FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA4307A

Product name: PRIMARY MX

Chemical active substances:

Rimsulfuron, 30 g/kg
Nicosulfuron, 120 g/kg
Mesotrione, 360 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT/

(authorization)

Applicant: Sharda Cropchem España S.L.

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Version history

When	**What**
July 2021	Applicant update
August 2021	zRMS first evaluation
December 2022	Revision based on comments received
March 2023	The final Registration Report

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The text highlighted in grey (comments and corrections) is provided by the evaluator.

Critical GAP: maize; CEU; 1 application at BBCH 12-18; application rate per treatment: 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione kg as/ha

<u>Rimsulfuron</u>

Storage stability

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

Rimsulfuron is stable in maize forage and grain for 24 months, when stored frozen at approximately –20°C (EFSA 2005, EFSA Journal 2018;16(5):5258)

Metabolism in plants and animals

Metabolism in plants and livestock data was assessed during the EU review of rimsulfuron.

The residue definition for plant commodities both for risk assessment and monitoring is set as rimsulfuron.

Data gap was set to address nature and/or magnitude of residue in rotational crops (EFSA Journal 2018;16(5):5258)

Animal residue definitions: "*not appropriate to propose a residue definition because intake of residues by animals from primary crops is not significant. A residue definition for animals might be needed pending the outcome of studies on nature and/or magnitude of residues in rotational crops* (EFSA Journal 2018;16(5):5258)"

Renewal of rimsulfuron is still pending the inclusion document by the Standing Committee, therefore when the document is published the evaluation of this product will have to be re-viewed.

Magnitude of residues in plants

Proposed GAP is less critical than EU GAP (EU GAP: max. 20 g a.s./ha).

Applicant refers to data available in Draft Assessment Report, Germany 2005. Residue trials complying with the EU GAPs but with an LOQ of 0.05 mg/kg, nevertheless, considering the metabolism studies that showed a no residue situation at exaggerated rates, it is concluded however that residues will be below the enforcement LOQ of 0.01 mg/kg.

New overdosed study on the magnitude of residue have been submitted by the applicant in the framework of this application to confirm this state.

GAP of one new trial from NEU: 1 x 0.060 kg as/ha; BBCH 12

Method of analysis: LC/MS/MS, LOQ: 0.001 mg/kg, storage time: 76 days. Trial is accepted. Residues from this trial: 1 x <0.001 mg/kg

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

The uses are considered acceptable.

Magnitude of residues in livestock

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

A residue definition for animals is not needed.

Magnitude of residues in processed commodities

As residues of Rimsulfuron 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.

After the end of the of the renewal process "magnitude of residues in representative succeeding crops" should be re-viewed.

Estimation of exposure through diet and other means

The proposed uses of rimsulfuron in the formulation Primary MX do not represent unacceptable chronic risks for the consumer.

Note:

Renewal of rimsulfuron is still pending the inclusion document by the Standing Committee, therefore when the document is published, the evaluation of this product will have to be re-viewed.

Nicosulfuron

Storage stability

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

The results demonstrate that residues are stable in maize grain and whole plant for 9 months.

Metabolism in plants and animals

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

The residue definition for plant commodities both for risk assessment and monitoring is set as nicosulfuron.

Magnitude of residues in plants

Proposed GAP is less critical than EU GAP (EU GAP: max. 60 g a.s./ha).

The number of trials (EU unprotected trials) is sufficient as to support the use of nicosulfuron in maize according to the proposed GAP in Nouthern Zone.

The residues arising from the proposed use will not exceed the MRLs for maize grain set at 0.01 mg/kg (Reg. (EU) No 617/2014).

Use is accepted.

Magnitude of residues in livestock

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

Magnitude of residues in processed commodities

As residues of nicosulfuron 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.

Estimation of exposure through diet and other means

The proposed uses of Primary MX do not represent unacceptable chronic risks for the consumer.

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

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 is less critical than EU GAP (EU GAP: max. 120 to 150 g as/ha; proposed: 90 g as/ha)

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.

Magnitude of residues in livestock

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

Magnitude of residues in processed commodities

As residues of nicosulfuron 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.

Estimation of exposure through diet and other means

The proposed uses of Primary MX do not represent unacceptable chronic risks for the consumer. EFSA PRIMo rev. 3.1 calculations for rimsulfuron and PRIMo rev.3.0 for nicosulfuron and for mesotrione (provided by the applicant) are accepted. Due to the large margin of safety for the consumer, recalculations using PRIMo rev. 3.1 are not necessary.

Calculation of acute risk assessment for uses under evaluation using ARfD values from EFSA 2018 was added. The proposed uses of rimsulfuron in the formulation Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 12% do not represent unacceptable acute risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation SHA4307A are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU zone for maize. A list of all intended uses within the CEU 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 rimsulfuron, nicosulfuron and mesotrione as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of rimsulfuron, nicosulfuron and mesotione residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

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

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- none

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	**Maize**	CEU	SHA4307A	F	Broadleaved and grass weeds	WG	30 g/kg rimsulfuron, 120 g/kg nicosulfuron, 360 g/kg mesotrione	Foliar spray	BBCH 12-18	a) 1 b) 1	-	0.001875-0.00375 rimsulfuron + 0.0075-0.015 nicosulfuron + 0.0225-0.045 mesotrione	200-400	a) 0.0075 rimsulfuron + 0.03 nicosul-furon + 0.09 mesotrione b) 0.0075 rimsulfuron + 0.03 nicosul-furon + 0.09 mesotrione	-	A

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

Explanation for Column 11 "Conclusion"

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

7.1.2 Summary of the evaluation

The preparation SHA4307A is composed of rimsulfuron, nicosulfuron and mesotrione.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Rimsulfuron					
ADI	SANCO/10528/2005 – rev. 2 –27 January 2006	2006	0.1 mg/kg bw/day	Rat 2-year oral	100
ARfD	EFSA Journal 2018;16(5):5258	~~20006~~ 2018	~~Not necessary – not required~~ 1.7	Developmental study in rabbit	100
Nicosulfuron					
ADI	EFSA Scientific Report 2007; 120, 1-91	2007	2 mg/kg bw/d	Chronic rat supported by subchronic dog	100
ARfD		2007	Not necessary – not required		
Mesotrione					
ADI	SANTE/11654/2016	2016	0.01	Mouse multigeneration	200
ARfD		2016	0.02	Mouse multigeneration	100

7.1.2.1 Summary for Rimsulfuron

Table 7.1-3: Summary for rimsulfuron

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?
0	Maize	Yes	Yes	NR	Yes	Yes	No	NR

* 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 rimsulfuron 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.

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

7.1.2.2 Summary for Nicosulfuron

Table 7.1-4: Summary for nicosulfuron

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?
0	Maize	Yes	Yes	NR	Yes	Yes	No	NR

* 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 nicosulfuron 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.

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

7.1.2.3 Summary for Mesotrione

Table 7.1-5: 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?
0	Maize	Yes	Yes	NR	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.

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.

An acute risk has not been identified for maize. The use of SHA4307A on maize is therefore acceptable.

