FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: MEZ-HER 100 SC

Product names: MECORN 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023, March 2024

MS Finalisation date: May 2024, August 2024

Version history

When	What
03/2024	Applicant's update
05/2024	zRMS assessment of dRR
08/2024	The final Registration Report after 1st commenting period

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

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 -18ºC±5ºC for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at -18ºC±5ºC 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 and Reg. (EU) 2024/1077: Mesotrione.

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 (1 application, BBCH 14-15, 100 g as/ha) is less critical than 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.

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 considered 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.

Since the residues are below 0.01 mg/kg, no further calculations are required.

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

The proposed uses of mesotrione in the formulation MEZ-HER 100 SC do not represent unacceptable acute and chronic risks for the consumer. Calculations are accepted.

7.1.1 Critical GAP(s) and overall conclusion

Overall conclusion

This is the application for registration of a plant protection product under working name MEZ-HER 100 SC according to Article 33 and Article 34 of Regulation 1107/2009. MEZ-HER 100 SC is a suspension concentrate, containing 100 g/L of mesotrione to be used as an herbicide to protect maize.

The reference product Callisto 100 SC was registered in Poland in 2004 (authorisation no. R-2/2004 of 02.02.2004). Then in 2009 and 2020 the authorisation was renewed with authorisation no R-25/2009 of 27.02.2009 and decision no. R-990/2020d of 29.12.2020, respectively. In accordance with above, the data for protection for the formulation Callisto 100 SC and active substance mesotrione have expired.

In respect to the above and taking into account Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant do not provide residue data and apply for using unprotected data of Callisto 100 SC.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for mesotrione as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of mesotrione residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authorities agrees with the authorization of the intended use(s).
According to available data, no specific mitigation measures should apply.

Data gaps

None.

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

1	2	3	4	5	6	7		8				9			10	11
						Formulation		Application				Application rate				
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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Conclusion
1	Maize 0500030	N-EU	MEZ-HER 100 SC	F	Please refer to Part A or Part B0	SC	100 g/L	broadcast spraying	BBCH 14-15 Spring, post emergence	1	N/A	1 L/ha a) 1 L/ha b) 1 L/ha	100g mesotrione a) 100g mesotrione b) 100g mesotrione	200-300 L/ha	NR	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

Summary of the evaluation is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

The preparation MEZ-HER 100 SC is composed of mesotrione.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesotrione					
ADI	EFSA	2016	0.01 mg/kg bw/d	Mouse multi-generation study	200
ARfD	EFSA	2016	0.02 mg/kg bw/d	Mouse multi-generation study	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 (15)	Yes	Yes	Yes	No	No

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

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

Residues in succeeding crops have been sufficiently investigated. It is very unlikely that residues will be present in succeeding crops.

No new MRLs or mitigation measures have been proposed.

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

No acute risk has been identified for maize. The use of MEZ-HER 100 SC on proposed crops is therefore acceptable.

7.1.2.2 Summary for MEZ-HER 100 SC

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

Crop	PHI for MEZ-HER 100 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for mesotrione	PHI for MEZ-HER 100 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
Maize	F**	Yes		

* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for MEZ-HER 100 SC
Crop group	Led by mesotrione	
All	NR	

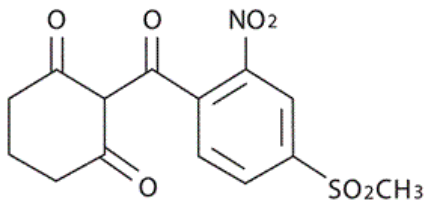
NR: not relevant

Information from Renewal RR for Callisto 100 SC that are also relevant for evaluation of MEZ-HER 100 SC is provided below. Since data protection for this information expired, summary of relevant information was copied from Renewal RR for Callisto 100 SC. Information copied form Renewal RR for Callisto 100 SC were evaluated and accepted in renewal process of Callisto 100 SC and are deemed to be acceptable for MEZ-HER 100 SC.

