FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **MEZOFLOR 103 SC**

Product names: **MEZOFLOR 103 SC / FLOCORN 103 SC**

Chemical active substances:

Mesotrione, 100 g/L

Florasulam, 3 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 07/2023

MS Finalisation date: 05/2024, 12/2024

Version history

When	What
07/2023	Initial dRR
05/2024	ZRMS assessment
12/2024	The final Registration Report

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Mesotrione

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.

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 12-18, 100 - 125 g as/ha) 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.

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.

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 MEZOFLOR 103 SC do not represent unacceptable acute and chronic risks for the consumer. Calculations are accepted.

Florasulam

Stability of Residues

Storage stability of florasulam was demonstrated in cereal grain, cereal straw and immature cereal plants for a period of 18 to 23 month at temperature ranging from -18°C to -25°C.

Sufficient stability has been demonstrated to support the residue data presented in this document.

No further data are required to support the proposed uses.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion and renewal process of the active substance are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Plant and animal residue definitions for monitoring: Florasulam (Reg. (EU) 2022/1363)

Plant residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam and provisionally 4-OH- phenyl-florasulam (data gap)

Animal residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam pending assessment with regard to 4-OH-phenyl-florasulam

Conversion factor (monitoring to risk assessment): For milk, liver, kidney and eggs: 1

The data gap concerns the further toxicological evaluation of the plant metabolite 4-OH- phenyl-florasulam.

Magnitude of residues in plants

Proposed GAP (maize): 1 application, BBCH 12-18, 3.00 -3.75 g as/ha

Applicant refers to unprotected EU data.

Sufficient trials on cereals are available to support the proposed uses.

Residues from trials are all below 0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (0.01 mg/kg; Reg. (EU) 2022/1363)

Magnitude of residues in livestock

The new animal model calculation (Excel spreadsheet Animal model 2017) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded. Supplementary livestock feeding studies are not required. Calculations provident by the applicant are accepted.

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

As quantifiable residues of florasulam are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

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

EFSA Journal 2015; 13(1):*3984: In the section on residues data gaps were identified with regard to residues in animal commodities and rotational crops. Nonetheless, the margin of safety in the consumer risk assessment is considered big even if the potentially relevant toxicological burden for consumers via their diet might have been underestimated in the current assessment.*

Residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

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 Florasulam in the formulation MEZOFLOR 103 SC do not represent unacceptable chronic risks for the consumer.

Proposed use is accepted

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 MEZOFLOR 103 SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for maize. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for mesotrione as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of mesotrione residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s) on maize.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for florasulam as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of florasulam residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland agrees with the authorization of the in-

tended use(s) on maize.

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
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**g as/ha min max**		
1	Maize	Poland	MEZOFLOR 103 SC	F	**<u>In dose 1,0 L/ha of formulated product</u> susceptible weeds:** *Tripleurospermum inodorum, Galinsoga parviflora, Thlaspi arvense, Fallopia convolvulus, Persicaria maculosa, Capsella bursa-pastoris, Anthemis arvensis, Sinapis sp, Matricaria chamomilla, Anchusa arvensis* **moderate susceptible weeds:** *Galium aparine, Chenopodium album, Geranium pusillum, Viola arvensis, Centaurea cyanus, Amaranthus retroflexus, Brassoca napus var. oleifera, Stellaria media, Solanum nigrum, Tripleurospermum*	SC	Mesotrione 100 g/l Florasulam 3 g/l	Foliar spraying	BBCH 12-18	1	N/A	0.06	200	Mesotrione 100 - 125 g as/ha Florasulam 3.00 -3.75 g as/ha	Not relevant	A

					maritimum, **Medium resistance:** *Echinochloa crus-galli* **<u>In dose 1,25 L/ha of formulated product</u>** **susceptible weeds:** *Tripleurospermum inodorum*, *Galinsoga parviflora*, *Thlaspi arvense*, *Fallopia convolvulus*, *Persicaria maculosa*, *Stellaria media*, *Capsella bursa-pastoris*, *Anthemis arvensis*, *Sinapis sp.*, *Matricaria chamomilla*, *Anchusa arvensis* **moderate susceptible weeds:** *Echinochloa crus-galli*, *Galium aparine*, *Chenopodium album*, *Geranium pusillum*, *Viola arvensis*, *Centaurea cyanus*, *Amaranthus retroflexus*, *Brassoca napus var. oleifera*, *Solanum nigrum*, *Tripleurospermum maritimum*											

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation MEZOFLOR 103 SC is composed of mesotrione and florasulam.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesotrione					
ADI	EFSA	2016	0.01 mg/kg bw/day	Mouse multigeneration study	200
ARfD	EFSA	2016	0.02 mg/kg bw	Mouse multigeneration study	100
Florasulam					
ADI	EFSA	2015	0.05 mg/kg bw/day	1-year dog study	100
ARfD	EFSA	2015	ARfD was not considered necessary.		

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

7.1.2.2 Summary for Florasulam

Table 7.1-4: Summary for Florasulam

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

7.1.2.3 Summary for MEZOFLOR 103 SC

Table 7.1-5: Information on MEZOFLOR 103 SC (KCA 6.8)

Crop	PHI for MEZOFLOR 103 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for MEZOFLOR 103 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mesotrione	Florasulam		
Maize	NR	NR	NR	NR	

NR: not relevant

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for MEZOFLOR 103 SC
Crop group	Led by mesotrione	Led by florasulam	
Leafy vegetables	NR	NR	
Root vegetables	NR	NR	
Cereals	NR	NR	

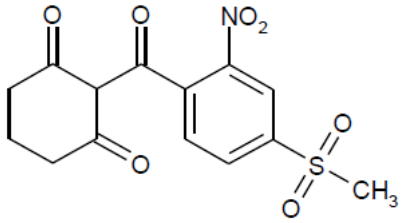
NR: not relevant

Assessment

7.2 Mesotrione

General data on Mesotrione are summarized in the table below (last updated 2023/07)