7.1.2.4 Summary for SHA4307A

Table 7.1-6: Information on SHA4307A (KCA 6.8)

Crop	PHI for SHA4307A proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for SHA4307A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Rimsulfuron	Nicosulfuron	Mesotrione		
Maize	NR	NR	NR	NR		

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

Table 7.1-7: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for SHA4307A
Crop group	Led by rimsulfuron	Led by nicosulfuron	Led by mesotrione	
Maize	NR	NR	NR	

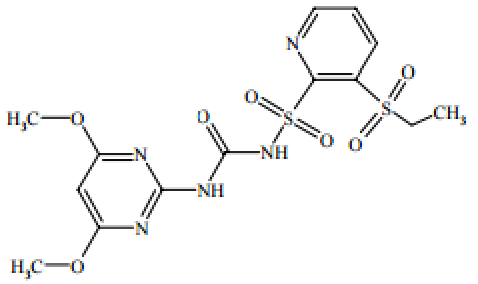
NR: not relevant

Assessment

7.2 Rimsulfuron

General data on rimsulfuron are summarized in the table below (last updated 2006/01/27)

Table 7.2-1: General information on rimsulfuron

Active substance (ISO Common Name)	Rimsulfuron
IUPAC	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea
Chemical structure	
Molecular formula	C14H17N5O7S2
Molar mass	431.45 g/mol
Chemical group	pyrimidinylsulfonylurea herbicides
Mode of action (if available)	It is a selective systemic herbicide taken up by leaves and roots and acts as an effective inhibitor of plant root and shoot growth by blocking the enzyme acetolalate synthase (ALS).
Systemic	Yes
Company (ies)	DuPont
Rapporteur Member State (RMS)	Germany
Approval status	Approved Date of (01/02/2007) and reference to decision (COMMISSION DIRECTIVE 06/39/EC - Reg. (EU) No 540/2011).
Restriction	Only uses as herbicide may be authorised. see COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011
Review Report	SANCO/10528/2005 – rev. 2 27/01/2006
Current MRL regulation	Reg. (EU) No 617/2014
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 2005)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2012;10(10):2911)
Current MRL applications on intended uses	-

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Maize forage	High water content	24 months	EFSA 2005
Maize grain	high protein/starch content	24 months	EFSA 2005
Potato	high protein/starch content	24 months	EFSA 2005
Tomato	High water content	6 months	EFSA 2005

Conclusion on stability of residues during storage

The stability of rimsulfuron residues was studied by fortifying samples of maize forage and maize grain with rimsulfuron at 0.20 mg/kg. Following storage at approximately -20°C, residue of rimsulfuron in maize forage and maize grain were sufficiently stable for at least 24 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Rimsulfuron.

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 (g a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruit-	Tomatoes	2- ^{14}C-	Foliar, F	72	1	0, 7, 30,		Germany

ing vegetable		pyridine and 2-^{14}Cpyrimidine				46, 53, 60		2005
			Foliar, G	178.5, 357.5 or 715	1	Foliage: 0, 7 Fruits: 74		Germany 2005
Root and tuber vegetables	Potatoes	2- ^{14}C-pyridine and 2-^{14}Cpyrimidine	Foliar, G	70	1	0, 8, 14, 30, 82		Germany 2005
					2	0, 7, 14, 14, 28, 68		
Cereals	Maize	2- ^{14}C-pyridine and 2-^{14}Cpyrimidine	Foliar, G	52	1	Silage: 0, 8, 15, 30, 50, 80 Mature crop: 105		Germany 2005

Summary of plant metabolism studies reported in the EU

- A brief summary of metabolism in plants are presented below (refer to the *DAR of July 2005, Volume 3, Annex B, B7.1. and EFSA Journal 2005;45, 1-65*).

The metabolism of [^{14}C]rimsulfuron has been studied in maize, potatoes and tomatoes. Crops were treated with one or two applications of [pyridine-2-^{14}C]Rimsulfuron or [pyrimidine-2-^{14}C]Rimsulfuron. Maize was grown in pots maintained in a greenhouse and treated with a single application at 52 g as/ha, the highest rate that could be used without significant injury. Potatoes were also grown in pots in the greenhouse and were treated with 1 or 2 application of either radiolabelled form of Rimsulfuron, each at 70 g as/ha. The applications were 16 days apart. Tomatoes were grown in field plots and treated with a single application of either radiolabelled form of rimsulfuron at 72 g as/ha.
Mature maize grain, potato tubers and tomato fruit all contained non quantifiable residues above the LOQ (0.02 mg/kg parent equivalents). The metabolic pathway was therefore established by characterization of residues in immature foliage. Two primary degradation pathways were identified. A first mechanism is contraction of the sulfonylurea bridge to form IN-70941, leading further to IN-70942 from loss of $CONH_2$. The second pathway is cleavage of the sulfonylurea bridge to produce IN-E9260 and IN-J290. These first degradation products were further metabolized to a number of minor, polar compounds. None of the metabolites formed is found to be of particular concern. The metabolism of rimsulfuron in plants is similar to that found in rats. Due to rapid and extensive metabolism in the tested crops, only parent rimsulfuron should be considered in the residue definition for both monitoring and risk assessment.

Summary of new plant metabolism studies

No new data have been submitted.

Conclusion on metabolism in primary crops

Due to the rapid and extensive metabolism of rimsulfuron in the tested crops, the residue for enforcement and risk assessment in all plant commodities is defined as rimsulfuron.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	**Rate (kg a.s./ha)**	**Sowing intervals (DAT)**	**Harvest Intervals (DAT)**	**Remarks**	
EU data								
Leafy vegetables	Lettuce	2- ^{14}C-pyridine and 2-^{14}Cpyrimidine	Soil, G	0.052	30	106		Germany 2005
					120	184		
Root and tuber vegetables	Sugar beet				30	88, 226		
					120	150, 267		
Pulses and oilseeds	Soya bean				30	60, 121		
					120	150, 226		
					±300	330, 389		
	Sunflower				120	150, 226		
Cereals	Sorghum				±300	328, 428		
	Wheat				30	60, 121		
					120	150, 226		
					±300	328, 389		

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

Summary of plant metabolism studies reported in the EU

The summary of the residue trials in succeeding crops is presented below (refer to the *DAR of July 2005 Volume 3, Annex B, B7.9 and EFSA Scientific Report (2005) 45, 1-61*).

A confined rotational crop study of [^{14}C]rimsulfuron was conducted using sassafras sandy loam soil under green house. The test soils were treated with either [pyridine-2-^{14}C]rimsulfuron or [pyrimidine-2-^{14}C]Rimsulfuron at a rate of 52 g as/ha. Total [^{14}C] residues in the food items from the lettuce, sugar-beets, sunflower, soya beans, sorghum and wheat, grown in the soil treated with [^{14}C]rimsulfuron at the rate of 52 g as/ha and aged for either 30 days, 120 days or 10 months prior the planting, were below LOQ of 0.05 mg/kg.

Metabolite IN-70941 (< 0.05 0.07 mg/kg) was the principle metabolite along with minor amounts of IN-70942 in the organic soluble fraction of the wheat and soya bean straw. IN-E9260 and IN-H1043 were tentatively identified as the major components of the water-soluble fraction of the wheat straw extracts.
There is no reasonable expectation of concentration of rimsulfuron or its metabolites/degradation products in the succeeding crop food and feed items after the application of Rimsulfuron under the normal agricultural practices. As this study has shown that detectable rimsulfuron residues are not expected to occur in succeeding crops no field testing is required.

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops

Considering the overdosing factor of the above study and the fact that rimsulfuron was applied to a bare soil (interception of rimsulfuron by the plants might be expected in practice), it can be concluded that a specific residue definition for rotational crops is not deemed necessary and that rimsulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg.

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

Conclusion drawn from EFSA Scientific Report (2005) 45, 1-61 are reported below:
Due to the very low residue level in the raw agricultural commodities when Rimsulfuron is used according to the GAP supported as representative use, no residues are expected in processed products.

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), root vegetables (potato), fruits (tomato)
Rotational crops covered	Lettuce, soybeans, sugarbeets, sunflower, sorghum, and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	-
Residue pattern in processed commodities similar to pattern in raw commodities?	-
Plant residue definition for monitoring	Rimsulfuron (Reg. (EU) No 617/2014)
Plant residue definition for risk assessment	Rimsulfuron (EFSA 2005)
Conversion factor from enforcement to RA	-

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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	Goat	2- ^{14}C-pyridine and 2-^{14}Cpyrimidine	2	12.1 mg/kg and 9.9 mg/kg of feed	3	Milk	twice daily	Germany 2005
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	2- ^{14}C-pyridine and 2-^{14}Cpyrimidine		12.0 mg/kg and 9.6 mg/kg of feed	5	Eggs	daily	Germany 2005
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Conclusions drawn from DAR, 2005 are reported below:
Goats study:
Minimal transfer of Rimsulfuron equivalent residues to the milk, fat, liver, kidney and muscle tissues was observed following a daily single oral dose for 3 consecutive days at the levels well in excess of the anticipated maximum dietary burden (12.1 mg/kg and 9.9 mg/kg feed for [pyridine-2-^{14}C]-Rimsulfuron and [pyrimidine-2-^{14}C]-Rimsulfuron test goats, respectively).
Almost the entire administered radioactivity was recovered in the urine (approx. 55%) and faeces and GI track contents (approx. 41-43%). Despite the exaggerated dose administered in the test goats, the total [^{14}C] residues levels in the milk were all below the limit of detection. Liver (0.132 mg/kg and 0.144 mg/kg) and kidney -0.128 mg/kg) contained low levels of TRR. Unmetabolized Rimsulfuron was not detected in the liver and kidney. All of the liver and kidney metabolites were < 0.05 mg/kg. IN-70941, IN-70942, IN-E9260, IN-J290, IN-69190 and IN-H1043 were identified from urine and faeces. The metabolic pathway was established based on the compounds identified from the urine and faeces. Overalls the metabolic pathway was consistent with that in the rate and hen.