7.2 Active substance mesotrione

Active substance data is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

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 herbicide
Mode of action (if available)	Inhibition of HPPD (p-Hydroxyphenylpyruvate dioxygenase)
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved Date of approval: 01/10/2003 Date of renewal: 01/06/2017 Expiration of approval: 31/05/2032 Reg. (EU) 2017/725
Restriction	Restricted to uses as a herbicide
Review Report	SANCO/1416/2001 – Final 14/04/2003 SANTE/11654/2016, 23 March 2017
Current MRL regulation	Reg. (EU) 2017/626 , Reg. (EU) 2024/1077
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA, 2015)
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2016)
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Stability of Residues (KCA 6.1)

Data on stability of residues is included in RR for the reference product Callisto 100 SC. Please refer to

Renewal RR prepared for Callisto 100 SC. No further data are required.

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)

Commodity category	Commodity	Acceptable Maximum Storage duration	Report Reference	Source
EU reviewed data				
Plant products				
High water content	Maize, forage	31 months (mesotrione) 42 months (MNBA)	Wiebe, 1997 Report No: RR 97-042B INT Wiebe & Peyton, 1999 Report No. RR 97-042B FIN	UK, 2015, 2015a
	Maize, fodder	42 months (mesotrione, MNBA)		
	Radish, root	44 months		
High starch content	Maize, grain	42 months (mesotrione, MNBA)		
High protein content	Soybean, seed	40 months		
Animal Products				
-	-	-	Not required	UK, 2015, 2015a

Conclusion on stability of residues during storage

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

7.2.2 Nature of residues in plants, livestock and processed commodities

Data on nature of residues in plants, livestock and processed commodities is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Information from Renewal RR for Callisto 100 SC that are also relevant for evaluation of MEZ-HER 100 SC is provided below. Since data protection for this information expired, summary of relevant information was copied from Renewal RR for Callisto 100 SC. Information copied form Renewal RR for Callisto 100 SC were evaluated and accepted in renewal process of Callisto 100 SC and are deemed to be acceptable for MEZ-HER 100 SC.

RR Calisto 100 SC:

"With relevance to the nature of residues in crops, new data have been submitted in the framework of this application to address further the toxicological profile of metabolite AMBA[1]. A full assessment of the new study is given in the Appendix 2 to Section B 6.4.2 (KCA 5.8.1)"
[1] 2-amino-4-methylsulfonyl benzoic acid

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DAT)		
EU reviewed data								
Pulses and oilseeds	Peanut	phenyl-(U)-^{14}C	Pre-emergence, F	305 g a.s./ha 796 g a.s./ha	1 (1d after planting)	Foliage: 90 Hay: 153 Hulls, nutmeat: 169	Brown, 2003. Report No: 1286-01	UK, 2015, 2015a
		cyclohexane-(U)-^{14}C	Pre-emergence, F	327 g a.s./ha 836 g a.s./ha	1 (1d after planting)	Foliage: 90 Hay, hulls, nutmeat: 154	Brumback, 2003 Report No: 1287-01	
	HT soybean	phenyl-(U)-^{14}C	Pre-emergence, G	217.7 g a.s./ha	1 (1d after planting)	Forage: 28 Hay: 42 Seed: 123	Dohn & Chu, 2012 Report No. NC 27419	UK, 2015, 2015a
			Pre-/postemergence, G	345.5 g a.s./ha (217.7 g a.s./ha pre- plus 127.8 g a.s./ha postemerg.)	2 (1 d, 34 d after planting)	Forage: 28/-- Hay: 42/9 Seed: 123/90		
			Post-emergence, G	224.2 g a.s./ha	1 (12 d after planting)	Forage: 22 Hay: 40 Seed: 110		
		cyclohexane-(U)-^{14}C	Pre-emergence, G	225.8 g a.s./ha	1 (1d after planting)	Forage: 28 Hay: 42 Seed: 123		
			Pre-/post-emergence, G	356 g a.s./ha (225.8 g a.s./ha pre-, plus 130.2 g a.s./ha postemerg.)	2 (1 d, 34 d after planting)	Forage: 28/-- Hay: 42/9 Seed: 123/90		
			Post-emergence, G	229.6 g a.s./ha	1 (12 d after planting)	Forage: 22 Hay: 40 Seed: 118		
Cereals/grass	Maize	phenyl-(U)-^{14}C	Pre-emergen	280 g a.s./ha	1 (at	Forage: 27 Grain,	Tarr & van Neste, 1997	UK, 2015, 2015a