Table 7.2-1: General information on Mesotrione

Active substance (ISO Common Name)	Mesotrione
IUPAC	2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione
Chemical structure	
Molecular formula	$C_{14}H_{13}NO_7S$
Molar mass	339.3 g/mol
Chemical group	Triketone
Mode of action (if available)	Mesotrione inhibits the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD).
Systemic	Yes
Company (ies)	Syngenta
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved Date of (01/06/2017) and reference to decision (REGULATION (EU) No 2017/725).
Restriction	Only use as herbicide may be authorised.
Review Report	SANCO/1416/2001- Final 14/04/2003 and SANTE/11654/2016 23/03/2017
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 Journal : Conclusion on the peer review	Yes EFSA Journal 2016;14(3):4419
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2015;13(1):3976
Current MRL applications on intended uses	~~EFSA Journal 2015;13(1):3976~~ none

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Maize forage	High water content	Mesotrione – 31 months MNBA – 42 months	RAR, 2015 EFSA, 2016
Maize grain	High starch content	Mesortione and MNBA – 42 months	RAR 2015 EFSA, 2016

Conclusion on stability of residues during storage

Mesotrione and MNBA is considered to be stable under freezer storage (at -18°C ±5°C) for at least 42 month in maize grains and for 31 month in maize forage. Frozen storage stability of metabolite MNBA in maize grain and forage was demonstrated for at least 42 month (RAR, 2015; EFSA, 2016).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant for this application. The supervised studies are presented in DAR, 1990, RAR, 2015 and were evaluated at European level.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Maize	[cyclohexane-2-^{14}C] ZA 1296 and [phenyl-U-14C] ZA 1296	foliar treatment, F	0.140 kg/ha	2	28 DAT (forage) 125 DAT (fodder, grain)		DAR, 1999, EFSA 2016
	Maize	phenyl-U-^{14}C or cyclohexane-2-^{14}C labelled mesotrione	foliar treatment, F Pre-emergence	0.280 or 0.307 kg/ha	-	27 DAT (forage) 154 DAT (fodder, grain)		RAR, 2015; EFSA, 2016
	Maize	phenyl-U-^{14}C or cyclohexane-2-^{14}C labelled mesotrione	foliar treatment, F Post-emergence	0.164 or 0.161 kg/ha	-	28 DAT (forage) 125 DAT (fodder, grain)		RAR, 2015; EFSA, 2016
Pulses and oilseeds	Peanuts	[Cyclohexane-2-^{14}C]-mesotrione	Soil, F Pre-emergence	0.327 kg/ha or 0.836 kg/ha	1	90 DAT (foliage); 154 DAT (peanuts, peanaut hay)		RAR, 2015; EFSA, 2016
	Peanuts	[Phenyl-U-^{14}C]-mesotrione	Soil, F Pre-emergence	0.305 kg/ha or 0.796 kg/ha	1	90 DAT (foliage); 154 DAT (peanuts, peanaut hay)		
	Soybean (genetically modified	[Phenyl-U-^{14}C]-mesotrione	Soil, G Pre-emergence	0.218 kg/ha	1	28 DAT (forage); 42 DAT (hay); 123-123 DAT (seeds)		
		[Phenyl-U-^{14}C]-mesotrione	Soil, G Pre-emergence + Foliar, G	0.218 + 0.128 kg/ha	2	28 DAT (forage); 51 DAT (hay); 90 DAT (seeds)		
		[Phenyl-U-^{14}C]-mesotrione	Foliar, G Post-emergence	0.224 kg/ha	1	22 DAT (forage); 40 DAT		

						(hay); 118 DAT (seeds)		
		[Cyclohex-ane-2-^{14}C]-mesotrione	Soil, G Pre-emergence	0.226 kg/ha	1	28 DAT (forage); 42 DAT (hay); 123-123 DAT (seeds)		
		[Cyclohex-ane-2-^{14}C]-mesotrione	Soil, G Pre-emergence + Foliar, G	0.226 + 130 kg/ha	2	28 DAT (forage); 51 DAT (hay); 90 DAT (seeds)		
		[Cyclohex-ane-2-^{14}C]-mesotrione	Foliar, G Post emergence	0.230 kg/ha	1	22 DAT (forage); 40 DAT (hay); 110 DAT (seeds)		

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

Summary of plant metabolism studies reported in the EU

Metabolism studies were conducted with crops representative of two different crop groups (cereal/grass: maize and pulses and oilseeds: peanut and herbicide tolerant (HT) soybean) and based on the commercially recommended use pattern, i.e. pre- or post- and pre- and postemergence foliar applications. The metabolism pathways operating in genetically modified HT soybeans are qualitatively similar to those operating in unmodified crops.

In the metabolism in maize study the active substance was labelled in the cyclohexane and phenyl rings and applied either preemergence at approximately 2N rate, or post-emergence at a 1N rate. The post-emergence treatments lead to higher residues and most of the results reported during the original assessment were due to this application regime.

The only significant metabolite identified as including the cyclohexane ring was the oxidation product of mesotrione; 4-hydroxymesotrione, this accounted for 0.012 mg/kg (5.8 % TRR) and 0.006 mg/kg (6.1 % TRR) in the leaf samples and forage samples respectively as a result of a post-emergence application. The remaining radioactivity was characterised as minor extractable components, including carbohydrates, suggesting that the cyclohexane ring is extensively metabolised. Mesotrione accounted for 0.002 mg/kg (1.1 % TRR) and 0.001 mg/kg (1.0 % TRR) in the leaf samples and forage samples respectively. Extractable radioactivity from the grain samples characterised by partition between aqueous and organic layers, the non-extractable residue was less than 0.01 mg/kg and was not analysed further.

From the phenyl label study a number of metabolites were detected, notably 4-hydroxymesotrione, 4-glucosyloxymesotrione, MNBA, AMBA and conjugates or derivatives of AMBA. In the post-emergence treated forage 4-hydroxymesotrione, 4-glucosyloxymesotrione and MNBA accounted for 0.007 mg/kg (3.0 % TRR), 0.009 mg/kg (3.6 % TRR) and 0.008 mg/kg (3.4 % TRR) respectively, and in the post-emergence treated fodder 0.007 mg/kg (0.7 % TRR), < 0.010 mg/kg (< 0.1 % TRR) and 0.019 mg/kg (1.9 % TRR). The total amount of AMBA (total after extractions and, for fodder only, hydrolysis) accounted for 0.032 mg/kg (13.2 % TRR) and 0.301 mg/kg (28.2 % TRR) in forage and fodder respectively. The pre-emergence use produced similar results with the only significant difference being a higher proportion of MNBA. For post emergence treated grain < 0.01 mg/kg was extracted and only AMBA, < 5 % TRR, was detected (RAR, 2015).

