as laid down in Reg. (EC) No 396/2005 is not expected.

#### Magnitude of residues in livestock

No new data were submitted in the framework of this application and no required. Dietary burden calculations made by the Applicant are accepted.

Animals are not exposed to residues via feed above the trigger value (0.004 mg/kg). Therefore livestock feeding studies are not required.

Dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data were tentatively estimated by EFSA (EFSA Journal 2016;14(3):4419).

EFSA (2016): *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.*

According to the EFSA Supporting publication 2018:EN-1527, genotoxic potential of AMBA is consid-

ered clarified:

*EFSA: we agree with the RMS conclusion that the micronucleus test gave sufficient evidence of lack of genotoxic (clastogenic and aneugenic) potential of the metabolite AMBA since bone marrow exposure was demonstrated after 2 dosing with the substance with 24 h interval and measurement of AMBA in whole blood. We agree with the RMS that the confirmatory data requirement (1) has been fulfilled. It is however noted that the data gap identified in the EFSA conclusion (EFSA, 2016) regarding the relative toxicity of the metabolite compared with mesotrione has not been addressed.*

#### **Magnitude of residues in processed commodities**

As residues of Mesotrione are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

#### **Magnitude of residues in representative succeeding crops**

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

Field rotational crop study are not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate. No mitigation measures for rotational crops are necessary.

#### **Other / special studies**

Studies are not required. Maize is not a melliferous crop foraged by bees.

#### **Estimation of exposure through diet and other means**

Chronic consumer risk assessment was performed by zRMS with EFSA PRIMo model rev. 3.1 for all commodities; the current MRLs for mesotrione (Regulation (EU) 2017/626), were used as input values.

For acute risk assessment only the crop of interest was used for the assessment.

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

### **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 Mezot 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 regarding Maize 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, Poland agrees with the authorization of the intended use(s).

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

**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	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Maize	F	<i>Anthemis arvensis</i> , <i>Elymus repens</i> , <i>Amaranthus retro- flexus</i> , <i>Capsella bursa-pastoris</i> , <i>Chenopodium album</i> , <i>Echi- nochloa crus-galli</i> , <i>Falconeria</i> , <i>Fu- maria officinalis</i> , <i>Galium aparine</i> , <i>Galium palustre</i> , <i>Lamium pur- pureum</i> , <i>Tripleu- rospermum ino- dorum</i> , <i>Fallopia convolvulus</i> , <i>Sina- pis arvensis</i> , <i>Sola- num nigrum</i> , <i>Stel- laria media</i> , <i>Thlas- pi arvense</i> , <i>Viola arvensis</i> .	Foliar spraying; small drops	BBCH 12- 18	1	-	a) 1,5 a) 1,5	a) Mesotrione - 150	200- 300	-	Herbicide for use with field sprayers	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

Mezot 100 SC is composed of one active substance - 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	2016	0,01 mg/ka/day	Mouse multi-generation	200
ARfD	EFSA	2016	0,02 mg/ka/day	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	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

### 7.1.2.2 Summary for Mezot 100 SC

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

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mesotrione		
Maize	Na	Yes		

NR: not relevant

\* Purpose of withholding period to be specified

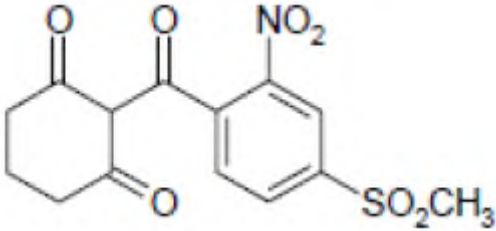
\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

## Assessment

### 7.2 Mesotrione

General data on Mesotrione are summarized in the table below.

**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 <sub>14</sub> H <sub>13</sub> NO <sub>7</sub> S
Molar mass	339,3
Group	Triketons
Mode of action (if available)	Systemic
Systemic	Yes
Company (ies)	Syngenta Crop Protection AG
Rapporteur Member State (RMS)	UK
Approval status	Approved Date: 01.06.2017
Restriction	Only uses as herbicide may be authorised.
Review Report	EFSA Journal 2016;14(3):4419
Current MRL regulation	REGULATION (EU) No 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, 2016)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2016)
Current MRL applications on intended uses	EFSA Journal 2016;14(3):4419 Commodities

\* 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.

