

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GF-3969

Chemical active substances:

Rimsulfuron, 148.15 g/kg

Thifensulfuron methyl, 92.60 g/kg

Isoxadifen-ethyl, 111.1 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Corteva/DuPont/DowAgroScience/Pioneer*

Submission date: December 2020

MS Finalisation date: December 2021(initial Core Assessment)

May 2022 (final Core Assessment)

*Corteva Agriscience is new Legal Entity in most of EU countries and should be treated as an Applicant for GF-3969 registration. Information about Applicant for each country is provided in dRR Part A.

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Version history

When	What
December 2021	Applicant initial dRR
December 2021	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
May 2022	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded .

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Thifensulfuron methyl information belongs to FMC, but all datapoints originate from the EFSA conclusion. Unless otherwise specified, endpoints used in this section for isoxadifen-ethyl originate from Bayer CropScience and Corteva has a letter of access.

7 Metabolism and residue data (KCA section 6)

Endpoints for the active substances in GF-3969, rimsulfuron and thifensulfuron methyl, relevant for the metabolism and residue evaluation are derived from the respective EFSA conclusions for these actives as indicated below.

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

For thifensulfuron methyl: EFSA Journal 2015;13(7):4201. Conclusion on the peer review of the pesticide risk assessment of the active substance thifensulfuron methyl.

For isoxadifen-ethyl:

Summary of the German national evaluation of the safener isoxadifen-ethyl (2002), and summary of the Austrian (AGES) evaluation product Laudis in 2006.

7.1 Summary and zRMS conclusion

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 GF-3969 are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central European zone for maize. A list of all intended uses within the Central European 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 and 0.01* mg/kg for thifensulfuron methyl as laid down in Reg. (EU) 396/2005 (Reg. (EU) No 617/2014) for maize/corn is not expected.

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

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

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

Data gaps

No data gaps were identified.

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)	g a.s./hL ^a min max	water L/ha min max	g a.s./ha ^c min max		
1	Maize (ZEAMX) (silage and grain)	CEU	GF-3969	F	Annual monocotyledonous weeds (TTTMS), Annual dicotyledonous weeds (TTTDS), Perennial grass weeds (GGGPE)	WG	148.15 g/kg 92.6 g/kg	Hydraulic sprayer overall	BBCH 11 to BBCH 18 Spring March-July	1-1	n.a. ^b	max: 32.5 (20 + 12.5)	100 / 400	max: 32.5 (20 + 12.5)	n.a.	A
14	Maize (ZEAMX) (silage and grain)	CEU	GF-3969	F	Annual monocotyledonous weeds (TTTMS), Annual dicotyledonous weeds (TTTDS), Perennial grass weeds (GGGPE)	WG	148.15 g/kg 92.6 g/kg	Hydraulic sprayer overall	BBCH 11 to BBCH 18 Spring March-July	1-2 (split)	7	max: 32.5 (20+12.5)	100 / 400	max: 32.5 (20 + 12.5)	n.a.	A Split application possible without exceeding the total maximum of 135 g product/ha (20+12.5 g a.s./ha)

* 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

a Dose expressed as total g active substance (g rimsulfuron + g thifensulfuron methyl)

b n.a. = not applicable

c formulated product contains 111.1 g/kg safener - isoxadifen ethyl (max. 15 g/ha)

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 GF-3969 is composed of rimsulfuron, thifensulfuron methyl and isoxadifen-ethyl (safener).

Table 7.1-2: Toxicological reference values for the dietary risk assessment of rimsulfuron, thifensulfuron methyl and isoxadifen-ethyl (safener)

Rimsulfuron				
End-Point	Value (mg/kg/day)	Study	Uncertainty factor	Reference
Acceptable Daily Intake (ADI)	0.1	2-year rat study	100	EFSA Scientific Report (2005) 45: 1–64 EFSA Journal 2018;16(5):5258
Acute Reference Dose (ARfD)	1.7	Rabbit, developmental study	100	
Thifensulfuron methyl				
End-Point	Value (mg/kg/day)	Study	Uncertainty factor	Reference
Acceptable Daily Intake (ADI)	0.01	2-year rat study	100	EFSA Journal 2015;13(7):4201
Acute Reference Dose (ARfD)	2	Developmental toxicity rat study	100	
Isoxadifen-ethyl				
End-Point	Value (mg/kg/day)	Study	Uncertainty factor	Reference
Acceptable Daily Intake (ADI)	0.03	1-year dog study	100	2002 German national Evaluation*
Acute Reference Dose (ARfD)	0.5	Rabbit developmental toxicity study	100	