Conclusion on metabolism in primary crops

The metabolism in maize proceeds via oxidation of mesotrione to 4-hydroxymesotrione and/or MNBA. MNBA is then further metabolised to AMBA and final it is proposed that AMBA is incorporated in to natural products. None of the metabolites are considered significantly more toxic than mesotrione, and absolute levels of all residue in grain were low (maximum 0.014 mg/kg). Therefore the residue definition for monitoring and risk assessment in cereal grains should be set as mesotrione parent 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					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (Days after planting)	Remarks	
EU data								
Leafy vegetables	Endive	[phenyl-U-14C] ZA 1296 or [cyclohexane-2-14C] ZA 1296	Soil application, G	0.164 kg/ha	120 DAT, 300 DAT	78	-	DAR, 1999, EFSA, 2016
Root and tuber vegetables	Radish	[phenyl-U-14C] ZA 1296 or [cyclohexane-2-14C] ZA 1296	Soil application, G	0.164 kg/ha	120 DAT, 300 DAT	Roots, tops 56	-	DAR, 1999, EFSA, 2016
Cereals	Wheat	[phenyl-U-14C] ZA 1296 or [cyclohexane-2-14C] ZA 1296	Soil application, G	0.164 kg/ha	120 DAT, 300 DAT	Forage 22 Hay 57 Straw 134 Grain 134	-	DAR, 1999, EFSA, 2016

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

Summary of plant metabolism studies reported in the EU

The metabolism and distribution of ZA 1296 was investigated in the rotational crops wheat, endive and radish planted 120 and 300 days following soil application of [^{14}C] ZA 1296 to soil in pots at ca 1.2N. A replanting interval of 30 days was not investigated but is not of concern since replanting after this interval would not be anticipated for this crop. TRR in the plants grown in the soil treated with [^{14}C]-cyclohexane labelled ZA 1296 were <0.001-0.002 mg/kg. TRR in the crops grown in soil treated with [^{14}C]-phenyl labelled ZA 1296 were 0.004 mg/kg in both radish roots and tops, 0.012 mg/kg in endive and 0.033, 0.018, 0.031 and 0.006 mg/kg in wheat forage, hay, straw and grain respectively. The

300 DAT crops were not harvested due to the low levels of radioactivity in the 120 DAT crops.

MNBA, AMBA sulphate and AMBA conjugate were present in all extracts of wheat forage, hay and straw, the only significant component was MNBA at 0.011 mg/kg in wheat forage (33% TRR). ZA 1296 was not detected (DAR, 1999).

Conclusion on metabolism in rotational crops

The metabolism of mesotrione is similar in rotational crops to that observed in 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.

Conclusion on nature of residues in processed commodities

Mesotrione residue level in maize grain was below a limit of quantification (< 0.01 mg/kg). Therefore it is considered that processing studies are not required.

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

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

Endpoints	
Plant groups covered	Cereals (Maize)
Rotational crops covered	Wheat, Endive, Radish
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Processing studies are not required.
Residue pattern in processed commodities similar to pattern in raw commodities?	Processing studies are not required.
Plant residue definition for monitoring	Mesotrione (Regulation (EU) 2017/626 and Reg. (EU) 2024/1077)
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, 2016)
Conversion factor from enforcement to RA	Not applicable (EFSA, 2016)

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

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	[phenyl-U-^{14}C] labelled AMBA	-	0.4 mg/kg bw/d	7 days	Milk	daily	DAR, 1999; RAR, 2015; EFSA 2016
						Tissues	at sacrifice	
Laying poultry	Hens	-	-	-	-	-		-

Summary of plant metabolism studies reported in the EU

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

Conclusion on metabolism in livestock

Animal residue definition for monitoring and risk assessment are 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	Lactating cow
Time needed to reach a plateau concentration	5 days in milk
Animal residue definition for monitoring	Not required for the representative use (provisional) (EFSA, 2016)
Animal residue definition for risk assessment	Not required for the representative use (provisional) (EFSA, 2016)

Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	AMBA residues in muscle (< 0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat soluble.

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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 MEZOFLOR 103 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	DAR, 1999;	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.150 kg as/ha, BBCH 12-18, outdoor E: Forage: 5 x <0.01, 4 x <0.01[a] , Silage: 5 x <0.01, 4 x <0.01[a] Grain: 5 x <0.01, 4 x <0.01[a] RA: Forage: 5 x <0.01, 4 x <0.01[a] Silage: 5 x <0.01, 4 x <0.01[a] Grain: 5 x <0.01, 4 x <0.01[a] ([a]determined sa mesotrione +MNBA, expressed as mesortione)	N/A				
	RAR, 2015; EFSA, 2016	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.143 -0.156 kg as/ha, BBCH 15-18, outdoor Forage: 4 x <0.01 Silage: 4 x <0.01 Grain: 6 x <0.01					

	Overall supporting data for cGAP	N-EU	E: Forage: 13x < 0.01 Silage: 13x <0.01 Grain: 15x <0.01 RA: Forage: 13x < 0.01 Silage: 13x <0.01 Grain: 15x <0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.01	Yes

* Source of EU MRL: Reg. (EU) 2017/626 and Reg. (EU) 2024/1077

LOQ for method: 0.01 mg/kg

7.2.3.2 Conclusion on the magnitude of residues in plants

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

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition mesotrione				
Maize grain	0.01	Median residue (EFSA, 2015)	0.01	Median residue (EFSA, 2015)

Table 7.2-10: Results of the dietary burden calculation (Animal model 2017)

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					
Dairy cattle	0.001	0.001	Corn, field (gluten feed)	0.03	No
Dairy cattle	0.001	0.001	Corn, field (gluten feed)	0.02	No
Lamb	0.001	0.001	Corn, field (gluten feed)	0.02	No
Ram/Ewe	0.001	0.001	Corn, field (gluten feed)	0.02	No
Swine (finishing)	0.001	0.001	Corn, field (gluten feed)	0.02	No
Poultry layer	0.001	0.001	Corn, field (hominy meal)	0.02	No
Poultry layer	0.001	0.001	Corn, field (hominy meal)	0.02	No

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

The dietary burden calculation was made using Animal model 2017.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The calculated dietary burdens for all groups of livestock were not found to exceed the trigger value of 0.1 mg/kg DM. Further investigation on residues is not required.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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 level of mesotrione residues in forage, silage and grain is below the limit of quantification (< 0.01 mg/kg). Further investigation on mesotrione residues in processed commodities is not required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

Studies investigating the potential for residues being present in rotational crops are not necessary considering that residues in any part maize plant are below the LOQ (< 0.01 mg/kg).