The stability of residues for the active substance was reviewed during the Annex I inclusion and renewal process (Annex II) and no further data is required. Conclusions of these studies are presented in EFSA Journal 2016;14(3):4419 and RAR for Mesotrione – Volume 3 Annex B.7: Residues.

Mesotrione and MNBA stable for up to two years when stored at approximately –18°C in: Maize (forage and grain).

### **7.2.1.2 Stability of residues in sample extracts (KCA 6.1)**

#### **Available data**

No additional data.

#### **Conclusion on stability of residues in sample extracts**

The stability of residues for the active substance was reviewed during the Annex I inclusion process (Annex II) and no further data is required. See point IIIA 7.2.1.1

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of mesotrione and MNBA in sample extracts.

## **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.

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.

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.

**Table 7.2-2 Metabolism in plants:**

Primary crops (Plant groups covered)	Crop groups	Crop(s)	Application(s)	DAT (days)
	Fruit crops	n.a.		
	Root crops	n.a.		
	Leafy crops	n.a.		
				Forage: 27
			280–307 g a.s./ha (pre-emergence)	Fodder: 154
	Cereals/grass crops	Maize		Grain: 154
				Forage: 28
			161–164 g a.s./ha (post- emergence)	Fodder: 125 Grain: 125
				Foliage: 90
		Peanut	305–327 g a.s./ha (pre-emergence)	Hay: 153 – 154 Nutmeat: 154 – 169
			796–836 g a.s./ha (pre-emergence)	
				Forage: 28
	Pulses/Oilseeds		218–226 g a.s./ha (pre-emergence)	Hay: 42 Seed: 123-124
		Herbicide tolerant soya bean	218–226 g a.s./ha (pre-emergence) fol- lowed by 128–130 g a.s./ha (post- emergence)	Forage: 28 Hay: 51 Seed: 90
				Forage: 22
			224–230 g a.s./ha (post- emergence)	Hay: 40 Seed: 110 - 118
	Miscellaneous			
	Studies conducted with mesotrione labelled on cyclohexane-2- <sup>14</sup> C and phenyl-U- <sup>14</sup> C.			

### 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.

The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

**Table 7.2-3 Metabolism in plants:**

Rotational crops (metabolic pattern)	Crop groups	Crop(s)	PBI (days)	Comments
	Root/tuber crops	Radish	120, 300	Mesotrione labelled on cyclohexane-2- <sup>14</sup> C and phenyl-U- <sup>14</sup> C was applied separately at a rate of 164 g a.s./ha to
	Leafy crops	Broad leaves Endive	120, 300	
Rotational crop and primary crop metabolism similar?	Cereal (small grain)	Wheat	120, 300	bare soil.
	Other			The 300 DAT crops were not harvested.
	Metabolism similar to primary crops.			

### 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.

**Table 7.2-4 Metabolism in plants:**

Processed commodities (standard hydrolysis study)	Conditions				
	20 min, 90°C, pH 4				
	60 min, 100°C, pH 5				
	20 min, 120°C, pH 6				
Residue pattern in processed commodities similar to residue pattern in raw 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).				

Plant residue definition for monitoring (RD-Mo)	Mesotrione (cereals and pulses/oilseeds only)
Plant residue definition for risk assessment (RD-RA)	Food commodities: Mesotrione (cereals and pulses/oilseeds only)  Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional.
Conversion factor (monitoring to risk assessment)	Not applicable

#### 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	Maize
Rotational crops covered	Radish, Broad leaves, Endive, Wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Mesotrione (Regulation n° 2017/626)
Plant residue definition for risk assessment	Mesotrione (EFSA 2016)
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**

	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	-	-	-
	Goat/Cow	0.4 (phenyl-U- <sup>14</sup> C AM-BA)	7	200 N (beef cattle) 130 N (dairy cattle)
	Pig	-	-	-

	Fish	-	-	-
	<p>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.</p> <p>A fish metabolism study is also not requested.</p>			
Time needed to reach a plateau concentration in milk and eggs (days)	Day 5			
Animal residue definition for monitoring (RD-Mo)	Not required (provisional)	for	the	representative use
Animal residue definition for risk assessment (RD-RA)	Not required (provisional)	for	the	representative use
Conversion factor (monitoring to risk assessment)	Not applicable			
Metabolism in rat and ruminant similar (Yes/No)	Yes			
Fat soluble residues (Yes/No)	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.			