* Summary of the German national evaluation of the safener isoxadifen-ethyl, 14 August 2002, RMS: Germany. BCS document ID: M-263999-01-1

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?
1	Maize (ZEAMX)	Yes	Yes (18 + 6 new N-EU trials)	Yes	Yes	Yes	No	No
14	Maize (ZEAMX)	Yes	Yes (18 + 6 new N-EU trials)	Yes	Yes	Yes		No

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

The nature and magnitude of residues in corn/maize were previously evaluated in the Rimsulfuron Draft Assessment Report, Volume 3, Annex B7 (2005).

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.

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

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

7.1.2.2 Summary for thifensulfuron methyl

Table 7.1-4: Summary for thifensulfuron methyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	Yes	Yes (4 + 6 new N-EU trials)	Yes	Yes	Yes	No	No
14	Maize	Yes	Yes (4 + 6 new N-EU trials)	Yes	Yes	Yes		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 thifensulfuron methyl do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

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

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

7.1.2.3 Summary for isoxadifen-ethyl (safener)

Isoxadifen-ethyl as crop safener is not considered as an active substance, and consequently has not been subject to review on EU level for inclusion into Annex I of Directive 91/414/EEC or Regulation (EC) No 1107/2009. Nevertheless, an Annex II dossier has been prepared by Bayer CropScience for isoxadifen-ethyl and was submitted for evaluation at Member State level. The data has been reviewed by Germany in 2002 resulting in a comprehensive evaluation report including a standard List of Endpoints. All exposure and risk assessments presented in the following will be based on these country-agreed endpoints, if not otherwise stated. Only brief summaries of the overall findings will be given for data already evaluated. Only new studies not included in the German evaluation will be presented as full Tier 2 study summaries.

Isoxadifen-ethyl is a safener and as such does not fall under the Regulation (EC) 396/2005. At present MRLs are not set in the EU for safeners.

The behaviour and metabolism of isoxadifen-ethyl was investigated in two crops (maize and rice). Additionally, metabolism of isoxadifen-ethyl in poppy seeds was examined.

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

Studies on the behaviour in soil did not indicate that significant residues of isoxadifen-ethyl and/or its metabolites and degradation products might remain in soil or in plant material up to the sowing or planting of succeeding crops.

Therefore, no residues above the LOQ resulting from soil uptake are to be anticipated and a theoretical

consideration of the nature and level of the residue in succeeding crops is not required. Studies on the metabolism of isoxadifen-ethyl in soil showed that less than 10% of isoxadifen-ethyl and metabolites remain in soil after 100 days. Therefore, studies to evaluate the residue behaviour in succeeding crops are not required.

The dietary burden calculations were performed using the OECD feeding stuff tables and OECD approaches presented in the Guidance Document on residue in livestock No. 73. Metabolism studies in livestock at exaggerated rates did not indicate that significant residues may occur in food of animal origin after use of the safener isoxadifen-ethyl. Considering the calculated dietary livestock exposure, anticipated residue levels in ruminant commodities are very low.

Based on an ADI of 0.03 mg/kg bw/day, the TMDI of isoxadifen-ethyl was calculated to be 0.5% of the ADI. Based on an ARfD of 0.5 mg/kg bw/day, the highest IESTI of isoxadifen-ethyl was 0.1% in processed commodity (maize/oil) for the GAP under consideration.

Therefore, it can be concluded that the use of isoxadifen-ethyl in crop does not imply any unacceptable chronic or acute dietary risk to consumers when used according to the proposed critical GAP.

7.1.2.4 Summary for GF-3969

Table 7.1-5: Information on GF-3969 (KCA 6.8)

Crop	PHI for GF-3969 proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for GF-3969 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Rimsulfuron	Thifensulfuron methyl	Isoxadifen-ethyl (safener)		
Maize	NR F**	NR Yes	NR Yes	NR Yes	NR F**	-

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 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for GF-3969
Crop group	Led by rimsulfuron	Led by thifensulfuron methyl	Led by isoxadifen-ethyl (safener)	
All	Not required	Not required	Not required	Not required

Assessment

The reasoned opinion on rimsulfuron (EFSA Journal 2012;10(10):2911 [EFSA RO, 2012]) provides evaluation of MRLs for maize.