crops			ce, F		planting)	fodder: 153	Report No: RR 96-007B	
			Post-emergence, F	164 g a.s./ha	1 (28 d after planting)	Forage: 28 Grain, fodder: 125	Wei & Dohn, 1997 Report No: RR 96-026B	
		cyclohexane-(U)-^{14}C	Pre-emergence, F	307 g a.s./ha	1 (at planting)	Forage: 27 Grain, fodder: 153	Tarr & van Neste, 1997 Report No: RR 96-007B	
			Post-emergence, F	161 g a.s./ha	1 (28 d after planting)	Forage: 28 Grain, fodder: 153	Wei & Dohn, 1997 Report No: RR 96-026B	

Summary of plant metabolism studies reported in the EU

EFSA, 2016
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-^{14}C and phenyl-U-^{14}C.

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 MNBA1 (up to 20% TRR in maize forage leaves) and AMBA2, free and conjugated (13% and 28% TRR respectively in maize forage leaves and fodder; 15% TRR in peanut meat). Further identification of metabolites was not conducted in maize grain due to the very low recovered total residues (0.014 mg/kg).

In genetically modified herbicide tolerant soya bean, parent mesotrione was less extensively metabolised compared to conventional crops and occurred in forage at up to 18% TRR and in soya bean seed (10% TRR). The predominant compounds were identified as 4/5-hydroxy mesotrione (forage 19% TRR; hay 25% TRR; seed 8% TRR) and MNBA (forage 25% TRR; hay 20% TRR; seed 5% TRR). AMBA compound was never detected.

The unextracted radioactivity was further characterized as polar compounds (soya bean), lipids (peanut meat) and carbohydrates (maize) incorporated into the natural constituents of the plant. The metabolism of mesotrione in maize, peanuts and soya bean proceeds by oxidation of the parent molecule to 4/5-hydroxy mesotrione and to MNBA with subsequent reduction to AMBA and its conjugates observed in conventional maize and peanuts only. The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

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

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

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

provisionally proposed as mesotrione and AMBA (including its conjugates).

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

New data:

Information from Renewal RR for Callisto 100 SC that are also relevant for evaluation of MEZ-HER 100 SC is provided below. Since data protection for this information expired, summary of relevant information was copied from Renewal RR for Callisto 100 SC. Information copied form Renewal RR for Callisto 100 SC were evaluated and accepted in renewal process of Callisto 100 SC and are deemed to be acceptable for MEZ-HER 100 SC.

RR Calisto 100 SC:
A new study was conducted to address the data gap regarding the toxicological profile of AMBA.

AMBA is of low toxicity by the oral route. Although repeat dose studies have not been conducted with AMBA, data available shows that MNBA is almost quantitatively reduced to AMBA in the gastrointestinal tract within 24 hours and it is therefore possible to use data from studies with MNBA to conclude that AMBA would be of low toxicity by the oral route when administered for up to 90 days.

Conclusion on metabolism in primary crops

Based on the available metabolism studies, it can be concluded that the residue definition for risk assessment in food and feed commodities should include mesotrione parent compound only.