#### 7.2.2.6 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	Laying hen Goat/Cow Pig Fish
Time needed to reach a plateau concentration	7 days in milk 5 days in eggs
Animal residue definition for monitoring	Mesotrione (Regulation n° 2017/626)
Animal residue definition for risk assessment	Mesotrione (EFSA 2016)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

## 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 Mezot 100 SC and conformity to existing MRL**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg)	MRL compliance
Maize	EFSA, 2016 RAR	N-EU	GAP on which MRL is based: 1 x 0.14-0.20 kg as/ha, BBCH 15-18, PHI 12-15d, outdoor All < 0.01	N/A				
		S-EU	GAP on which MRL is based: 1 x 0.14-0.20 kg as/ha, BBCH 13-18, PHI 12-15d, outdoor All < 0.01					
	Overall supporting data for cGAP	N-EU	Forage: 13 x < 0.01 Silage: 13 x < 0.01 Grain: 15 x < 0.01	0.01	0.01	0.01	0.01	Yes
		S-EU	Forage: 15 x < 0.01 Silage: 19 x < 0.01 Grain: 19 x < 0.01	0.01	0.01	0.01	0.01	Yes



### 7.2.3.2 Conclusion on the magnitude of residues in plants

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

### 7.2.4 Residues in livestock

#### 7.2.4.1 Dietary burden calculation

**Table 7.2-8.1: Input values for the dietary burden calculation (considering 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: mesotrione				
Corn, Field, Forage/Silage (Forages group)	0.01	Median residue	0.01	Highest residue
Corn, Field, Grain (Grain/Seeds group)	0.01	Median residue	0.01	Median residue
Corn, Field, Milled Byprods. (By-products group)	0.01	Median residue	0.01	Median residue
Corn, Field, Hominy Meal (By-products group)	0.01	Median residue	0.01	Median residue
Corn, Field, Gluten Feed (By-products group)	0.01	Median residue	0.01	Median residue
Corn, Field, Gluten Meal (By-products group)	0.01	Median residue	0.01	Median residue
Distiller's grain, Dried (By-products group)	0.01	Median residue	0.01	Median residue
Risk assessment residue definition: AMBA (including its conjugates)				
Corn, Field, Forage/Silage (Forages group)	0.043 (provisional)	-	0.043 (provisional)	Maximum residue levels of total AMBA (including its conjugates) recovered from the metabolism data. Pending clarification of the genotoxic potential of AMBA and of its toxicological profile GAP-compliant residue trials for the determination of AMBA

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
				conjugates residues in maize fodder, forage may be needed and the livestock dietary burden to be revised accordingly.*
Corn, Field, Grain (Grain/Seeds group)	0.014	-	0.014	Total residues from the metabolism data.
Corn, Field, Milled Byprods. (By-products group)	0.014	-	0.014	Total residues from the metabolism data.
Corn, Field, Hominy Meal (By-products group)	0.014	-	0.014	Total residues from the metabolism data.
Corn, Field, Gluten Feed (By-products group)	0.014	-	0.014	Total residues from the metabolism data.
Corn, Field, Gluten Meal (By-products group)	0.014	-	0.014	Total residues from the metabolism data.
Distiller's grain, Dried (By-products group)	0.014	-	0.014	Total residues from the metabolism data.

\* Based on the confirmatory data of mesotrione (EFSA Supporting publication 2018: EN-1527), it was agreed that the metabolite AMBA is unlikely to be genotoxic, however it was proposed to further discuss its toxicological profile in an experts' consultation since the metabolite is relevant to consumer exposure.