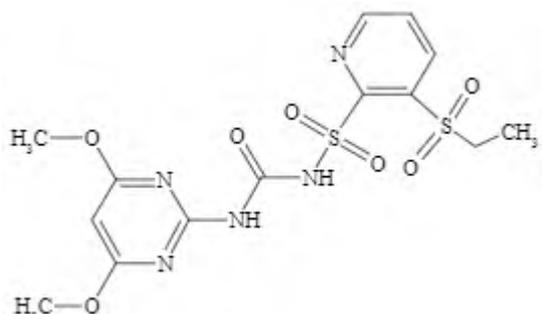
The reasoned opinion on thifensulfuron methyl (EFSA Journal 2012;10(8):2863 [EFSA RO, 2012]) provides evaluation of MRLs for maize.

The summary of the German national evaluation of the safener isoxadifen-ethyl (2002) provides evaluation of MRLs for maize.

7.2 Rimsulfuron

General data on rimsulfuron are summarized in the table below (last updated 19 December 2020).

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	C ₁₄ H ₁₇ N ₅ O ₇ S ₂
Molar mass	431.45 g/mol
Chemical group	Sulfonylurea
Mode of action (if available)	Selective, systemic, absorbed through foliage and roots and translocated. Inhibits plant amino acid synthesis - acetoxyacid synthase (AHAS)
Systemic	Yes
Company (ies)	DuPont*
Rapporteur Member State (RMS)	Slovenia is designated for AIR IV, previous RMS was Germany
Approval status	Approved 18 March 2020 and reference to decision (Commission Directive 2009/1107/EC - Regulation (EU) No 2020/421) – extension of approval 12/04/2006 Commission Directive 2006/39/EC (Annex I of Council Directive 91/414/EEC) 25/05/2010 Commission Implementing Regulation (EU) No. 540/2011) list of active substances approved under Regulation 1107/2009)
Restriction	Use as an herbicide
Review Report	SANCO/10528/2005– rev. 2 27 January 2006
Current MRL regulation	Regulation (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, 2012a)
Current MRL applications on intended uses	Status: Reasoned opinion available (EFSA Journal 2012a;10(10):2911)

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data: EFSA, 2005

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 (Rimsulfuron)	Reference
Data relied on in EU			
Plant products (rimsulfuron)			
Maize forage	High water content	24 months	EFSA, 2005
Maize grain	High starch content	24 months	EFSA, 2005
Potato tubers	High starch content	24 months	EFSA, 2005
Animal products – not required			

Conclusion on stability of residues during storage

The data show that residues of rimsulfuron are stable for at least 24 months in corn/maize commodities stored under frozen conditions. These conditions are consistent with the storage of actual field samples.

zRMS comments:

zRMS agrees with information provided by the Applicant above.
 Corn/maize seed belongs to high starch content matrices, maize silage belongs to high water content matrices. The potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review; storage stability of rimsulfuron was demonstrated for a period of 24 months at -20°C in commodities with high water content (potatoes and maize forage) and in dry commodities (maize grain).

As the trial samples were stored for a maximum period of 14 months between sampling and analysis, it is concluded that the residue data are valid with regard to storage stability.
 No additional data are required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Stability of analyte residues in sample extracts is verified by the acceptable fortification recovery data summarised in each study. These fortifications were run with the specimens in each analysis set and were stored and treated in every way as the treated and control specimens in that set.

zRMS comments:

zRMS agrees with information provided by the Applicant above.
 No additional data are required.

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: Germany, 2005

Plant metabolism studies relevant to the uses of rimsulfuron were submitted and evaluated in the

Rimsulfuron DAR, Volume 3, Annex B.7, July 2005. Maize, potato, and tomato metabolism studies were conducted with [¹⁴C]rimsulfuron as a test substance. No new data are 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)	
EU data							
Fruits and fruiting vegetable	Tomatoes	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	foliar treatment, F	72	1	Foliage: 0, 7, 30, 46 and 60 DAT Fruit: 30, 46, 53 and 60 DAT	Germany, 2005 EFSA, 2005
			foliar treatment, G	178.5, 357.5 or 715	1	Foliage: 0 and 7 DAT Fruit: 74 DAT	Germany, 2005 EFSA, 2005
Root and tuber vegetables	Potatoes	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	foliar treatment, G	70	1	Whole plant: 0 Foliage and tubers: 8, 14, 30 and 82 DAT	Germany, 2005 EFSA, 2005
					2	Foliage and tubers: 0, 7, 14, 14, 28 and 66 DAT	Collected after 2 nd application
Cereals	Maize	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	foliar treatment, G	52	1	Silage: 0, 8, 15, 30, 50, 80 Mature crop: 105	Germany, 2005 EFSA, 2005