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

Studies investigating the potential for residues being present in rotational crops are not necessary considering that residues in any part maize plant are below the LOQ (0.01 mg/kg).

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 MEZOFLOR 103 SC. Therefore, other special studies are not needed.

According SANTE/11956/2016 rev.9 maize are not melliferous crop. The studies on effect on the residue level in pollen and bee products are not required. In addition the product MEZOFLOR 103 SC is applied at early growth stages (BBCH 12-18), therefore, the risk of residues appearing in honey is negligible.

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 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition; Mesotrione				
Maize grain	0.01	Median residue (EFSA, 2015)	0.01	Highest residue (EFSA, 2015)
Other products of plant and animal	various MRLs	according to Reg. (EU) 2017/626 and Reg. (EU) 2024/1077	N/A	

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.1.	12 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	See TMDI value
IESTI (% ARfD) according to EFSA PRIMo* rev. 3.1.	Raw commodities 0.3% Maize/corn
	Processed commodities: 1% Maize/oil 0.1% Maize/processed
NTMDI (% ADI) **	Not assessed
NEDI (% ADI)**	Not assessed
NESTI (% ARfD) **	Not assessed

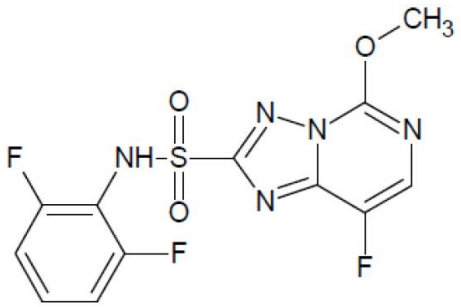
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of mesotrione in the formulation MEZOFLOR 103 SC do not represent unacceptable acute and chronic risks for the consumer. The calculation for consumer risk assessment was made using EFSA PRIMo 3.1.

7.3 Florasulam

General data on Florasulam are summarized in the table below (last updated 2023/06)

Table 7.3-1: General information on Florasulam

Active substance (ISO Common Name)	Florasulam
IUPAC	2′,6′,8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2- sulfonanilide
Chemical structure	
Molecular formula	$C_{12}H_8O_3N_5F_3S$
Molar mass	359.3 g/mol
Chemical group	Triazolopyrimidine
Mode of action (if available)	ALS inhibitor. Inhibition of acetolactate synthase, which inhibits biosynthesis of the amino acids valine, leucine and isoleucine.
Systemic	Yes
Company (ies)	Dow AgroSciences Limited
Rapporteur Member State (RMS)	Poland
Approval status	Approved Date of (01/01/2016) and reference to decision (REGULATION (EU) No 2015/1397).
Restriction	Only use as herbicide may be authorised.
Review Report	SANCO/1406/2001 - final 18/09/2002 and SANTE/10542/2015 Rev 1 14/07/2015
Current MRL regulation	Reg. (EU) 2022/1363
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes EFSA Journal 2015;13(1):3984
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2012;10(3):2626
Current MRL applications on intended uses	EFSA Journal 2012;10(3):2626

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cereal (grain)	High starch content	18 – 23 months	Belgium, 1999
Cereal (immature plant)	High water content	18 – 23 months	Belgium, 1999
Cereal (straw)	Dry content	18 – 23 months	Belgium, 1999

Conclusion on stability of residues during storage

Storage stability of florasulam was demonstrated in cereal grain, cereal straw and immature cereal plants for a period of 18 to 23 month at temperature ranging from -18˚C to -25˚C.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

The procedural recoveries in the residue studies demonstrate the stability of the analyte during storage in extract prior to analysis (Belgium, 1999).

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Winter wheat	[^{14}C-phenyl]-florasulam and [^{14}C-triazolopyrimidine]-florasulam	Foliar treatment (F)	50 g a.s./ha	1	Immature plants: 0, 30 DAT Crop maturity (straw, grain and shaff): 65 DAT	Application at BBCH 49 (post flag leaf emergence/first awns visible-late application).	Belgium, 1999 EFSA, 2015
						Immature plants: 0, 30 DAT Crop maturity (straw, grain and shaff): 129 DAT	Application at BBCH 30 (stem elongation-early application).	

Summary of plant metabolism studies reported in the EU

The metabolic pathway of florasulam in winter wheat has been established. Treatment was done of two subsets at two different growth stages. At the immature plant stage (forage), florasulam (28-33% TRR) and metabolite 4-OH-phenyl-florasulam plus glucose-conjugate (19-42% TRR) were the major residues. In the mature wheat plants (straw), parent florasulam was only recovered in one of the two experimental subsets with later application (7-14% TRR). Metabolite 4-OH-phenyl-florasulam plus glucose-conjugate was major (up to 36% TRR). Finally, residues levels in the grain were extremely low in plants treated at either application timing. 4-OH-phenyl –florasulam is a minor metabolite and there is no toxicological data available for this metabolite to sufficiently conclude on its toxicological properties. While present in significant proportions in the metabolism study at the relevant PHIs for commodities used as livestock feed items (e.g. cereal straw, forage, grass, hay, silage), the actual levels upon using florasulam under GAP conditions in the field remain unclear since residue trials did not determine residues of 4-OH-phenyl-florasulam (free and conjugated). Results from study shows that metabolism of florasulam is rapid and with minimal transport or storage of active substance in grain (Belgium, 1999; EFSA, 2015).