**Table 7.2-8.2: 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	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: mesotrione					
Beef cattle*	0.0009	0.0009	Corn, field, gluten feed	0.04	N
Dairy cattle*	0.0013	0.0013	Corn, field, gluten feed	0.03	N
Ram/ewe	0.0007	0.0007	Corn, field, gluten feed	0.02	N
Lamb	0.0009	0.0009	Corn, field, gluten feed	0.02	N
Breeding swine	0.001	0.001	Corn, field, gluten feed	0.02	N
Finishing swine*	0.001	0.001	Corn, field, gluten feed	0.02	N
Broiler poultry	0.001	0.001	Corn, field, milled byproducts	0.01	N

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Layer poultry*	0.002	0.002	Corn, field, hominy meal	0.02	N
Turkey	0.001	0.001	Corn, field, hominy meal	0.02	N
Fish	-	-	-	> 0.1 mg/kg DM	N
Risk assessment residue definition: AMBA (and its conjugates) (provisional)					
Beef cattle*	0.0025	0.0025	Corn, field, forage/silage	Not calculated	N
Dairy cattle*	0.0036	0.0036	Corn, field, forage/silage	Not calculated	N
Ram/ewe	0.0010	0.0010	Corn, field, gluten feed	Not calculated	N
Lamb	0.0013	0.0013	Corn, field, gluten feed	Not calculated	N
Breeding swine	0.001	0.001	Corn, field, forage/silage	Not calculated	N
Finishing swine*	0.001	0.001	Corn, field, gluten feed	Not calculated	N
Broiler poultry	0.001	0.001	Corn, field, milled byproducts	Not calculated	N
Layer poultry*	0.003	0.003	Corn, field, forage/silage	Not calculated	N
Turkey	0.002	0.002	Corn, field, hominy meal	Not calculated	N
Fish	-	-	-	-	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)

##### Available data

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

Maize is listed as potential feed item for domestic animals in EU SANCO Guidance Document 7031/VI/95 rev.4.

In the peer review for EU approval studies on the metabolism of mesotrione and its metabolite MNBA in livestock have not been carried out because mesotrione was detected at very low levels in maize forage and was not detectable in the maize fodder samples (either label).

But ruminant metabolism data have been provided for metabolite AMBA dosed at ca. 150N total free and conjugated AMBA or ca. 3000N based on free AMBA only. The conjugates of AMBA were not readily released by acid, base or enzyme hydrolysis. Based on the proposed GAP, residues in animal products are not expected to be significant (> 0.01 mg/kg). Therefore it was concluded in the EU review that livestock feeding studies for AMBA are not required. (RMS UK, 1999).

## **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**

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

### **7.2.5.2 Conclusion on processing studies**

The proposed uses of mesotrione in maize will not give rise to residues in the grain above 0.01 mg/kg. Since no significant residues occur in any relevant commodity and the total theoretical maximum daily intake (TMDI) is calculated to be less than <10% of the ADI, no studies are required for the renewal of approval..

## **7.2.6 Magnitude of residues in representative succeeding crops**

A limited crop rotation study was conducted to address the residue situation of mesotrione in succeeding or rotated crops under field conditions.

The following data were evaluated under Council Directive 91/414/EEC and are presented in the mesotrione monograph (Vol.3, Annex B, Section B.7.10, December 1999).

### **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. Residues in succeeding crops**

<b>Confined rotational crop study</b> (Quantitative aspect)	Bare soil application of mesotrione labelled respectively on cyclohexane-2- <sup>14</sup> C and phenyl-U- <sup>14</sup> 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.
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<b>Field rotational crop study</b>	<p>Not triggered considering the very low TRRs in rotational crops after a bare soil application at <i>ca.</i> 1N rate and considering also the low to moderate persistence of mesotrione, MNBA and AMBA.</p> <p>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 &lt; 0.01 mg/kg in all crop parts.</p>
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## 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 Mezot 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 7.1.2).