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				Report Reference	Source
			Method, F or G [a]	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU data								
Leafy vegetables	Endive	phenyl-(U)-^{14}C	Soil application, G	164	120, 300[b]	Maturity: 198	Gorder et al., 1997. Report No: RR 96-084B	UK, 2015, 2015a
		cyclohexane-(U)-^{14}C	Soil application, G	164	120, 300[b]	Maturity: 198	Spillner et al., 1997 Report No: RR 95-042B	

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

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) Crops sown 300 DAT were not harvested due to the low level of radioactive residues in the 120 DAT crops.

Summary of plant metabolism studies reported in the EU

United Kingdom, 2015, 2015a:
One confined rotational crop study investigating the nature of residues following different plant-back intervals is available.

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

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

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

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

Conclusion on metabolism in rotational crops

EFSA Journal 2015;13(1):3976:
The metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

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).

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

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

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

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**		**Report reference**	**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of samp-ling**		
EU data									

Lactating ruminants[(a)]	Cow	phenyl-(U)-^{14}C- AMBA	1	0.389 mg/kg bw/day AMBA	7	Milk	Twice daily	[redacted] Report No. RJ2309B	UK, 2015, 2015a
						Liver	23h after sacrifice		
						Kidney	23h after sacrifice		
						Subcutaneous fat	23h after sacrifice		
						Perirenal fat	23h after sacrifice		
Laying poultry[(a)]	-	-	-	-	-	-	-	None	
Fish[(b)]	-	-	-	-	-	-	-	None	

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

Summary of plant metabolism studies reported in the EU

EFSA, 2016:
The livestock dietary burden was tentatively estimated using the highest magnitude of AMBA conjugates residues in maize forage, fodder from the metabolism study and the total residues in maize grain. In this case, livestock metabolism studies are not triggered. A ruminant metabolism study was however conducted with phenyl-U-^{14}C AMBA. 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. 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. This assessment has however to be reconsidered pending the outcome of AMBA toxicity. Furthermore, the setting of residue definitions for products of animal origin will also have to be assessed with regard to the authorized European uses for mesotrione (maize forage, grass) (EFSA, 2015), and in the case animals are fed with genetically modified soya bean seed (meal) where mesotrione can be found at significant proportions.

A fish metabolism study is also not requested.

New data

Information from Renewal RR for Callisto 100 SC that are also relevant for evaluation of MEZ-HER 100 SC is provided below. Since data protection for this information expired, summary of relevant information was copied from Renewal RR for Callisto 100 SC. Information copied form Renewal RR for Callisto 100 SC were evaluated and accepted in renewal process of Callisto 100 SC and are deemed to be acceptable for MEZ-HER 100 SC.

RR Callisto 100 SC:
A new study assessing the toxicological profile of AMBA[1] has shown that AMBA does not present a genotoxic hazard. Further, a recently conducted rat micronucleus assay on AMBA confirms that it is not clastogenic in vivo. There was no evidence of clastogenicity or aneugenicity following oral (gavage) administration of AMBA up to the OECD 474 limit dose of 2000 mg/kg/day in male rats. AMBA is considered to be neither clastogenic nor aneugenic in the rat bone marrow micronucleus assay.

It is concluded that with regard to AMBA toxicity, a residue definition for animal commodities is not required.

Conclusion on metabolism in livestock

EFSA Journal 2016;14(3):4419:
The residue definitions for animal commodities are provisionally not required for the representative use.

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	Not applicable (cow for [phenyl-U-^{14}C]- AMBA)
Time needed to reach a plateau concentration	Not applicable (milk: 5 days for [phenyl-U-^{14}C]-AMBA)
Animal residue definition for monitoring	~~Not applicable for the representative use (provisional)~~ Mesotrione Reg. (EU) 2017/626 and Reg. (EU) 2024/1077
Animal residue definition for risk assessment	Not applicable for the representative use (provisional)
Conversion factor	Not applicable.
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	AMBA residues in muscle (<0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat soluble.