Conclusion on metabolism in primary crops

The plant residue definition for risk assessment should provisionally include both florasulam and 4-OH-phenylflorasulam, pending the submission of sufficient evidence demonstrating the inclusion of this metabolite will not be necessary to appropriately describe the toxicological dietary burden. The plant residue definition for MRL enforcement purposes is florasulam only.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Cabbage	[^{14}C-phenyl]-florasulam and [^{14}C-triazolopyrimidine]- florasulam	Not reported	0.0075	30	195	-	Belgium, 1999, EFSA, 2015
Root and tuber vegetables	Carrot					156	-	
Pulses and oilseeds	Sunflower					168	-	
Cereals	Spring wheat					168	-	

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

Summary of plant metabolism studies reported in the EU

The metabolism of florasulam in rotational crops – spring wheat, sunflower, cabbage and carrot - has been evaluated (Belgium, 1999). A rotational crop study investigating the nature of residues following a plant-back interval of 30 days is available. At maturity, in spring wheat (ears and straw), sunflower (heads and stems), cabbage (heads) and carrots (leaves and roots) no radioactivity was detected or TRR was ranging between 0.001 (spring wheat) and 0.006 (carrots) mg/kg florasulam equivalent. Residues exceeding 0.01 mg/kg are therefore not expected in rotational crops and specific plant-back restrictions related to the use of florasulam are not required (EFSA, 2015).

Conclusion on metabolism in rotational crops

Residues exceeding 0.01 mg/kg are not expected in rotational crops.

7.3.2.3 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

Florasulam residue level in maize exceeding 0.01 mg/kg are not expected. Therefore it is considered that an industrial and/or household processing studies are not required.

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

Table 7.3-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Winter Wheat)
Rotational crops covered	Four rotational crops (cabbage, carrot, sunflower and wheat)

Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Florasulam Reg. (EU) 2022/1363
Plant residue definition for risk assessment	Florasulam and provisionally 4-OH-phenyl-florasulam (data gap at EU level) (EFSA, 2015)
Conversion factor from enforcement to RA	Not applicable

7.3.2.5 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 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[phenyl ^{14}C]-florasulam	1	11[a]	5	Milk	twice daily	Belgium, 1999; EFSA, 2012
						Urine and faeces	daily	
						Tissues	at sacrifice	
		[triazolopyrimidine ^{14}C]-florasulam	1	11[a]	5	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[phenyl ^{14}C]-florasulam	10	11[b]	5	Eggs	daily	
						Excreta	daily	
						Tissues	after sacrifice	
		[triazolopyrimidine ^{14}C]-florasulam	10	11[b]	5	Eggs	daily	
						Excreta	daily	
						Tissues	after sacrifice	

(a): considering a weight of 50-90 kg for a goat, the rate is comprised between 0.11 and 0.22 mg/kg bw/d.
(b): considering a weight of 1.9 kg for a hen, the rate is around 5.79 mg/kg bw/d.

Summary of plant metabolism studies reported in the EU

The metabolism of florasulam was investigated in goat and hen with [^{14}C-phenyl]-florasulam and [^{14}C-triazolopyrimidine]-florasulam. Metabolism of florasulam was not extensive, resulting in florasulam being the pertinent residue (80% up to 99% TRR) in the different goat and hen matrices with the exception of goat liver (15% TRR with 82-87% TRR not extracted). Livestock exposure estimates are pending for permanent pasture and new leys and further evidence with regard to occurrence, behaviour and/or toxicity of 4-OH-phenyl-florasulam is required. Therefore the finalisation of the livestock residue definition for risk assessment is pending. For monitoring, given there was occurrence of florasulam in grass and silage and florasulam is hardly metabolised by the animals, parent florasulam alone might be sufficient for inclusion in the residue definition for enforcement/MRL setting (Belgium, 1999; EFSA, 2015).

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

Table 7.3-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	Not determined
Animal residue definition for monitoring	Florasulam (~~Reg. (EU) No 1317/2013~~ Reg. (EU) 2022/1363)
Animal residue definition for risk assessment	Florasulam and provisionally 4-OH-phenyl-florasulam
Conversion factor	For milk, liver, kidney and eggs: 1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of MEZOFLOR 103 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	EFSA, 2015	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 6.25 g as/ha, BBCH 15, PHI n/a, outdoor E: 4 x < 0.01* mg/kg RA: 4 x < 0.01* mg/kg	N/A				
	RMS, 2013	N-EU	Trials GAP: 1 x 5 g as/ha, BBCH 19-20, PHI n/a, outdoor Cobs: E: 9 x < 0.01* mg/kg RA: 9 x < 0.01* mg/kg Grain: E: 9 x < 0.01* mg/kg RA: 9 x < 0.01* mg/kg					
	Overall supporting data for cGAP	N-EU	Cobs: 13 x < 0.01 Grain: 13 x < 0.01	0.01	0.01	0.01	0.01	Yes

* Source of EU MRL: ~~Reg. (EU) No 1317/2013~~ Reg. (EU) 2022/1363
*LOQ = 0.01 mg/kg

7.3.3.2 Conclusion on the magnitude of residues in plants

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

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

For risk assessment, results only for parent florasulam are presented. EFSA Journal 2015;13(1): 3984 proposes a plant residue definition for risk assessment as florasulam and provisionally 4-OH-phenyl-florasulam and the animal residue definition for risk assessment as florasulam pending assessment with regard to 4-OH-phenyl-florasulam.

At European level, studies of the metabolism of florasulam in cereals (winter wheat) have been presented. Metabolism studies show that the transport of florasulam and its metabolite 4-OH-phenyl-florasulam to the top of the plant (grains) is very limited. During the metabolism analysis, a very low level of residues was observed in the wheat grains (<LOQ = 0.01 mg/kg), hence the risk of residues appearing in the edible parts of the plant for both florasulam and 4-OH-phenyl-florasulam is negligible. Taking into account the uses of florasulam in maize, it can be expected that any residues of 4-OH-phenyl-florasulam will occur mainly in animal feed and not in human food.

Based on OECD Guidance Document on the Definition of Residue (2006), there is no need or sufficient justification to support including 4-OH-phenyl-florasulam in the residue definition for risk assessment. According to the OECD Guidance, a metabolite for which a toxicological significance has been established can be included in the definition of risk assessment. At European level, no toxicological data are available on the metabolite 4-OH-phenyl-florasulam to sufficiently conclude on its toxicological properties. While present in significant proportions in the metabolism study at the relevant PHIs for commodities used as livestock feed items (e.g. cereal straw, forage, grass, hay, silage), the actual levels upon using florasulam under GAP conditions in the field remain unclear since residue trials did not determine residues of 4-OH-phenyl-florasulam (free and conjugated). The plant metabolite 4-OH-phenylflorasulam is a minor rat metabolite (≤ 5% of administered dose), it cannot be considered as covered by the toxicological data with the parent compound. Further toxicological assessment of the plant metabolite 4-OH-phenyl-florasulam has to be provided (data gap at EU level). In addition, the risk assessment for the 4-OH-phenyl-florasulam is not possible as ADI and ARfD values have not been established for this metabolite. Until now, as long as these data are absent at EU level and the toxicological significance for the metabolite has not been proven, the determination of florasulam only is sufficient.