### 7.2.8.1 Input values for the consumer risk assessment

**Table 7.2-10: Toxicological reference values**

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesotrione					
ADI	EFSA	2016	0,01 mg/ka/day	Mouse multi-generation	200
ArfD	EFSA	2016	0,02 mg/ka/day	Mouse multi-generation	100

**Table 7.2-11: Input values for the consumer risk assessment**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize	0.05	Existing EU MRL	0.05	Existing EU MRL
All other crops	Existing EU MRL		Not required	

### 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-2: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo	<2% ADI for all diets included in the PRIMo model
IEDI (% ADI) according to EFSA PRIMo	-
IENTI (% ARfD) according to EFSA PRIMo*	Not relevant
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 Mezot 100 SC do not represent unacceptable acute and chronic risks for the consumer.

#### **zRMS comment:**

Chronic consumer risk assessment was performed with EFSA PRIMo model rev. 3.1 for all commodities; the current MRLs for mesotrione (Regulation (EU) 2017/626), were used as input values. For acute risk assessment only the crop of interest was used for the assessment.

TMDI (% ADI) according to EFSA PRIMo rev 3	12% NL toddler (highest contributor to MS diet: 6 % Milk, Cattle)
IEDI (% ADI) according to EFSA PRIMo rev.3	n.r.
IENTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: 0.3% Maize/corn (children) Unprocessed commodities: 0.1% Maize/corn (adults)  Processed commodities: 1% Maize/oil (children) Processed commodities: 0.6% Maize/oil (adults)
NTMDI (% ADI) **	n.r.
NEDI (% ADI)**	n.r.
NESTI (% ARfD) **	n.r.

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

 <p>European Food Safety Authority</p> <p>EFSA PRiMo revision 3.1; 2019/03/19</p>		<b>Mesotrione</b>				Input values					
		LOQs (mg/kg) range from: _____ to: _____									
		<b>Toxicological reference values</b>									
		ADI (mg/kg bw/day): <b>0.01</b>				ARID (mg/kg bw): <b>0.02</b>					
		Source of ADI: _____				Source of ARID: _____					
		Year of evaluation: _____				Year of evaluation: _____					
Comments:											
<b>Normal mode</b>											
<b>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</b>											
		No of diets exceeding the ADI : _____								Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	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		
	7%	NL child	0.66	2%	Milk: Cattle	0.8%	Sugar beet roots	0.6%	Apples		
	6%	DE child	0.63	2%	Milk: Cattle	1%	Apples	0.4%	Wheat		
	6%	UK infant	0.61	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat		
	6%	FR toddler 2 3 yr	0.56	3%	Milk: Cattle	0.3%	Apples	0.3%	Wheat		
	5%	FR child 3 15 yr	0.55	2%	Milk: Cattle	0.5%	Wheat	0.4%	Sugar beet roots		
	4%	UK toddler	0.45	2%	Milk: Cattle	0.4%	Wheat	0.3%	Potatoes		
	4%	GEMS/Food G11	0.42	0.8%	Milk: Cattle	0.4%	Potatoes	0.4%	Soyabeans		
	4%	DK child	0.41	1%	Milk: Cattle	0.6%	Rye	0.4%	Wheat		
	4%	GEMS/Food G07	0.38	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes		
	4%	GEMS/Food G06	0.38	0.7%	Wheat	0.4%	Tomatoes	0.2%	Milk: Cattle		
	4%	GEMS/Food G15	0.38	0.7%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes		
	4%	GEMS/Food G08	0.38	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes		
	4%	RO general	0.38	1%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes		
	4%	ES child	0.37	1%	Milk: Cattle	0.4%	Wheat	0.3%	Cocoa beans		
	4%	SE general	0.37	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.4%	Potatoes		
	4%	DE women 14-50 yr	0.37	1%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Apples		
	4%	GEMS/Food G10	0.37	0.5%	Milk: Cattle	0.4%	Wheat	0.3%	Soyabeans		
	4%	DE general	0.36	1%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Apples		
	4%	FI adult	0.35	3%	Coffee beans	0.1%	Potatoes	0.1%	Rye		
	3%	IE adult	0.33	0.4%	Milk: Cattle	0.4%	Sweet potatoes	0.2%	Wheat		
	3%	NL general	0.30	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Potatoes		
	3%	FR infant	0.29	2%	Milk: Cattle	0.2%	Potatoes	0.2%	Apples		
	2%	FR adult	0.22	0.4%	Milk: Cattle	0.2%	Wine grapes	0.2%	Wheat		
	2%	PT general	0.21	0.5%	Potatoes	0.4%	Wheat	0.2%	Wine grapes		
	2%	ES adult	0.21	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges		
	2%	FI 3 yr	0.18	0.5%	Potatoes	0.1%	Bananas	0.1%	Wheat		
	2%	IT toddler	0.16	0.7%	Wheat	0.2%	Other cereals	0.1%	Tomatoes		
	2%	DK adult	0.16	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat		
	2%	LT adult	0.16	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Apples		
	1%	UK vegetarian	0.15	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		
	1%	FI 6 yr	0.14	0.4%	Potatoes	0.1%	Cocoa beans	0.1%	Wheat		
1%	UK adult	0.14	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes			
1%	IT adult	0.12	0.4%	Wheat	0.1%	Tomatoes	0.1%	Apples			
1.0%	PL general	0.10	0.3%	Potatoes	0.2%	Apples	0.1%	Tomatoes			
0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes			
<b>Conclusion:</b> 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.											