Hen study:
Minimal transfer of Rimsulfuron equivalent residues to the egg, fat, liver and muscle tissues of laying hens was observed following administration of 5 consecutive daily single doses at a level equivalent to either 9.6 mg/kg or 12.0 mg/kg Rimsulfuron in the total diet.
Most of the administered radioactivity (86.4 and 88.9%) was recovered in the excreta, including GI tract contents and pan paper wash. Total radioactivity residues in eggs, tissues, fat and skin were low (< 0.01 to 0.016 mg/kg), despite dosing the test birds at more than 200 times the anticipated dietary burden.
In addition to unmetabolized Rimsulfuron (0.03 mg/kg), IN-70941 (0.01 mg/kg) was identified from the liver. Excreta were the major source of isolation and identification of ^{14}C-residues. Rimsulfuron and IN-70941 were identified from both dose groups. IN6E9260 and IN-J290 were minor metabolites in the excreta from the [pyridine-2-^{14}C]-Rimsulfuron and [pyrimidine-2-^{14}C]-Rimsulfuron dosed hens, respectively. The metabolic fate of Rimsulfuron in the laying hen was consistent with that in the laboratory rate and lactating goat.

A brief summary of metabolism in livestock are presented below (refer to the *DAR of July 2005, Volume 3, Annex B, B7.2 and EFSA Scientific Report (2005) 45, 1-65*).
The metabolic pathway in ruminant (goat) and mono-gastric animals (rat and hen) was similar. Therefore no pig metabolism study is required. The unique and primary pathway in animals was through sulfonylurea bridge contraction to yield IN-70941, which looses NH_2-C = O group to form IN-70942. The other pathway was the cleavage of sulfonylurea to yield IN-E9260 and IN-J290.

Summary of new animal metabolism studies

No new data have been submitted in framework of this application.

Conclusion on metabolism in livestock

As no significant residues are expected to be present in maize or potato products intended for livestock consumption, metabolism studies are not in principle required.

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 goats
	Laying hens
Time needed to reach a plateau concentration	-
	-
Animal residue definition for monitoring	Rimsulfuron (Reg. (EU) No 617/2014)
Animal residue definition for risk assessment	Rimsulfuron (EFSA 2012)
Conversion factor	-
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

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

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of SHA4307A 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, Germany 2005	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.0125-0.020 kg as/ha, BBCH 12-17, PHI 13-124, outdoor E/RA: 25 x < 0.05	Residue trials complying with the GAPs but with an LOQ of 0.05 mg/kg Considering the metabolism studies, it is concluded however that residues will be below the enforcement LOQ of 0.01 mg/kg.				
	New trials	N-EU	Trials GAP: 1 x 0.06 kg as/ha, BBCH 12, PHI 139d, outdoor E: n.d. RA: n.d.					
	Overall supporting data for cGAP	N-EU	E : 25 x <0.05, 1 x n.d. RA: 25 x <0.05, 1 x n.d.	<0.01	<0.01		0.01	Yes

* Source of EU MRL: Reg. (EU) No. 617/2014

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.

Applicant refers to data available in Draft Assessment Report, Germany 2005. Residue trials complying with the GAPs but with an LOQ of 0.05 mg/kg, nevertheless, considering the metabolism studies that showed a no residue situation at exaggerated rates, it is concluded however that residues will be below the enforcement LOQ of 0.01 mg/kg.
Moreover, applicant hereby delivers new studies on magnitude of residues to confirm this state.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: rimsulfuron				
Maize grain	0.01	Median residue	0.01	Median residue
Maize silage	0.01	Median residue	0.01	Median residue
Potatoes	0.01	Median residue	0.01	Highest residue

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: rimsulfuron					
Cattle (all diets)	0.002	0.002	Potatoes proces waste	0.06	N
Cattle (dairy only)	0.002	0.002	Potatoes proces waste	0.05	N
Poultry (layer only)	0.001	0.001	Potatoes culls	0.02	N
Swine (all diets)	0.001	0.001	Potatoes proces waste	0.05	N

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Conclusion on feeding studies

Conclusions drawn from EFSA Scientific Report (2005) 45, 1-61 are reported below:
No livestock feeding studies were conducted/required since no residues (< 0.005 mg/kg) were detected in any crops of concern intended for feeding of domestic animals.

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

As residues of Rimsulfuron 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.
Moreover, there is a large margin of safety on the consumer risk assessment (chronic exposure does not exceed 10% of ADI).

7.2.6 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 SHA4307A. Therefore, other special studies are not needed.

7.2.7 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).

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

7.2.7.1 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
Rimsulfuron				
All commodities (chronic risk assessment)	Reg. (EU) No 617/2014		~~NR~~ Maize: 0.01 (Reg. (EU) No 617/2014)	

7.2.7.2 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	2 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not relevant.
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	Unprocessed commodities Based on adults Maize/Corn: 0.00% Based on children Maize/Corn: 0.00% Processed commodities Based on adults Maize/oil: 0.00% Based on children: Maize/oil: 0.00% Maize/processed (not specified): 0.00%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

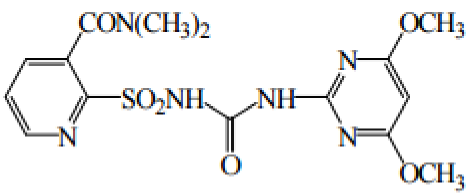
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of rimsulfuron in the formulation Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 12% do not represent unacceptable chronic and acute risks for the consumer.

7.3 Nicosulfuron

General data on Nicosulfuron are summarized in the table below (last updated 2008/01/22)

Table 7.3-1: General information on nicosulfuron

Active substance (ISO Common Name)	Nicosulfuron
IUPAC	2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-N,N-dimethylnicotinamide or 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3- dimethylcarbamoyl-2-pyridylsulfonyl)urea
Chemical structure	
Molecular formula	C15H18N6O6S

Molar mass	410.4 g/mol
Chemical group	pyrimidinylsulfonylurea herbicides
Mode of action (if available)	It is a selective systemic herbicide taken up by leaves and roots and acts as an effective inhibitor of plant root and shoot growth by blocking the enzyme acetolalate synthase (ALS).
Systemic	Yes
Company (ies)	ISK Biosciences Europe S.A.
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved Date of (01/01/2009) and reference to decision (COMMISSION DIRECTIVE 2008/40 - Reg. (EU) No 540/2011).
Restriction	Only uses as herbicide may be authorised. see COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011
Review Report	SANCO/3780/07 – rev. 1 22/01/2008
Current MRL regulation	Reg. (EU) No 617/2014
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 2007)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2012;10(12):3048)
Current MRL applications on intended uses	-

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

7.3.1 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.

7.3.2 Stability of Residues (KCA 6.1)

7.3.2.1 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			
Maize whole plant	High water content	9 months	United Kingdom 2007
Maize grain	high protein/starch content	9 months	United Kingdom 2007

Conclusion on stability of residues during storage

The results demonstrate that residues are stable ≥ 70% for 9 months.

7.3.2.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Peer Review of Nicosulfuron.