In addition, the GAP proposed by the applicant (1 x 3.25 g a.s. florasulam, BBCH 12-18, PHI – not relevant) is less critical compared to GAP approved at the European level. Therefore, it is unlikely that residues appear in the edible parts of the plant above the LOQ (<0.01 mg/kg) value.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Florasulam				
Maize grain	0.01	Median residue	0.01	Median residue

Table 7.3-10: Results of the dietary burden calculation (Animal Model 2017)

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)
Florasulam and provisionally 4-OH-phenyl-florasulam (data gap) (EFSA, 2015)					
Dairy cattle	0.001	0.001	Corn, field (gluten feed)	0.03	No
Dairy cattle	0.001	0.001	Corn, field (gluten feed)	0.02	No
Lamb	0.001	0.001	Corn, field (gluten feed)	0.02	No
Swine (finishing)	0.001	0.001	Corn, field (gluten feed)	0.02	No
Poultry layer	0.001	0.001	Corn, field (hominy meal)	0.02	No
Poultry layer	0.001	0.001	Corn, field (hominy meal)	0.02	No

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

The dietary burden calculation was made using Animal model 2017.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3

Available data

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

The calculated dietary burdens for all groups of livestock were not found to exceed the trigger value of 0.1 mg/kg DM. Further investigation on residues is not required.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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

7.3.5.1 Available data for all crops under consideration

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

7.3.5.2 Conclusion on processing studies

The level of florasulam residues in cobs and grains is below the limit of quantification (< 0.01 mg/kg). Further investigation on florasulam residues in processed commodities is not required.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

According to the EFSA, 2015 residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

7.3.7 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 MEZOFLOR 103 SC. Therefore, other special studies are not needed.

According SANTE/11956/2016 rev.9 maize are not melliferous crop. The studies on effect on the residue level in pollen and bee products are not required.

In addition the product MEZOFLOR 103 SC is applied at early growth stages (BBCH 12-18), therefore, the risk of residues appearing in honey is negligible.

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

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Florasulam				
Maize grain	0.01	Median residue = LOQ (EFSA, 2012)	Not applicable	
Other products of plant and animal	various MRLs	according to Reg. (~~EU) No 1317/2013~~ Reg. (EU) 2022/1363		

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	2 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	See TMDI value
IESTI (% ARfD) according to EFSA PRIMo*	Not applicable
NTMDI (% ADI) **	Not assessed
NEDI (% ADI)**	Not assessed
NESTI (% ARfD) **	Not assessed

The proposed uses of florasulam in the formulation MEZOFLOR 103 SC do not represent unacceptable acute and chronic risks for the consumer.

The calculation of risk assessment was performed by EFSA PRIMo rev. 3.1. program.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

7.5 References

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RAR, 2015 Renewal Assessment Report prepared according to the Commission Regulation (EU) No 1107/2009. Mesotrione. Volume 3 – B.7 (AS).

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Belgium, 1999. Draft Assessment Report for florasulam.

RMS, 2013. Florasulam. Assessment Report and Proposed Decision. Summary, Scientific Evaluation and Assessment of the new data information. Volume 3 – B.7.

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for florasulam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(3):2626.

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam. EFSA Journal 2015;13(1):3984.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1. (7.2.1.)	Wiebe, L.A.	1997	ZA 1296: Stability of ZA 1296 and the Metabolite MNBA in Frozen Crops (Interim Report) Zeneca Report No: RR 97-042B INT GLP, not published	N	Syngenta
KCA 6.1. (7.2.1.)	Wiebe LA, Peyton CS	1999	ZA1296: Stability of ZA1296 & the Metabolite MNBA in Frozen Crops Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-042B FIN GLP, not published Syngenta File No ZA1296/0125	N	Syngenta
KCA 6.2. (7.2.2.)	Wei, Y. et al	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B	N	Syngenta
KCA 6.2. (7.2.2.)	Tarr, J.B. et al	1997	[Phenyl-U-14C]ZA 1296: nature of the residues in corn.	N	Syngenta
KCA 6.2.	Brumback D.	2003	[Cyclohexane-2-^{14}C] Mesotrione: Nature of the Residue in Peanuts.	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
(7.2.2.)			Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001287-01 1287-01 GLP, not published Syngenta File No ZA1296/1350		
KCA 6.2. (7.2.2.)	Brown K.	2003	[Phenyl-U-14C] Mesotrione: Nature of the Residue in Peanuts. Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001286-01 1286-01 GLP, not published Syngenta File No ZA1296/1349	N	Syngenta
KCA 6.2. (7.2.2.)	Dohn D., Chu J.	2012	14C-Mesotrione - Nature of the Residue in Herbicide Tolerant (HT) Soybeans. Syngenta PTRL West, Hercules CA, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA, Landis International, Valdosta, USA, Agvise Laboratories, Northwood, ND, USA, 1943W, 860.1300-09-433-07B-03 GLP, not published Syngenta File No ZA1296_50531	N	Syngenta
KCA 6.2. (7.2.2.)	Unknown	1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow.	N	Syngenta
KCA 6.3. (7.2.3.)	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1995 (WRC-96099) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-071B GLP, not published Syngenta File No ZA1296/0412	N	Syngenta
KCA 6.3. (7.2.3.)	Barnes J.	1997a	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-078B GLP, not published Syngenta File No ZA1296/0409	N	Syngenta
KCA 6.3. (7.2.3.)	Barnes J., Atger J., Wiebe L., Miller M.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 (Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-045B GLP, not published Syngenta File No ZA1296/0421	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
KCA 6.3. (7.2.3.)	Miller M., Atger J., Wiebe L., Elvira D.	1998	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 (Pre-emergence) (WRC-97-138) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-062B GLP, not published Syngenta File No ZA1296/0417	N	Syngenta
KCA 6.3. (7.2.3.)	Miller M., Griehl T., Wiebe L., Elvira D.	1998	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Preiemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-063B GLP, not published Syngenta File No ZA1296/0418	N	Syngenta
KCA 6.3. (7.2.3.)	Barnes J., Chamier O., Wiebe L., Miller M.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-048B GLP, not published Syngenta File No ZA1296/0414	N	Syngenta
KCA 6.3. (7.2.3.)	Klimmek S., Gizler A.	2008	MESOTRIONE AND NICOSULFURON: RESIDUE STUDY ON MAIZE IN NORTHERN FRANCE IN 2007. Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, T011368-07 GLP, not published Syngenta File No A14351BX_10205	N	Syngenta
KCA 6.3. (7.2.3.)	Heillaut C.	2009	Glyphosate (ASF71), Mesotrione (ZA1296) and S-Metolachlor (CGA77102) - Residue Study on GA21 (MON-ØØØ21-9) Corn in France (North) and Czech Republic in 2007. Syngenta ADME - Bioanalyses, Vergeze, France, T01108506 GLP, not published Syngenta File No A15189G_10009	N	Syngenta
KCA 6.3. (7.2.3.)	Schulz H	2010	Mesotrione and Nicosulfuron - Residue Study on Maize in France (North) in 2008. Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T009530-07REG GLP, not published Syngenta File No ZA1296_10049	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
KCA 6.3. (7.2.3.)	Heillaut C.	2009a	Glyphosate, Mesotrione and S-Metolachlor Residue Study on GA21 (MON-00021-9) Corn in Denmark and Sweden in 2008. Syngenta ADME - Bioanalyses, Vergeze, France, T00953307-REG GLP, not published Syngenta File No A15189G_10014	N	Syngenta
KCA 6.3. (7.2.3.)	Meyer M.	2011	Mesotrione - Residue Study on Field Corn in Germany and the United Kingdom in 2009. Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T000920-09REG GLP, not published Syngenta File No A14203B_10105	N	Syngenta
KCA 6.6.1 (7.2.2.2.)	Spillner, C. et al	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	Syngenta
KCA 6.6.1 (7.2.2.2.)	Gorder, G.W. et al	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	Syngenta
KCA 6.6.1 (7.2.2.2.)	Barnes, J.P., Wiebe, L.A.	1997	ZA 1296: Residue Levels on Rotated Crops from Trials Carried Out in the United States During 1995-1996. Zeneca Report No:RR 97-044B	N	Syngenta
KCA 6.1. (7.3.1.)	Butler, RE, Gambie, A.	1997	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Interim Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP Unpublished	N	Dow AgroSciences
KCA 6.1. (7.3.1.)	Gambie, A, Teasdale R.	1999	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Final Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP Unpublished	N	Dow AgroSciences
KCA 6.2. (7.3.2)	Pillar, F.	1997	The Metabolism of XDE-570 in Winter Wheat - Final Report 5U DowElanco Europe, Letcombe Regis, Oxon, UK	N	Dow AgroSciences