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 ARID. The calculation is based on the large portion of the most critical consumer group.									<b>IENTI new calculations:</b> 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. <b>Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</b>															
Show results for all crops																								
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IENTI):				---				Results for adults No. of commodities for which ARID/ADI is exceeded (IENTI):				---				IENTI new Results for children No. of commodities for which ARID/ADI is exceeded (IENTI new):				IENTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IENTI new):			
	IENTI								IENTI								IENTI new							
	Highest % of ARID/ADI		Commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARID/ADI		Commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARID/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		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 ARID/ADI in children and adult diets (IENTI calculation)									Total number of commodities found exceeding the ARID/ADI in children and adult diets (IENTI new calculation)															
Processed commodities	Results for children No of processed commodities for which ARID/ADI is exceeded (IENTI):				---				Results for adults No of processed commodities for which ARID/ADI is exceeded (IENTI):				---				Results for children No of processed commodities for which ARID/ADI is exceeded (IENTI new):				Results for adults No of processed commodities for which ARID/ADI is exceeded (IENTI new):			
	IENTI								IENTI								IENTI new							
	Highest % of ARID/ADI		Processed commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARID/ADI		Processed commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARID/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 speci		0.01 / 0.01		0.01	
	0.1%		Maize / processed (not speci		0.01 / 0.01		0.01		0.1%		Maize / processed (not speci		0.01 / 0.01		0.01		0.1%		Maize / processed (not speci		0.01 / 0.01		0.01	
Expand/collapse list																								
<b>Conclusion:</b> No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Mesotrione is unlikely to present For processed commodities, no exceedance of the ARID/ADI was identified																								



### **7.3 Combined exposure and risk assessment**

Not relevant. The product contains only one active substance.

## **7.4           References**

Assessment report on the active substance Mesotrione prepared by the rapporteur Member State United Kingdom.

COMMISSION REGULATION (EU) 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products.

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

## Appendix 1 Lists of data considered in support of the evaluation

No studies submitted.

### 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
CP 8.1	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 DPDB Ref. 59800 GLP unpublished	N	Syngenta
CP 8.2.1	Wei, Y. <i>et al.</i>	1997	[Cyclohexane-2- <sup>14</sup> C]ZA 1296: Nature of the Residues in Corn ( <i>Zea mays</i> ) Zeneca Report No: RR 96-026B DPDB Ref. 59801 GLP unpublished	N	Syngenta
CP 8.2.1	Tarr, J.B. <i>et al.</i>	1997	[Phenyl-U- <sup>14</sup> C]ZA 1296: nature of the residues in corn Report No: not given DPDB Ref. 59802 GLP unpublished	N	Syngenta