7.2.3 Magnitude of residues in plants (KCA 6.3)

Data on magnitude of residues in plants is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

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 MEZ-HER 100 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize grain	UK, 2015, 2015a	N-EU	GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A[(b)] 15x <0.01[(a)]	N/A				
		~~S-EU~~	~~GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A[(b)] 19x <0.01[(a)]~~					
	Overall supporting data for cGAP	N-EU	15x <0.01[(a)]	<0.01	<0.01	0.01	0.01	Yes
Maize stover	UK, 2015, 2015a	N-EU	GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A[(b)] 10x <0.01[(c)]	N/A				
		~~S-EU~~	~~GAP: 1x 0.15 kg as/ha, BBCH 12-18, PHI N/A[(b)] 10x <0.01[(c)]~~					

	Overall supporting data for cGAP	N-EU	10x <0.01[(c)]	<0.01	<0.01	N/A	N/A	N/A

* Source of EU MRL: Regulation (EU) No. 2017/626 and Reg. (EU) 2024/1077
N/A – not applicable
(a) Definition of residue for enforcement and risk assessment are the same: mesotrione
(b) PHI is determined by crop maturity
(c) Definition of residue for enforcement is not relevant for feed items since no MRL is set.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to SANTE/2019/12752 - rev. 1 - 10 May 2023 maize is a major crop in N-EU residue zone. Sufficient trials (15 N-EU) evaluated at the EU level in the original DAR (United Kingdom, 2015, 2015a) are available to support the proposed uses. The residue data clearly indicates that no residues above 0.01 mg/kg should be detectable at harvest in maize whole and maize grain at harvest.
The residue data are sufficient to support the proposed use and are valid with regard to storage stability.
The residues arising from the proposed uses will not exceed the MRL established for maize (0.01 mg/kg).
The proposed uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The active substance mesotrione is authorised in EU for use on crops that might be fed to livestock, so dietary burden calculation was performed in EFSA reasoned opinion on the review of the existing maximum residue levels/import tolerances for mesotrione according to Article 12 of Regulation (EC) No 396/2005.

Nonetheless in this document, the additional calculation of the dietary burden was conducted based on requested uses of MEZ-HER 100 SC i.e. maize. The modelling was performed by Excel spreadsheet Animal model 2017.

The input values and results of the dietary burden calculations are summarised below. For the evaluation data included in *Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mesotrione according to Article 12 of Regulation (EC) No 396/2005* (EFSA Journal 2015;13(1):3976) as well as study results included in Renewal RR for Callisto 100 SC for were applied.

Table 7.2-9: Input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Corn, field (maize)	0.01	STMR from maize trials	0.01	STMR from maize trials

Table 7.2-10: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.000	0.000	0.02	0.02	Dairy cattle	Flaxseed/linseed	meal	No	
Cattle (dairy only)	0.000	0.000	0.01	0.01	Dairy cattle	Flaxseed/linseed	meal	No	
Sheep (all diets)	0.001	0.001	0.03	0.03	Lamb	Soybean	hulls	No	
Sheep (ewe only)	0.001	0.001	0.03	0.03	Ram/Ewe	Soybean	hulls	No	
Swine (all diets)	0.001	0.001	0.02	0.02	Swine (finishing)	Soybean	hulls	No	
Poultry (all diets)	0.001	0.001	0.01	0.01	Turkey	Canola	meal	No	
Poultry (layer only)	0.001	0.001	0.01	0.01	Poultry layer	Soybean	hulls	No	

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The calculated dietary burdens for ruminants, swine and poultry are below the trigger of 0.004 mg/kg bw.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Data on livestock feeding studies is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

No new data were submitted in the framework of this application.
Livestock animals are not exposed to residues via feed above the trigger value (Reg. (EC) No 1107/2009). The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw hence no livestock feeding studies are required.

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

Data on magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

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

7.2.6 Magnitude of residues in representative succeeding crops

Data on magnitude of residues in representative succeeding crops is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

The crops under consideration can be grown in rotation.