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**
			GLP Unpublished		
KCA 6.2. (7.3.2)	Unknown	1994	Nature of the Residue of [14C] XDE-570 in Laying Hens MET 94018 [redacted] GLP Unpublished	N	Dow AgroSciences
KCA 6.2. (7.3.2)	Unknown	1994	Nature of the Residue of [14C]XDE-570 in Lactating Goats MET94017 [redacted] GLP Unpublished	N	Dow AgroSciences
KCA 6.2. (7.3.2)	MacDonald, A.	1997	The uptake of XDE-570 into Four Seeceeding Crops 7U DowElanco Europe, Letcombe Regis, Oxon, UK GLP Unpublished	N	Dow AgroSciences
KCA 6.3. (7.3.3.)	Proiner, I.	2011	Residues of florasulam in sweet corn at harvest and at intervals following a single application of EF-1343, Northern and Southern Europe – 2010. Dow AgroSciences, European Development Centre Report number: GHE-P-12645 GLP Unpublished	N	Dow AgroSciences
KCA 6.3. (7.3.3.)	Proiner, I.	2012	Residues of florasulam in maize at harvest and at intervals following a single application of EF-1343. Northern and Southern Europe – 2011. Dow AgroSciences, European Development Centre Report number: GHE-P-12800 GLP Unpublished	N	Dow AgroSciences

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 applicable. No new studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

A 3.1.1. Mesotrione

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Mesotrione

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,02
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values

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

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

Comments:

Use hyperlir

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		0,7%
	7%	NL child	0,67	2%	Milk: Cattle	0,8%	Sugar beet roots	0,6%	Apples		0,0%
	6%	DE child	0,64	2%	Milk: Cattle	1%	Apples	0,4%	Wheat		0,0%
	6%	UK infant	0,61	4%	Milk: Cattle	0,3%	Potatoes	0,3%	Wheat		0,1%
	6%	FR toddler 2 3 yr	0,56	3%	Milk: Cattle	0,3%	Apples	0,3%	Wheat		0,0%
	6%	FR child 3 15 yr	0,55	2%	Milk: Cattle	0,5%	Wheat	0,4%	Sugar beet roots		0,0%
	5%	GEMS/Food G11	0,47	1%	Soyabeans	0,8%	Milk: Cattle	0,4%	Potatoes		0,0%
	4%	UK toddler	0,45	2%	Milk: Cattle	0,4%	Wheat	0,3%	Potatoes		0,0%
	4%	GEMS/Food G10	0,42	1,0%	Soyabeans	0,5%	Milk: Cattle	0,4%	Wheat		0,1%
	4%	DK child	0,41	1%	Milk: Cattle	0,6%	Rye	0,4%	Wheat		0,0%
	4%	GEMS/Food G07	0,40	0,6%	Milk: Cattle	0,5%	Soyabeans	0,4%	Wheat		0,0%
	4%	GEMS/Food G15	0,40	0,7%	Milk: Cattle	0,5%	Soyabeans	0,5%	Wheat		0,1%
	4%	GEMS/Food G08	0,40	0,6%	Soyabeans	0,6%	Milk: Cattle	0,4%	Wheat		0,0%
	4%	GEMS/Food G06	0,39	0,7%	Wheat	0,4%	Soyabeans	0,4%	Tomatoes		0,1%
	4%	RO general	0,38	1%	Milk: Cattle	0,5%	Wheat	0,4%	Potatoes		0,1%
	4%	ES child	0,38	1%	Milk: Cattle	0,4%	Wheat	0,3%	Cocoa beans		0,0%
	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		0,0%
	4%	DE general	0,36	1%	Milk: Cattle	0,4%	Sugar beet roots	0,2%	Apples		0,0%
	4%	FI adult	0,35	3%	Coffee beans	0,1%	Potatoes	0,1%	Rye		0,0%
	3%	IE adult	0,33	0,4%	Milk: Cattle	0,4%	Sweet potatoes	0,2%	Wheat		0,0%
	3%	NL general	0,30	0,8%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Potatoes		0,0%
	3%	FR infant	0,29	2%	Milk: Cattle	0,2%	Potatoes	0,2%	Apples		0,0%
	2%	FR adult	0,22	0,4%	Milk: Cattle	0,2%	Wine grapes	0,2%	Wheat		0,0%
	2%	PT general	0,21	0,5%	Potatoes	0,4%	Wheat	0,2%	Wine grapes		0,0%
	2%	ES adult	0,21	0,5%	Milk: Cattle	0,2%	Wheat	0,1%	Oranges		0,0%
	2%	FI 3 yr	0,18	0,5%	Potatoes	0,1%	Bananas	0,1%	Wheat		0,0%
	2%	IT toddler	0,16	0,7%	Wheat	0,2%	Other cereals	0,1%	Tomatoes		0,0%
	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		0,0%
	1%	UK vegetarian	0,15	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes		0,0%
	1%	FI 6 yr	0,14	0,4%	Potatoes	0,1%	Cocoa beans	0,1%	Wheat		0,0%
	1%	UK adult	0,14	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes		0,0%
	1%	IT adult	0,12	0,4%	Wheat	0,1%	Tomatoes	0,1%	Apples		0,0%
	1,0%	PL general	0,10	0,3%	Potatoes	0,2%	Apples	0,1%	Tomatoes		0,0%
	0,8%	IE child	0,08	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes		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 3.1.2. Florasulam