7.3.3 Nature of residues in plants, livestock and processed commodities

7.3.3.1 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 (g a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Maize	5- ^{14}C-pyrimidinyl	Foliar, G	60, 300	1	0, 14, 30, 60 (silage), 102 (harvest)		EFSA 2012
		2- ^{14}C-pyridyl	Foliar, G	60, 300	1	0, 14, 30, 60 (silage), 102 (harvest)		EFSA 2012

Summary of plant metabolism studies reported in the EU

- A brief summary of metabolism in plants are presented below (refer to the *DAR of June 2006, Volume 3, Annex B, B.7.1 and EFSA Scientific Report 2007; 120, 1-91*).

Metabolism of nicosulfuron was studied in maize. Two studies, one for pyridyl- and one for pyrimidinyl-labelled nicosulfuron are available for maize grown in soil. The field rate (N) and 5N application rates were used, with a 4% SC formulation and direct foliar application.

In the pyrimidinyl study, a few hours after application a considerable amount of metabolism had already occurred. Nicosulfuron was present at 24 % TRR (0.69 mg/kg) and metabolite HMUD 4 % TRR (0.11 mg/kg). At the 60 day time interval the TRR was low with only 0.06 mg/kg in the straw and only 0.003 mg/kg in the grain and the metabolite profile has changed considerably. The metabolites identified were not present initially. Nicosulfuron was still the most significant residue at 52 % TRR (0.029 mg/kg), and metabolites identified were DMPU 5.9 % TRR (0.003 mg/kg) and ADMP 5.5 % TRR (0.003 mg/kg). The other two metabolites were M1 and M5, with M1 being the most significant at 13% TRR (0.007 mg/kg). At the 102 day harvest point the residue profile was very similar to the 60 day harvest; however some slight increases in metabolite levels were noted which is deemed a result of a decrease in water content.

In the pyridyl labelled study, immediately after application nicosulfuron was the predominant residue at 51 % TRR (0.79 mg/kg). Six metabolite fractions were characterised and three identified as AUSN 20.4 % TRR (0.32 mg/kg), HMUD 3.6 % TRR (0.056 mg/kg) and ASDM 17.3 % TRR (0.27 mg/kg). AUSN and ASDM were not identified in the pyrimidinyl study since cleavage of the ring structures has occurred. The only other significant metabolite fraction present was M1 at 1.6 % TRR (0.025 mg/kg). At day 60 the TRR had decreased to 0.05 mg/kg in the straw and 0.001 mg/kg in the grain, and the same fractions and compounds were characterised as at the 0 day sampling interval. Nicosulfuron was still present at 41% TRR (0.024 mg/kg), AUSN 13.5 % TRR (0.008 mg/kg), ASDM 16.7 % TRR (0.01 mg/kg.) and HMUD 0.1 % TRR (0.001 mg/kg). No other metabolites were present at significant levels. At the 102 day interval it would appear that the M1 metabolite fraction had increased from 0.1 % TRR to 29 % TRR. Further work was undertaken to clarify how metabolite M1 was formed, the reason for the significant difference in levels of M1 found between the day 60 and day 102 interval is still unknown. However, M1 was shown to be a fraction of metabolites (partially conjugates of parent and ASDM) rather than one single metabolite and individual residues are generally low. Of the metabolites identified, none of them are considered to be toxicologically significant as they are found in the rat metabolism or are conjugates of rat metabolites.

Summary of new plant metabolism studies

No new data have been submitted in the framework of this application.

Conclusion on metabolism in primary crops

The residue for enforcement and risk assessment in cereals is defined as nicosulfuron only.

7.3.3.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops

The summary of the residue trials in succeeding crops is presented below (refer to the *DAR of June 2006, Volume 3, Annex B, B7.1.4 and EFSA Scientific Report 2007; 120, 1-91*).

The DT_{50} in soil from field studies is 63 days; therefore at 100 days there will be greater than 10 % of substance remaining in the soil. However, the main concern was that metabolites ADMP and ASDM have a similar toxicity to nicosulfuron, and that at least ASDM is medium to high persistent in soil. Nevertheless, lysimeter studies indicated low uptake by cereal plants (TRR <0.01 mg/kg). Moreover, the phytotoxic effect of nicosulfuron and its soil metabolites on dicot plants leads to a self-limitation in the re-planting period. So, where after a plant back interval of 27 to 30 days marked phytotoxic effects observed in following crops while residues of nicosulfuron, ADMP and ASDM in the soil were found to be below the LOQ (0.01 mg/kg). Thus, other crops than cereals could not be grown until the following spring at which time residues in soil of nicosulfuron and relevant metabolites have decreased to <0.001 mg/kg. It can be concluded that at this level in soil no significant residues will occur in rotational crops. It was agreed during the Peer Review process that no further data would be necessary.

7.3.3.3 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

No data was required as quanitifiable residues are not expected in the treated crop and there is a large margin of safety on the consumer risk assessment (chronic exposure does not exceed 10% of ADI).

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

Table 7.3-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (maize)
Rotational crops covered	Not required. Lysimeter studies indicated low uptake by cereal plants (TRR <0.01 mg/kg) and the phytotoxic effect of nicosulfuron and its soil metabolites on dicot plants leads to a self-limitation in the re-planting period
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No data supplied or required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Nicosulfuron (Reg. (EU) No 617/2014)
Plant residue definition for risk assessment	Nicosulfuron (EFSA 2007)
Conversion factor from enforcement to RA	-

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.3.3.5 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 7.3-5: 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 samp-ling	
EU data								
Lactating ruminants	Goat	[^{14}C]nicosulfuron (pyridine)	1	8.3 mg/kg bw/d	3	Milk	twice daily	United Kingdom 2007
						Urine and faeces	daily	
						Tissues	at sacrifice	
		^{14}C]nicosulfuron (pyrimidine)	1	8.64 mg/kg bw/d	3	Milk	twice daily	United Kingdom 2007
						Urine and faeces	daily	
						Tissues	at sacrifice	
		^{14}C]nicosulfuron (pyrimidine)		0.0069 mg/kg bw/d	3	Milk	twice daily	United Kingdom 2007
						Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of new animal metabolism studies

No new data have been submitted in the framework or this application.

Conclusion on metabolism in livestock

- A brief summary of metabolism in livestock are presented below (refer to the *DAR of June 2006, Volume 3, Annex B, B7.2 and EFSA Scientific Report 2007; 120, 1-91*).

Intakes of nicosulfuron by domestic animals will not be significant and these metabolism studies were not necessary as detailed in Directive 96/68/EC. However, livestock metabolism data with lactating goats were evaluated and reported by RMS in the DAR for future reference.
The majority of radioactivity was rapidly excreted and identifiable residues were produced in the high dose level studies. In the more appropriate dose level study no significant residues were detected in edible tissues and organs (<0.001 mg/kg).

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

Table 7.3-6: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	-
Time needed to reach a plateau concentration	Unable to assess due to low total radioactive residues.
	-
Animal residue definition for monitoring	Nicosulfuron - Reg. (EU) No 617/2014
Animal residue definition for risk assessment	Nicosulfuron - EFSA Journal 2012;10(12):3048
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

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

7.3.4 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.3-7: Summary of EU reported and new data supporting the intended uses of SHA4307A 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	United Kingdom 2007	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.06 kg as/ha, BBCH 12-18, outdoor 20x<0.01	N/A				
	Overall supporting data for cGAP	N-EU	20x<0.01	<0.01	<0.01		0.01	Yes

* Source of EU MRL: Reg. (EU) No 617/2014

7.3.4.2 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.

7.3.5 Magnitude of residues in livestock

7.3.5.1 Dietary burden calculation

Table 7.3-8: 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
Risk assessment residue definition: nicosulfuron				
Maize grain	0.01	Median residue	0.01	Median residue
Maize forage	0.01	Median residue	0.015	Highest residue

Table 7.3-9: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: nicosulfuron					
Cattle (all diets)	0.001	0.001	Maize forage/silage	0.04	N
Cattle (dairy only)	0.001	0.001	Maize forage/silage	0.03	N
Poultry (all diets)	0.001	0.001	Maize forage/silage	0.01	N
Swine (all diets)	0.000	0.000	Maize forage/silage	0.02	N

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

7.3.5.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Conclusion on feeding studies

Since the calculated dietary burdens for all types of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation on the nature of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

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

7.3.6.1 Available data for all crops under consideration

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

7.3.6.2 Conclusion on processing studies

As quantifiable residues of nicosulfuron are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

7.3.7 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.