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

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.2-11: 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					
None/bare soil	340	Oilseeds/pulses	Soybean	30 29	Barnes & Wiebe, 1997 Report: RR 97-044B UK, 2015, 2015a
Maize	340 + 220	Leafy	Endive	74 98	
None/bare soil	340	Root and tuber vegetables	Radish	30 29 85 98	
Maize	340 + 220[(a)]				
None/bare soil	340[(a)]	Cereals	Millet	30 29	
None/bare soil	340[(a)]		Sorghum	30 29	
Maize	340 + 220[(a)]		Wheat	100 98	

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

Conclusion on rotational crops studies

EFSA Journal 2016;14(3):4419
Field rotational crop studies 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)

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. In accordance with Reg. 284/2013 no further data are required.

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 table below.

Table 7.2-12: 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

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Intended uses				
Maize	0.01	EU MRL*	0.01	EU MRL*
All other commodities of plant and animal origin	variable	EU MRL*	~~variable~~	~~EU MRL*~~

* Reg. (EU) No 2017/626 and Reg. (EU) 2024/1077

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 1.

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.

Table 7.2-14: Consumer risk assessment

ADI	0.01 mg/kg bw / day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	12 % (based on NL toddler Diet) Highest contributors: 6% Milk: cattle 1% Apples 0.7% Maize/corn
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	not relevant, TMDI < 100%
ARfD	0.02 mg/kg bw/day

IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Unprocessed commodities - children ~~potatoes: 8% (UK infant)~~ ~~melons: 8% (BE toddlers)~~ maize: 0.3% (UK infants) Unprocessed commodities - adults: ~~head cabbages: 2% (CZ females)~~ ~~watermelons: 2% (IT adult)~~ maize: 0.1% (FI men) Processed commodities - children ~~sugar beets (root)/sugar: 5.5% (NL child)~~ ~~potatoes/fried: 4.7% (NL toddler)~~ maize/oil: 1% (NL todler) maize / processed (not specified): 0.1% (NL todler) Processed commodities - adults ~~pumpkins/boiled: 2.8% (NL general population)~~ ~~sugar beets (root)/sugar: 2.19% (FR adult)~~ maize/oil: 0.6% (NL general population)
NTMDI (% ADI) **	not relevant
NEDI (% ADI)**	not relevant
NESTI (% ARfD) **	not relevant

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

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (https://www.efsa.europa.eu/). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

The proposed uses of mesotrione in the formulation MEZ-HER 100 SC does not represent unacceptable acute and chronic risks for the consumer.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	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
	Wei, Y. *et al.*	1997	[Cyclohexane-2-^{14}C]ZA 1296: Nature of the Residues in Corn (Zea mays) Zeneca Report No: RR 96-026B	N	Syngenta

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
			DPDB Ref. 59801 GLP unpublished		
	Tarr, J.B. *et al.*	1997	[Phenyl-U-^{14}C]ZA 1296: nature of the residues in corn Report No: not given DPDB Ref. 59802 GLP unpublished	N	Syngenta
		1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow Report No: not given DPDB Ref. 59803 GLP unpublished	Y	Syngenta
	Klimmek S., Gizler A.	2008	MESOTRIONE AND NICOSULFURON: RESIDUE STUDY ON MAIZE IN NORTHERN FRANCE IN 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, T011368-07 GLP not published Syngenta File No A14351BX_10205	N	SYN
	Schulz H	2010	Mesotrione and Nicosulfuron - Residue Study on Maize in France (North) in 2008 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T009530-07-REG GLP not published Syngenta File No ZA1296_10049	N	SYN