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Florasulam

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,05	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2015	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:

Use hyperlin

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)	2%	NL toddler	1,24	1%	Milk: Cattle	0,2%	Apples	0,1%	Maize/corn		0,1%
	1%	NL child	0,66	0,5%	Milk: Cattle	0,2%	Sugar beet roots	0,1%	Apples		0,0%
	1%	DE child	0,64	0,4%	Milk: Cattle	0,2%	Apples	0,1%	Wheat		0,0%
	1%	UK infant	0,61	0,8%	Milk: Cattle	0,1%	Potatoes	0,1%	Wheat		0,0%
	1%	FR toddler 2 3 yr	0,56	0,6%	Milk: Cattle	0,1%	Apples	0,1%	Wheat		0,0%
	1%	FR child 3 15 yr	0,55	0,5%	Milk: Cattle	0,1%	Wheat	0,1%	Sugar beet roots		0,0%
	0,9%	UK toddler	0,45	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes		0,0%
	0,8%	GEMS/Food G11	0,42	0,2%	Milk: Cattle	0,1%	Potatoes	0,1%	Soyabeans		0,0%
	0,8%	DK child	0,41	0,3%	Milk: Cattle	0,1%	Rye	0,1%	Wheat		0,0%
	0,8%	GEMS/Food G07	0,38	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes		0,0%
	0,8%	GEMS/Food G06	0,38	0,1%	Wheat	0,1%	Tomatoes	0,0%	Milk: Cattle		0,0%
	0,8%	GEMS/Food G15	0,38	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes		0,0%
	0,8%	GEMS/Food G08	0,38	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes		0,0%
	0,8%	RO general	0,38	0,2%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes		0,0%
	0,8%	ES child	0,38	0,2%	Milk: Cattle	0,1%	Wheat	0,1%	Cocoa beans		0,0%
	0,7%	SE general	0,37	0,2%	Milk: Cattle	0,1%	Bovine: Muscle/meat	0,1%	Potatoes		
	0,7%	DE women 14-50 yr	0,37	0,2%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Apples		0,0%
	0,7%	GEMS/Food G10	0,37	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Soyabeans		0,0%
	0,7%	DE general	0,36	0,2%	Milk: Cattle	0,1%	Sugar beet roots	0,0%	Apples		0,0%
	0,7%	FI adult	0,35	0,6%	Coffee beans	0,0%	Potatoes	0,0%	Rye		0,0%
	0,7%	IE adult	0,33	0,1%	Milk: Cattle	0,1%	Sweet potatoes	0,0%	Wheat		0,0%
	0,6%	NL general	0,30	0,2%	Milk: Cattle	0,1%	Sugar beet roots	0,0%	Potatoes		0,0%
	0,6%	FR infant	0,29	0,3%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples		0,0%
	0,4%	FR adult	0,22	0,1%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat		0,0%
	0,4%	PT general	0,21	0,1%	Potatoes	0,1%	Wheat	0,0%	Wine grapes		0,0%
	0,4%	ES adult	0,21	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Oranges		0,0%
	0,4%	FI 3 yr	0,18	0,1%	Potatoes	0,0%	Bananas	0,0%	Wheat		0,0%
	0,3%	IT toddler	0,16	0,1%	Wheat	0,0%	Other cereals	0,0%	Tomatoes		0,0%
	0,3%	DK adult	0,16	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat		
	0,3%	LT adult	0,16	0,1%	Milk: Cattle	0,1%	Potatoes	0,0%	Apples		0,0%
	0,3%	UK vegetarian	0,15	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,3%	FI 6 yr	0,14	0,1%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat		0,0%
	0,3%	UK adult	0,14	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,2%	IT adult	0,12	0,1%	Wheat	0,0%	Tomatoes	0,0%	Apples		0,0%
	0,2%	PL general	0,10	0,1%	Potatoes	0,0%	Apples	0,0%	Tomatoes		0,0%
	0,2%	IE child	0,08	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Florasulam 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 IESTI calculations - Raw commodities

A.3.2.1. Mesotrione

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. 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.

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

A.3.2.2. Florasulam

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.

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

Show results for all crops

Unprocessed commodities

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

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

Expand/collapse list

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

A 3.3 IESTI calculations - Processed commodities

A.3.3.1. Mesotrione

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	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!	0,1%	Maize / processed (not	0,01 / 0,01	0,02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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 a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A.3.3.2. Florasulam

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)
	Expand/collapse list															
	Conclusion:															

Appendix 4 Additional information provided by the applicant

Not required.