7.3.8 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 SHA4307A. Therefore, other special studies are not needed.

7.3.9 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).

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

7.3.9.1 Input values for the consumer risk assessment

Table 7.3-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Nicosulfuron				
All commodities	Current EU MRL – Reg. (EU) No 617/2014		-	-

7.3.9.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.0	0.1% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not relevant.
IESTI (% ARfD) according to EFSA PRIMo* rev.3.0	-
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

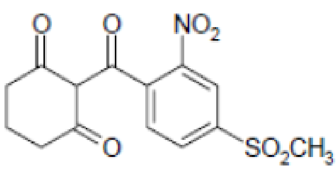
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of nicosulfuron in the formulation Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG do not represent unacceptable chronic risks for the consumer.

7.4 Mesotrione

General data on mesotrione are summarized in the table below (last updated 2018/12/13)

Table 7.4-1: 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	Benzoylcyclohexanedione
Mode of action (if available)	It acts by competitive inhibiton of the enzyme 4-

	hydroxyphenylpyruvate dioxygenase (HPPD)
Systemic	Yes
Company (ies)	Syngenta Crop Protection AG
Rapporteur Member State (RMS)	RMS: UK Co-RMS: Belgium
Approval status	Approved Date of (01/06/2017) and reference to decision (REGULATION (EU) No 2017/725- REGULATION (EU) No 540/2011) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0725&from=EN https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&from=EN
Restriction	Only uses as herbicide may be authorised.
Review Report	SANCO/1416/2001 – final 14/04/2003
Current MRL regulation	Regulation (EC) No 2017/626
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA Journal 2015;13(1):3976)
EFSA Journal : Conclusion on the peer review	Yes (EFSA Journal 2016;14(3):4419)
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2008-585 All commodities Status: Reasoned opinion available (EFSA Journal 2015;13(1):3976)

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

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.4-2: 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			
Mesotrione			
Maize forage	High water content	31 months	EFSA Journal 2016;14(3):4419
Maize grain	High starch content	42 months	
MNBA			
Maize forage	High water content	42 months	EFSA Journal

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Maize grain	High starch content	42 months	2016;14(3):4419

Conclusion on stability of residues during storage

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.

7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Mesotrione.

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.4-3: 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								
Pulses and oilseeds	peanuts	Cyclohexane-2-^{14}C and phenyl-U-^{14}C	Pre-emergence	0.305-0.327	1	90(a), 153-154(d), 154-169(e)	-	EFSA Journal 2016;14(3): 4419
			Pre-emergence	0.796-0.836	1		-	
	Herbicide tolerant soya bean		Pre-emergence	0.218-0.226	1	28(a), 42(d), 123-124(f)	-	
			Pre- + post-emergence	0.218-0.226 followed by 0.128-0.130	2	28(a), 51(d), 90(f)	-	
			Post-emergence	0.224-0.230	1	22(a), 40(d), 110-118(f)	-	

Cereals	maize		Pre-emergence	0.280-0.307	2	27(a), 154(a), 154(c)	-	
			Post-emergence	0.161-0.164	1	28(a), 125(a), 125(c)	-	

(a): forage and foliage
(b): fodder
(c): grain
(d): hay
(e): nutmeat
(f): seed

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2016;14(3):4419 are reported below:
Plant metabolism was studied in maize (pre- and post-emergence), peanuts (pre-emergence) and genetically modified soya bean (pre-, post-emergence and combined pre-/post-emergence) with Mesotrione labelled on cyclohexane-2-14C and phenyl-U-14C. The metabolic pattern of Mesotrione was found to be quantitatively different in conventional crops (maize, peanut) compared to genetically modified soya bean. In maize and peanuts, parent Mesotrione was hardly recovered (3% TRR in maize forage only) whilst the most pertinent metabolites identified in the feed items were MNBA (up to 20% TRR in maize forage leaves) and AMBA, free and conjugated (13% and 28% TRR respectively in maize forage leaves and fodder; 15% TRR in peanut meat). Further metabolites' identification was not conducted in maize grain due to the very low recovered total residues (0.014 mg/kg). In genetically modified herbicide tolerant soya bean, parent Mesotrione was less extensively metabolised compared to conventional crops and occurred in forage at up to 18% TRR and in soya bean seed (10% TRR). The predominant compounds were identified as 4/5-hydroxy Mesotrione (forage 19% TRR; hay 25% TRR; seed 8% TRR) and MNBA (forage 25% TRR; hay 20% TRR; seed 5% TRR). AMBA compound was never detected. The unextracted radioactivity was further characterized as polar compounds (soya bean), lipids (peanut meat) and carbohydrates (maize) incorporated into the natural constituents of the plant. The metabolism of Mesotrione in maize, peanuts and soya bean proceeds by oxidation of the parent molecule to 4/5-hydroxy Mesotrione and to MNBA with subsequent reduction to AMBA and its conjugates observed in conventional maize and peanuts only.

Summary of new plant metabolism studies

No new data have been submitted in the framework of this application.

Conclusion on metabolism in primary crops

Conclusions drawn from EFSA Journal 2016;14(3):4419 are reported below:
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.

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.4-4: Summary of metabolism studies in rotational crops

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

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

Summary of plant metabolism studies reported in the EU

The information provided in the Mesotrione RAR, 2015 Volume 3 Part B7 point B.7.6.2 is reported below:
The metabolism and distribution of ZA 1296 was investigated in the rotational crops wheat, endive and radish planted 120 and 300 days following soil application of [^{14}C] ZA 1296 to soil in pots at ca 1.2N. A replanting interval of 30 days was not investigated but is not of concern since replanting after this interval would not be anticipated for this crop. TRR in the plants grown in the soil treated with [^{14}C]-cyclohexane labelled ZA 1296 were <0.001-0.002 mg/kg. TRR in the crops grown in soil treated with [^{14}C]-phenyl labelled ZA 1296 were 0.004 mg/kg in both radish roots and tops, 0.012 mg/kg in endive and 0.033, 0.018, 0.031 and 0.006 mg/kg in wheat forage, hay, straw and grain respectively. The 300 DAT crops were not harvested due to the low levels of radioactivity in the 120 DAT crops.
MNBA, AMBA sulphate and AMBA conjugate were present in all extracts of wheat forage, hay and straw, the only significant component was MNBA at 0.011 mg/kg in wheat forage (33% TRR). ZA 1296 was not detected.
The metabolism of mesotrione is similar in rotational crops to that observed in primary crops.

Summary of new plant metabolism studies

No new data have been submitted in framework of this application.

Conclusion on metabolism in rotational crops

Conclusions drawn from EFSA Journal 2016;14(3):4419 are reported below:
The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

According to the EFSA Journal 2016;14(3):4419. *Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered.”*

Conclusion on nature of residues in processed commodities

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

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

Table 7.4-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (maize), Pulses and oilseed (peanut and soya bean)
Rotational crops covered	Root and tuber crops (radish), leafy crops (broadleaved endive) and cereal (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not relevant
Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	Mesotrione (cereals and pulses/oilseeds only) EFSA journal 2016;14(3):4419
Plant residue definition for risk assessment	Food commodities: Mesotrione (cereals and pulses/oilseeds only) Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional. EFSA journal 2016;14(3):4419
Conversion factor from enforcement to RA	Not applicable

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.4.2.5 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 7.4-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	phenyl-U-^{14}C AMBA	1	0.4	7	Milk	daily	EFSA journal 2016;14(3):4419
						Liver	at sacrifice	
						Kidney	at sacrifice	
						Subcutaneous fat	at sacrifice	
						Perirenal fat	at sacrifice	

Summary of plant metabolism studies reported in the EU

According to the EFSA Journal 2016;14(3):4419*: The total residues were below 0.01 mg/kg in all matrices except in kidney (0.053 mg/kg) and fat (0.018 mg/kg) with AMBA being the predominant compound that accounted for 79% TRR and 62% TRR, respectively. A fish metabolism study is also not requested. At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use*.