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

Not relevant. No new studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

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:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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%	0.7%
	7%	NL child	0.67	2%	Milk: Cattle	0.8%	Sugar beet roots	0.6%	Apples	7%	0.0%
	6%	DE child	0.64	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	6%	0.0%
	6%	UK infant	0.61	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat	6%	0.1%
	6%	FR toddler 2 3 yr	0.56	3%	Milk: Cattle	0.3%	Apples	0.3%	Wheat	6%	0.0%
	6%	FR child 3 15 yr	0.55	2%	Milk: Cattle	0.5%	Wheat	0.4%	Sugar beet roots	6%	0.0%
	5%	GEMS/Food G11	0.49	1%	Soyabeans	0.8%	Milk: Cattle	0.4%	Potatoes	4%	0.0%
	4%	UK toddler	0.45	2%	Milk: Cattle	0.4%	Wheat	0.3%	Potatoes	4%	0.0%
	4%	GEMS/Food G10	0.43	1.0%	Soyabeans	0.5%	Milk: Cattle	0.4%	Wheat	3%	0.1%
	4%	GEMS/Food G07	0.42	0.6%	Milk: Cattle	0.5%	Soyabeans	0.4%	Wheat	4%	0.0%
	4%	GEMS/Food G08	0.42	0.6%	Soyabeans	0.6%	Milk: Cattle	0.4%	Wheat	4%	0.0%
	4%	GEMS/Food G15	0.42	0.7%	Milk: Cattle	0.5%	Soyabeans	0.5%	Wheat	4%	0.1%
	4%	DK child	0.41	1%	Milk: Cattle	0.6%	Rye	0.4%	Wheat	4%	0.0%
	4%	GEMS/Food G06	0.41	0.7%	Wheat	0.4%	Soyabeans	0.4%	Tomatoes	4%	0.1%
	4%	RO general	0.38	1%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	0.1%
	4%	ES child	0.38	1%	Milk: Cattle	0.4%	Wheat	0.3%	Cocoa beans	4%	0.0%
	4%	SE general	0.37	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.4%	Potatoes	4%	
	4%	DE women 14-50 yr	0.37	1%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Apples	4%	0.0%
	4%	DE general	0.36	1%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Apples	4%	0.0%
	4%	FI adult	0.35	3%	Coffee beans	0.1%	Potatoes	0.1%	Rye	4%	0.0%
	3%	IE adult	0.33	0.4%	Milk: Cattle	0.4%	Sweet potatoes	0.2%	Wheat	3%	0.0%
	3%	NL general	0.30	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Potatoes	3%	0.0%
	3%	FR infant	0.29	2%	Milk: Cattle	0.2%	Potatoes	0.2%	Apples	3%	0.0%
	2%	FR adult	0.22	0.4%	Milk: Cattle	0.2%	Wine grapes	0.2%	Wheat	2%	0.0%
	2%	PT general	0.21	0.5%	Potatoes	0.4%	Wheat	0.2%	Wine grapes	2%	0.0%
	2%	ES adult	0.21	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges	2%	0.0%
	2%	FI 3 yr	0.18	0.5%	Potatoes	0.1%	Bananas	0.1%	Wheat	2%	0.0%
	2%	IT toddler	0.16	0.7%	Wheat	0.2%	Other cereals	0.1%	Tomatoes	2%	0.0%
	2%	DK adult	0.16	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	
	2%	LT adult	0.16	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Apples	2%	0.0%
	1%	UK vegetarian	0.15	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	0.0%
	1%	FI 6 yr	0.14	0.4%	Potatoes	0.1%	Cocoa beans	0.1%	Wheat	1%	0.0%
	1%	UK adult	0.14	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	0.0%
	1%	IT adult	0.12	0.4%	Wheat	0.1%	Tomatoes	0.1%	Apples	1%	0.0%
	1.0%	PL general	0.10	0.3%	Potatoes	0.2%	Apples	0.1%	Tomatoes	1.0%	0.0%
	0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.0%

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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

Not relevant.

~~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				**Results for adults**				**IESTI new Results for children**				**IESTI new Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI new):			---	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)**	

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 speci	0.01 / 0.01	0.01												
Expand/collapse list															

Conclusion:
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 ARfD/ADI was identified.