CP 8.2.3		1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow Report No: not given DPDB Ref. 59803 GLP unpublished	Y	Syngenta
CP 8.3	Barnes, J.P. <i>et al.</i>	1997a	ZA 1296: Residue Levels in Maize from Trials Carried Out in France during 1995 Zeneca Agrochemicals Report No: RR 96-071B DPDB Ref. 59806 GLP unpublished	N	Syngenta
CP 8.3	Barnes, J.P. <i>et al.</i>	1997b	ZA 1296: Residue Levels in Maize from Trials Carried Out in France during 1996 Zeneca Agrochemicals Report No: RR 97-045B DPDB Ref. 59808 GLP unpublished	N	Syngenta
CP 8.33	Barnes, J.P. <i>et al.</i>	1997c	ZA 1296: Residue Levels in Maize from Trials Carried Out in Germany during 1995 Zeneca Agrochemicals Report No: RR 96-078B DPDB Ref. 59810 GLP unpublished	N	Syngenta
CP 8.3	Barnes, J.P. <i>et al.</i>	1997d	ZA 1296: Residue Levels in Maize from Trials Carried Out in Germany during 1995 Zeneca Agrochemicals Report No: RR 97-048B DPDB Ref. 59812 GLP unpublished	N	Syngenta

CP 8.3	Barnes, J.P. <i>et al.</i>	1997e	ZA 1296: Residue Levels in Maize from Trials Carried Out in Italy during 1995. Zeneca Agrochemicals Report No: RR 96-077B DPDB Ref. 59813 GLP unpublished	N	Syngenta
CP 8.3	Barnes, J.P. <i>et al.</i>	1997f	ZA 1296: Residue Levels in Maize from Trials Carried Out in Italy during 1995. Zeneca Agrochemicals Report No: RR 97-049B DPDB Ref. 59815 GLP unpublished	N	Syngenta
CP 8.6.1	Spillner, C. <i>et al.</i>	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate Report No.: not given DPDB Ref. 59812 GLP unpublished	N	Syngenta
CP 8.6.1	Gorder, G.W. <i>et al.</i>	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate Re- port No: not given DPDB Ref. 59818 GLP unpublished	N	Syngenta
CP 8.6.2	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 DPDB Ref. 59819 GLP unpublished	N	Syngenta

CP 8.1	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 DPDB Ref. 59800 GLP unpublished	N	Syngenta
CP 8.2.1	Wei, Y. <i>et al.</i>	1997	[Cyclohexane-2- <sup>14</sup> C]ZA 1296: Nature of the Residues in Corn ( <i>Zea mays</i> ) Zeneca Report No: RR 96-026B DPDB Ref. 59801 GLP unpublished	N	Syngenta
CP 8.2.1	Tarr, J.B. <i>et al.</i>	1997	[Phenyl-U- <sup>14</sup> C]ZA 1296: nature of the residues in corn Report No: not given DPDB Ref. 59802 GLP unpublished	N	Syngenta

## **Appendix 2 Detailed evaluation of the additional studies relied upon**

### **A 2.1 Mesotrione**

#### **A 2.1.1 Stability of residues**

No study submitted by applicant.

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

##### **A 2.1.2.1 Nature of residue in plants**

No study submitted by applicant.

##### **A 2.1.2.2 Nature of residues in livestock**

No study submitted by applicant.

#### **A 2.1.3 Magnitude of residues in plants**

No study submitted by applicant.

#### **A 2.1.4 Magnitude of residues in livestock**

No study submitted by applicant.

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

No study submitted by applicant.

#### **A 2.1.6 Magnitude of residues in representative succeeding crops**

No study submitted by applicant.

#### **A 2.1.7 Other/Special Studies**

No additional studies.









EFSA PRIMo revision 3.1: 2021/01/06

<h2 style="text-align: center;">Mesotrione</h2>			
LOQs (mg/kg) range from:		0.01	to: 0.01
<b>Toxicological reference values</b>			
ADI (mg/kg bw/day):		0.01	ARID (mg/kg bw): <b>not necessary</b>
Source of ADI:		Source of ARID:	
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 : ---						Exposure resulting from	
	Calculated exposure (in % 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	MRLs set at the LOQ (in % of ADI)	commodities under assessment (in % of ADI)
TMD/INEDI calculation (based on average food consumption)	0.7%	NL toddler	0.07	0.7%	Maize/corn						0.7%
	0.1%	GEMS/Food G06	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS				0.1%
	0.1%	UK infant	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS				0.1%
	0.1%	RO general	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS				0.1%
	0.1%	GEMS/Food G10	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS				0.1%
	0.1%	GEMS/Food G15	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS				0.1%
	0.0%	PT general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G08	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	FR child 3-15 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	ES child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	NL child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	IE adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	DE child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	NL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	FR toddler 2-3 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	ES adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	DE women 14-50 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	FR adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	DE general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	IT toddler	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	FI 6 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	FR infant	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	IT adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	FI 3 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	UK toddler	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	UK vegetarian	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	LT adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
	0.0%	FI adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%
0.0%	UK adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%	
0.0%	PL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%	
0.0%	IE child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%	
0.0%	DK child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				0.0%	
	DK adult				FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				0.0%
	DK adult				FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				0.0%