Summary of new animal metabolism studies

No new data have been submitted in framework of this application.

Conclusion on metabolism in livestock

According to the EFSA Journal 2016;14(3):4419: Livestock metabolism studies are not triggered considering the estimated dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data. A fish metabolism study is also not requested

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

Table 7.4-7: Summary on the nature of residues in commodities of animal origin

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

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

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

7.4.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.4-8: Summary of EU reported and new data supporting the intended uses of SHA4307A 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 calcu-lator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL com-pliance
Maize	EFSA Journal 2016;14(3):4419	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 16-18, outdoor Forage: 6x < 0.01, PHI [30-63] Silage: 6x < 0.01, PHI [68-801] Grain: 6x < 0.01, PHI [78-120] Grain + cob: 6x < 0.01, PHI [78-120] Grain + cob + husk: 6x < 0.01, PHI [78-120] GAP on which MRL/EU a.s. assessment is based: 1 x 0.2 kg as/ha, BBCH 17-18, outdoor Forage: 4x < 0.01, PHI [14-56] Silage: 4x < 0.01, PHI [90-110] Grain: 4x < 0.01, PHI [109-135] Grain + cob: 4x < 0.01, PHI [109-135] Grain + cob + husk: 4x < 0.01, PHI [109-135]	N/A				
	Overall supporting data for cGAP	N-EU	Forage: 10 x <0.01 Silage: 10 x <0.01 Grain: 10 x <0.01 Grain+cob: 10 x <0.01 Grain+cob+husk: 10 x <0.01	<0.01	<0.01		0.01	Yes

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

7.4.3.2 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.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

Table 7.4-9: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
				livestock dietary burden to be revised accordingly

Table 7.4-10: Results of the dietary burden calculation

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

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

7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Conclusion on feeding studies

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

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

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

7.4.5.1 Available data for all crops under consideration

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

7.4.5.2 Conclusion on processing studies

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

7.4.6 Magnitude of residues in representative succeeding crops

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

7.4.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.4-11: 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					
Maize	0.340	Leafy vegetables	Soybean forage	30	EFSA Journal 2016;14(3):4419
			Soybean hay	30	EFSA Journal 2016;14(3):4419

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**
			Soybean seed	30	EFSA Journal 2016;14(3):4419
		Root and tuber vegetables	Radish tops	30	EFSA Journal 2016;14(3):4419
			Radish roots	30	EFSA Journal 2016;14(3):4419
		Small Grain	Millet forage	30	EFSA Journal 2016;14(3):4419
			Sorghum forage	30	EFSA Journal 2016;14(3):4419
			Millet hay	30	EFSA Journal 2016;14(3):4419
			Millet straw	30	EFSA Journal 2016;14(3):4419
			Millet grain	30	EFSA Journal 2016;14(3):4419
	0.34 + 0.22 (0.34 kg as/ha incorporated into soil before the maize crop was planted, and the 0.22 kg a.s./ha applied post emergent to the maize)	Leafy vegetables	Endive leaves	74	EFSA Journal 2016;14(3):4419
		Root and tuber vegetables	Radish tops	85	EFSA Journal 2016;14(3):4419
			Radish roots	85	EFSA Journal 2016;14(3):4419
		Small grain	Wheat forage	100	EFSA Journal 2016;14(3):4419
			Wheat hay	100	EFSA Journal 2016;14(3):4419
			Wheat straw	100	EFSA Journal 2016;14(3):4419
			Wheat grain	100	EFSA Journal 2016;14(3):4419
Maize	0.340	Leafy vegetables	Soybean forage	29	EFSA Journal 2016;14(3):4419
			Soybean hay	29	EFSA Journal 2016;14(3):4419
			Soybean seed	29	EFSA Journal 2016;14(3):4419
		Root and tuber	Radish tops	29	EFSA Journal

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
		vegetables			2016;14(3):4419
			Radish roots	29	EFSA Journal 2016;14(3):4419
		Small grain	Millet forage	29	EFSA Journal 2016;14(3):4419
			Sorghum forage	29	EFSA Journal 2016;14(3):4419
			Millet hay	29	EFSA Journal 2016;14(3):4419
			Millet straw	29	EFSA Journal 2016;14(3):4419
			Millet grain	29	EFSA Journal 2016;14(3):4419
	0.34 + 0.22 (0.34 kg as/ha incorporated into soil before the maize crop was planted, and the 0.22 kg a.s./ha applied post emergent to the maize)	Leafy vegetables	Endive leaves	98	EFSA Journal 2016;14(3):4419
		Root and tuber vegetables	Radish tops	98	EFSA Journal 2016;14(3):4419
			Radish roots	98	EFSA Journal 2016;14(3):4419
		Small grain	Wheat forage	98	EFSA Journal 2016;14(3):4419
			Wheat hay	98	EFSA Journal 2016;14(3):4419
			Wheat straw	98	EFSA Journal 2016;14(3):4419
			Wheat grain	98	EFSA Journal 2016;14(3):4419

Conclusion on rotational crops studies

Conclusions drawn from EFSA Journal 2016;14(3):4419 are reported below:

Confined rotational crop study

Bare soil application of Mesotrione labelled respectively on cyclohexane-2-14C and phenyl-U-14C at a dose rate of 164 g a.s./ha (1N). At 120-day plant back interval (PBI), TRRs are very low in all crop parts: <0.01 mg/kg in wheat grain and radish root, 0.012 mg/kg in broad-leaves endive and up to 0.033 mg/kg in wheat forage and straw.

Metabolites' identification at 300 d PBI not further investigated.

Field rotational crop study

Not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate and considering also the low to moderate persistence of Mesotrione, MNBA and AMBA.

US rotational crop field trials were conducted on pulses/oilseeds (soya bean), leafy vegetables (endive), root vegetables (radish) and cereals (small grains (wheat)) after bare soil application at 0.34 kg a.s./ha or after bare soil application (0.34 kg a.s./ha) followed by a post-emergence application (0.22 kg a.s./ha). Residues of Mesotrione and of MNBA were < 0.01 mg/kg in all crop parts.

7.4.7 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 SHA4307A. Therefore, other special studies are not needed.

7.4.8 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).

7.4.8.1 Input values for the consumer risk assessment

Table 7.4-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Mesotrione				
Maize	0.01	EU MRL Reg. (EU) 2017/626	0.01	EU MRL

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.4-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.0	12 % (based on NL toddler) 7 % (NL child)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo* rev.3.0	**Raw commodities** Maize/corn: 0,3% (based on acute risk assessment – children) Maize/corn: 0,1% (based on acute risk assessment –adult) **Processed commodities** Maize/oil: 1 % (based on acute risk assessment – children) Maize/processed: 0,1 % (based on acute risk assessment – children) Maize/oil: 0,6 % (based on acute risk assessment –adult)
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

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

The proposed uses of mesotrione in the formulation Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG do not represent unacceptable acute and chronic risks for the consumer.

7.5 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.

zRMS: Since IESTI values (for rimsulfuron) for unprocessed and processed maize commodities are 0.0% and there is no established ARfD for nicosulfuron, combined exposure calculation is not necessary.

7.5.1 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

7.6 References

Germany, 2005. Draft Assessment Report, Initial risk assessment provided by the rapporteur Member State Germany for the existing active substance Rimsulfuron, Volume 3, Annex B, B.7, July 2005.

EFSA Scientific Report (2005) 45, 1-61, Conclusion regarding the peer review or the pesticide risk assessment of the active substance rimsulfuron.

EFSA Journal 2012;10(10):2911 Reasoned opinion on the review of the existing maximum residue levels (MRLs) for rimsulfuron according to Aricle 12 of Regulation (EC) No 396/2005.

Reg. (EU) No 617/2014.

Review report for the active substance rimsulfuron, SANCO/10528/2005-rev. 2, 27 January 2006.

UK, 2006. Draft Assessment Report, Initial risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance Nicosulfuron, Volume 3, Annex B, B.7, June 2006.