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Potatoes	0.01 / 0.01	1.5
8%	Melons	0.01 / 0.01	1.5
7%	Pears	0.01 / 0.01	1.4
7%	Oranges	0.01 / 0.01	1.3
6%	Milk: Cattle	0.01 / 0.01	1.2
6%	Watermelons	0.01 / 0.01	1.2
5%	Apples	0.01 / 0.01	1.1
5%	Pineapples	0.01 / 0.01	1.0
5%	Bananas	0.01 / 0.01	0.97
5%	Peaches	0.01 / 0.01	0.95
4%	Mangoes	0.01 / 0.01	0.79
4%	Grapefruits	0.01 / 0.01	0.79
4%	Table grapes	0.01 / 0.01	0.73
3%	Cucumbers	0.01 / 0.01	0.66
3%	Carrots	0.01 / 0.01	0.63

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Head cabbages	0.01 / 0.01	0.42
2%	Watermelons	0.01 / 0.01	0.41
2%	Melons	0.01 / 0.01	0.39
2%	Milk: Cattle	0.01 / 0.01	0.39
2%	Swedes/rutabagas	0.01 / 0.01	0.34
2%	Table grapes	0.01 / 0.01	0.34
2%	Oranges	0.01 / 0.01	0.31
2%	Pears	0.01 / 0.01	0.31
1%	Potatoes	0.01 / 0.01	0.30
1%	Pineapples	0.01 / 0.01	0.30
1%	Yams	0.01 / 0.01	0.28
1%	Apples	0.01 / 0.01	0.28
1%	Cucumbers	0.01 / 0.01	0.28
1%	Aubergines/egg plants	0.01 / 0.01	0.27
1%	Mangoes	0.01 / 0.01	0.26

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Show results of IESTI calculation only for crops with GAPs under assessment

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				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
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)							

~~A 3.4 IESTI calculations - Processed commodities~~

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
5%	Potatoes / fried	0.01 / 0.01	0.93
4%	Pumpkins / boiled	0.01 / 0.01	0.89
4%	Witloofs / boiled	0.01 / 0.01	0.89
4%	Broccoli / boiled	0.01 / 0.01	0.79
3%	Cauliflowers / boiled	0.01 / 0.01	0.70
3%	Escaroles/broad-leaved er	0.01 / 0.01	0.66
3%	Potatoes / dried (flakes)	0.01 / 0.05	0.59
3%	Leeks / boiled	0.01 / 0.01	0.57
3%	Apples / juice	0.01 / 0.01	0.54
3%	Oranges / juice	0.01 / 0.01	0.53
3%	Turnips / boiled	0.01 / 0.01	0.51
3%	Parsnips / boiled	0.01 / 0.01	0.51
3%	Sweet potatoes / boiled	0.01 / 0.01	0.50
2%	Florence fennels / boiled	0.01 / 0.01	0.45

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Pumpkins / boiled	0.01 / 0.01	0.55
2%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
2%	Cauliflowers / boiled	0.01 / 0.01	0.42
2%	Beetroots / boiled	0.01 / 0.01	0.39
2%	Celeries / boiled	0.01 / 0.01	0.34
2%	Apples / juice	0.01 / 0.01	0.33
1%	Broccoli / boiled	0.01 / 0.01	0.24
1%	Coffee beans / extraction	0.05 / 0.01	0.24
1%	Courgettes / boiled	0.01 / 0.01	0.23
1%	Parsnips / boiled	0.01 / 0.01	0.21
1%	Kohlrabies / boiled	0.01 / 0.01	0.21
1%	Wine grapes / juice	0.01 / 0.01	0.21
1%	Escaroles/broad-leaved	0.01 / 0.01	0.20
1.0%	Florence fennels / boiled	0.01 / 0.01	0.19
1.0%	Turnips / boiled	0.01 / 0.01	0.19

Conclusion:
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 a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Maize / oil	0.01 / 0.25	0.23	0.6%	Maize / oil	0.01 / 0.25	0.13
0.1%	Maize / processed (not spe	0.01 / 0.01	0.02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Conclusion:
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 a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.