**Conclusion:**  
The estimated long-term dietary intake (TMDI/NEDI/EDI) was below the ADI.  
The long-term intake of residues of Mesotrione is unlikely to present a public health concern.  
**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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				
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.								<b>IESTI new calculations:</b> 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. <b>Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</b>								
Show results for all crops																
Unprocessed commodities	<b>Results for children</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):				<b>Results for adults</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):				<b>IESTI new Results for children</b> No. of commodities for which ARfD/ADI is exceeded (IESTI new):				<b>IESTI new Results for adults</b> No. of commodities for which ARfD/ADI is exceeded (IESTI new):			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI		Commodities		Highest % of ARfD/ADI		Commodities		Highest % of ARfD/ADI		Commodities		Highest % of ARfD/ADI		Commodities	
	MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	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)								
Processed commodities	<b>Results for children</b> No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				<b>Results for adults</b> No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				<b>Results for children</b> No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):				<b>Results for adults</b> No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI		Processed commodities		Highest % of ARfD/ADI		Processed commodities		Highest % of ARfD/ADI		Processed commodities		Highest % of ARfD/ADI		Processed commodities	
	MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	Expand/collapse list															

<b>Mesotrione</b>		Input values
		Go back to results - Overview
<b>Toxicological reference values</b>		Details - chronic risk assessment
ADI (mg/kg bw/day)	0.01	
Source of ADI		
Year of evaluation		
Comments		

Chronic risk assessment: Rees Day-model NEDI/TMDI=Σ 2 highest 97.5th percentile intakes + mean population intake for other foods) <sup>1</sup>									
TMDI/NEDI Rees-Day-model	Highest calculated TMDI/NEDI values in % of ADI	MS Diet		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
	0.5%	UK infant	*)	0.5%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	0.1%	UK toddler	*)	0.1%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	0.0%	UK vegetarian	*)	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	0.0%	FI 6 yr	*)	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	0.0%	FI 3 yr	*)	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	0.0%	UK adult	*)	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	0.0%	FI adult	*)	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	*) Calculation according to the UK approach (Rees-Day model equation; TMDI/NEDI = Σ 2 highest 97.5th percentile intakes + mean population intake for other foods) Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								

Chronic risk assessment:TMDI calculation										
	Calculated exposure (% of ADI)		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	commodities not under assessment (in % of ADI)
TMDI(NED)/ calculation (based on average food consumption)	0.7%	NL toddler	0.07	0.7%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.7%
	0.1%	GEMS/Food G06	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.1%
	0.1%	UK infant	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.1%
	0.1%	RO general	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.1%
	0.1%	GEMS/Food G10	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.1%
	0.1%	GEMS/Food G15	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.1%
	0.0%	PT general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	GEMS/Food G08	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	ES child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	NL child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	IE adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	DE child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	NL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	ES adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	DE women 14-50 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	FR adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	DE general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	IT toddler	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	FI 6 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	FR infant	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	IT adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	FI 3 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	UK toddler	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	UK vegetarian	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	LT adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	FI adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	UK adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
	0.0%	PL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%
0.0%	IE child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%	
0.0%	DK child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	0.0%	
	DK adult				FRUIT AND TREE NUTS		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
	DK adult				FRUIT AND TREE NUTS		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
	The TMDI calculations are for information purpose only. The results of the more refined intake calculations are presented in the spreadsheet "Results"									

## **Appendix 4    Additional information provided by the applicant**

No additional information.