EFSA Scientific Report (2007) 120, 1-91, Conclusion on the peer review of the pesticide risk assessment of the active substance.

EFSA Journal 2012;10(12):3048, Reasoned opinion on the review of the existing maximum residue levels (MRLs) for nicosulfuron according to Article 12 of Regulation (EC) No 396/2005

Reg. (EU) No 617/2014

Review report for the active substance nicosulfuron, SANCO/3780/07-rev. 1, 22 January 2008.

UK, 1999, Draft Assessment Report, Initial risk assessment provided by the Rapporteur Member state United Kingdom for the active substance Mesotrione, Volume 3, Annex B, B.7, December 1999.

EFSA Journal 2015;13(1):3976, 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 2016;14(3):4419, Peer review of the pesticide risk assessment of the active substance mesotrione,

Reg. (EU) No 2017/626

Final renewal report for the active substance mesotrione finalised in the standing committee on plants, animals, food and feed at its meeting on 23 March 2017 in view of the renewal of the approval of mesotrione as active substance in accordance with Regulation (EC) No 1107/2009, SANTE 11654/2016, 23 March 2017.

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
KCP 7.2.3-01	Pardo Martinez, M.	2018	Validation of the Analytical Method for the determination of rimsulfuron residues in maize grains matrix and determination of rimsulfuron residues in maize following one post emergence application with Rimsulfuron 25 WG in Germany in 2017 ChemService Report No CH-059/2018 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 7.2.3-01	Kull S.	2018	Residue study (Harvest) in maize following one post emergence application with Rimsulfuron 25% WG in Germany 2017 – field part CropTrials G,bH Report no. CT17-1-76 GLP Unpublished	N	Sharda Cropchem Ltd.

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

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

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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**
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Rimsulfuron

A 2.1.1 Stability of residues

No new studies have been submitted in framework of this application.

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

No new studies have been submitted in framework of this application.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Maize

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval be-tween applica-tion	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	2	0.02	7	BBCH 1-18	-
cGAP EU (Art. 12, EFSA, 2012)	2	0.02	7	BBCH 1-18	-
Intended cGAP (1*)	1	0.0075	NR	BBCH 12-18	-

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	The purpose of the study was to generate maize specimens for the determination of residues after one application post emergence with Rimsulfuron 25 WG at the product rate of 0.06 kg/ha in Germany 2017. The application was performed at crop stage BBCH 12. Analytical method used: HPLC/MS/MS in MRM mode (three product ions at m/z 182.0 (quantifier), 325.1 (1st qualifier) and 106.0 (2nd qualifier) from the same precursor ion at m/z 432.1). LOQ: 0.001 mg/kg. Method used and its validation is accepted.

Reference: KCP 7.2.3-01

Report	Residue study (Harvest) in maize following one post emergence application with Rimsulfuron 25 WG in Germany 2017 – field part, Kull S., 2018, Report no. CT17-1-76
Guideline(s):	Yes (OECD No. 509, EEC document 7029/1/95 rev. 5)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Report	Validation of the analytical method for the determination of rimsulfuron residues in maize grains matrix and Determination of rimsulfuron residues in maize following one post emergence application with Rimsulfuron 25 WG, Pardo Martines, M., 2018, Report no. CH-059/2018
Guideline(s):	Yes (SANCO/3029/99 rev. 4, SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	g a.s./hl				Rimsulfuron	Analyte 2		
GR-1U/CT17-1-76DE1/ Germany/ NEU/ 2017	Maize / Figaro	1.22.04.2017. 2.- 3.14.09.2017.	0.06	300	-	16.05.2017.	BBCH 12	grain	n.d.	-	139	Method of analysis: HPLC/MS/MS LOQ: 0.001 mg/kg Storage time: 76 days

n.d. – residues not detected

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

A 2.1.4 Magnitude of residues in livestock

No new studies have been submitted in framework of this application.

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

No new studies have been submitted in framework of this application.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies have been submitted in framework of this application.

A 2.1.7 Other/Special Studies

No new studies have been submitted in framework of this application.

A 2.2 Nicosulfuron

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

No new data have been submitted in the framework of this application.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

NO new data have been submitted in the framework of this application.

A 2.2.2.1.1 Nature of residue in rotational crops

NO new data have been submitted in the framework of this application.

A 2.2.2.1.2 Nature of residues in processed commodities

No new data have been submitted in the framework of this application.

A 2.2.2.2 Nature of residues in livestock

No new data have been submitted in the framework of this application.

A 2.2.3 Magnitude of residues in plants

No new data have been submitted in the framework of this application.

A 2.2.4 Magnitude of residues in livestock

No new data have been submitted in the framework of this application.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data have been submitted in the framework of this application.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data have been submitted in the framework of this application.

A 2.2.7 Other/Special Studies

No new data have been submitted in the framework of this application.

A 2.3 Mesotrione

A 2.3.1 Stability of residues

A 2.3.1.1 Stability of residues during storage of samples

No new data have been submitted in the framework of this application.

A 2.3.2 Nature of residues in plants, livestock and processed commodities

NO new data have been submitted in the framework of this application.

A 2.3.2.1.1 Nature of residue in rotational crops

NO new data have been submitted in the framework of this application.

A 2.3.2.1.2 Nature of residues in processed commodities

No new data have been submitted in the framework of this application.

A 2.3.2.2 Nature of residues in livestock

No new data have been submitted in the framework of this application.

A 2.3.3 Magnitude of residues in plants

No new data have been submitted in the framework of this application.

A 2.3.4 Magnitude of residues in livestock

No new data have been submitted in the framework of this application.

A 2.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data have been submitted in the framework of this application.

A 2.3.6 Magnitude of residues in representative succeeding crops

No new data have been submitted in the framework of this application.

A 2.3.7 Other/Special Studies

No new data have been submitted in the framework of this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations - Rimsulfuron

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

rimsulfuron

LOQs (mg/kg) range from:	0,01	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,1	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

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)
2%	NL toddler	1,91	1%	Milk: Cattle	0,1%	Apples	0,1%	Maize/corn	2%	0,1%
1%	UK infant	1,04	0,8%	Milk: Cattle	0,0%	Potatoes	0,0%	Eggs: Chicken	1%	0,0%
1,0%	NL child	0,97	0,5%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Apples	1,0%	0,0%
0,9%	FR toddler 2 3 yr	0,90	0,6%	Milk: Cattle	0,0%	Apples	0,0%	Wheat	0,9%	0,0%
0,9%	DE child	0,87	0,4%	Milk: Cattle	0,1%	Apples	0,0%	Wheat	0,9%	0,0%
0,9%	FR child 3 15 yr	0,85	0,5%	Milk: Cattle	0,0%	Wheat	0,0%	Sugar beet roots	0,9%	0,0%
0,7%	UK toddler	0,69	0,4%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,7%	0,0%
0,6%	DK child	0,59	0,3%	Milk: Cattle	0,1%	Rye	0,0%	Swine: Muscle/meat	0,6%	0,0%
0,6%	GEMS/Food G11	0,58	0,2%	Milk: Cattle	0,1%	Soyabeans	0,0%	Potatoes	0,6%	0,0%
0,6%	ES child	0,56	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat	0,6%	0,0%
0,6%	SE general	0,55	0,2%	Milk: Cattle	0,1%	Bovine: Muscle/meat	0,0%	Potatoes	0,6%	
0,5%	GEMS/Food G07	0,53	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,5%	0,0%
0,5%	RO general	0,53	0,2%	Milk: Cattle	0,1%	Wheat	0,0%	Potatoes	0,5%	0,0%
0,5%	GEMS/Food G15	0,52	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,5%	0,0%
0,5%	DE women 14-50 yr	0,52	0,2%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,5%	0,0%
0,5%	GEMS/Food G08	0,52	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Soyabeans	0,5%	0,0%
0,5%	DE general	0,51	0,2%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,5%	0,0%
0,5%	GEMS/Food G10	0,51	0,1%	Milk: Cattle	0,1%	Soyabeans	0,0%	Wheat	0,5%	0,0%
0,5%	FR infant	0,47	0,3%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples	0,5%	0,0%
0,5%	GEMS/Food G06	0,45	0,1%	Wheat	0,0%	Milk: Cattle	0,0%	Tomatoes	0,5%	0,0%
0,4%	NL general	0,43	0,2%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Potatoes	0,4%	0,0%
0,4%	IE adult	0,42	0,1%	Milk: Cattle	0,0%	Sweet potatoes	0,0%	Wheat	0,4%	0,0%
0,4%	FI adult	0,35	0,3%	Coffee beans	0,0%	Potatoes	0,0%	Rye	0,4%	0,0%
0,3%	FR adult	0,30	0,1%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat	0,3%	0,0%
0,3%	ES adult	0,29	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat	0,3%	0,0%
0,2%	DK adult	0,24	0,1%	Milk: Cattle	0,0%	Swine: Muscle/meat	0,0%	Potatoes	0,2%	
0,2%	LT adult	0,22	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Swine: Muscle/meat	0,2%	0,0%
0,2%	PT general	0,22	0,1%	Potatoes	0,0%	Wheat	0,0%	Wine grapes	0,2%	0,0%
0,2%	UK vegetarian	0,18	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,2%	0,0%
0,2%	UK adult	0,18	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,2%	0,0%
0,2%	FI 3 yr	0,18	0,0%	Potatoes	0,0%	Bananas	0,0%	Wheat	0,2%	0,0%
0,2%	IT toddler	0,17	0,1%	Wheat	0,0%	Other cereals	0,0%	Tomatoes	0,2%	0,0%
0,1%	FI 6 yr	0,14	0,0%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat	0,1%	0,0%
0,1%	IE child	0,12	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,1%	0,0%
0,1%	IT adult	0,12	0,0%	Wheat	0,0%	Tomatoes	0,0%	Apples	0,1%	0,0%
0,1%	PL general	0,10	0,0%	Potatoes	0,0%	Apples	0,0%	Tomatoes	0,1%	0,0%

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

A 3.2 IEDI calculations – Rimsulfuron

NR

A 3.3 IESTI calculations - Raw commodities – Rimsulfuron

~~NR~~

A 3.4 IESTI calculations - Processed commodities - Rimsulfuron

~~NR~~
IESTI

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 for all crops

Unprocessed commodities

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

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

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

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

IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,00%	Maize/corn	0,01 / 0,01	0,07	0,00%	Maize/corn	0,01 / 0,01	0,02	0,00%	Maize/corn	0,01 / 0,01	0,07	0,00%	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)
0,0%	Maize / oil	0,01 / 0,25	0,23	0,0%	Maize / oil	0,01 / 0,25	0,13	0,01%	Maize / oil	0,01 / 0,25	0,23	0,01%	Maize / oil	0,01 / 0,25	0,13
0,0%	Maize / processed (not spe	0,01 / 0,01	0,02					0,00%	Maize / processed (not	0,01 / 0,01	0,02				

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Rimsulfuron is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.5 TMDI calculations - Nicosulfuron

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Nicosulfuron

LOQs (mg/kg) range from:	0,01	to:	0,05	
Toxicological reference values				
ADI (mg/kg bw/day):	2	ARfD (mg/kg bw):	not necessary	
Source of ADI:	EFSA	Source of ARfD:	EFSA	
Year of evaluation:	2007	Year of evaluation:	2007	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
0,1%	NL toddler	1,91	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Maize/corn	0,1%	0,1%
0,1%	UK infant	1,04	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Eggs: Chicken	0,1%	0,1%
0,0%	NL child	0,97	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,0%	0,0%
0,0%	FR toddler 2 3 yr	0,90	0,0%	Milk: Cattle	0,0%	Apples	0,0%	Wheat	0,0%	0,0%
0,0%	DE child	0,87	0,0%	Milk: Cattle	0,0%	Apples	0,0%	Wheat	0,0%	0,0%
0,0%	FR child 3 15 yr	0,85	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Sugar beet roots	0,0%	0,0%
0,0%	UK toddler	0,69	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
0,0%	DK child	0,59	0,0%	Milk: Cattle	0,0%	Rye	0,0%	Swine: Muscle/meat	0,0%	0,0%
0,0%	GEMS/Food G11	0,58	0,0%	Milk: Cattle	0,0%	Soyabeans	0,0%	Potatoes	0,0%	0,0%
0,0%	ES child	0,56	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat	0,0%	0,0%
0,0%	SE general	0,55	0,0%	Milk: Cattle	0,0%	Bovine: Muscle/meat	0,0%	Potatoes	0,0%	0,0%
0,0%	GEMS/Food G07	0,53	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
0,0%	RO general	0,53	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
0,0%	GEMS/Food G15	0,52	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
0,0%	DE women 14-50 yr	0,52	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,0%	0,0%
0,0%	DE general	0,51	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,0%	0,0%
0,0%	GEMS/Food G08	0,51	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Soyabeans	0,0%	0,0%
0,0%	GEMS/Food G10	0,51	0,0%	Milk: Cattle	0,0%	Soyabeans	0,0%	Wheat	0,0%	0,0%
0,0%	FR infant	0,47	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples	0,0%	0,0%
0,0%	GEMS/Food G06	0,45	0,0%	Wheat	0,0%	Milk: Cattle	0,0%	Tomatoes	0,0%	0,0%
0,0%	NL general	0,43	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Potatoes	0,0%	0,0%
0,0%	IE adult	0,42	0,0%	Milk: Cattle	0,0%	Sweet potatoes	0,0%	Wheat	0,0%	0,0%
0,0%	FI adult	0,35	0,0%	Coffee beans	0,0%	Potatoes	0,0%	Rye	0,0%	0,0%
0,0%	FR adult	0,30	0,0%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat	0,0%	0,0%
0,0%	ES adult	0,29	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat	0,0%	0,0%
0,0%	DK adult	0,24	0,0%	Milk: Cattle	0,0%	Swine: Muscle/meat	0,0%	Potatoes	0,0%	0,0%
0,0%	LT adult	0,22	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Swine: Muscle/meat	0,0%	0,0%
0,0%	PT general	0,22	0,0%	Potatoes	0,0%	Wheat	0,0%	Wine grapes	0,0%	0,0%
0,0%	UK vegetarian	0,18	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
0,0%	UK adult	0,18	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
0,0%	FI 3 yr	0,18	0,0%	Potatoes	0,0%	Bananas	0,0%	Wheat	0,0%	0,0%
0,0%	IT toddler	0,17	0,0%	Wheat	0,0%	Other cereals	0,0%	Tomatoes	0,0%	0,0%
0,0%	FI 6 yr	0,14	0,0%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat	0,0%	0,0%
0,0%	IE child	0,12	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
0,0%	IT adult	0,12	0,0%	Wheat	0,0%	Tomatoes	0,0%	Apples	0,0%	0,0%
0,0%	PL general	0,10	0,0%	Potatoes	0,0%	Apples	0,0%	Tomatoes	0,0%	0,0%

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

A 3.6 IEDI calculations – Nicosulfuron

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A 3.7 IESTI calculations - Raw commodities – Nicosulfuron

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A 3.8 IESTI calculations - Processed commodities - Nicosulfuron

A 3.9 TMDI calculations - Mesotrione

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Mesotrione			
LOQs (mg/kg) range from:	**0,01**	to:	**0,05**
Toxicological reference values			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,02**
Source of ADI:	**EU**	Source of ARfD:	**EU Commission**
Year of evaluation:	**2003**	Year of evaluation:	**2003**

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

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

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

A 3.10 IEDI calculations

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A 3.11 IESTI calculations - Raw commodities - 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. 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															
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 3.12 IESTI calculations - Processed commodities - Mesotrione

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)
1%	Maize / oil	0,01 / 0,25	0,23
0,1%	Maize / processed (not speci	0,01 / 0,01	0,01

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)
0,6%	Maize / oil	0,01 / 0,25	0,13

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

IESTI new

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
0,06%	Maize / processed (not	0,01 / 0,01	0,01

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,6%	Maize / oil	0,01 / 0,25	0,13

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.

Appendix 4 Additional information provided by the applicant

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