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

Summary of plant metabolism studies reported in the EU

The metabolism of rimsulfuron has been studied in maize (cereal group), potatoes (root/tuber group) and tomatoes (fruit/fruiting vegetable group), using separate foliar application of 2 radiolabelled forms (pyridine and pyrimidine rings) in order to investigate the fate of the 2 moieties of the compound. Although plants were treated at exaggerated rates of 53-72 g/ha (and up to 715 g/ha in greenhouse grown tomatoes), total radioactive residues in edible plant parts (maize grains, potato tubers and tomato fruit) as well as in fractions intended for animal consumption (maize silage and fodder) were always <0.02 mg parent equivalent/kg. The metabolic pathway was therefore established by characterization of residues in immature foliage. Two primary degradation pathways were identified. One mechanism involved contraction of the sulfonylurea bridge to form IN-70941, leading further to IN-70942 from loss of CONH₂. The second pathway was cleavage of the sulfonylurea bridge to produce IN-E9260 and IN-J0290. These initial degradation products were further metabolized to a number of minor, polar compounds. None of the metabolites formed were found to be of particular concern. The metabolism of rimsulfuron in plants is similar to that found in rat and livestock (goat and hen) animals.

Summary of new plant metabolism studies

No new plant metabolism studies or data are submitted in support of this application.

Conclusion on metabolism in primary crops

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.

zRMS comments:

zRMS agrees with information provided by the Applicant above.

Metabolism of rimsulfuron was investigated for early foliar application (post-emergence) on fruits and fruiting vegetables (tomatoes), root and tuber vegetables (potatoes) and cereals (maize) both using ¹⁴C-pyridine and ¹⁴C-pyrimidine labelled rimsulfuron (EFSA, 2005). Although applied at exaggerated application rates of 2.6 N for tomato and maize and 3.1 N for potato, the total radioactive residues (TRRs) in the grain (both mature and immature), silage and fodder, potato and tomato were < 0.02 mg/kg. Metabolism was therefore studied in foliage of potato and tomato and in maize (whole plant) where detectable radioactivity occurred.

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. Validated analytical methods for enforcement of the proposed residue definition are available.

No additional data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data: Germany, 2005

The metabolism of rimsulfuron in rotational crops (lettuce, sugar beet, soya bean, sunflower, sorghum, wheat) was submitted and evaluated in the Rimsulfuron DAR, Volume 3, Annex B.7, July 2005). One confined rotational crop study investigating the nature of residues following 3 plant-back intervals is available. No new data are 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				Remarks	Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU data								
Leafy vegetables	Lettuce	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	G	52	30 and 120 days	30-day: 106 DAT 120-day: 184 DAT	Leaves at crop maturity	Germany 2005 EFSA, 2005
Root and tuber vegetables	Sugarbeet	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	G	52	30 and 120 days	30-day: 226 DAT 120-day: 267 DAT	Leaves and tops at crop maturity	Germany 2005 EFSA, 2005
Pulses and oilseeds	Soybean	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	G	52	30 and 120 days and 10 months	30-day: 121 DAT 120-day: 226 DAT 10 month: 389 DAT	Beans and straw at crop maturity	Germany 2005 EFSA, 2005
Pulses and oilseeds	Sunflower	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	G	52	120 days and 10 months	120-day: 226 DAT 10 month: 389 DAT	Seeds and leaves at crop maturity	Germany 2005 EFSA, 2005

Crop group	Crop	Label position	Application and sampling details				Remarks	Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU data								
Cereals	Sorghum	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	G	52	10 months	10 month: 428 DAT	Grain and straw at crop maturity	Germany 2005 EFSA, 2005
Cereals	Wheat	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	G	52	30 and 120 days and 10 months	30-day: 121 DAT 120-day: 226 DAT 10 month: 389 DAT	Grain and straw at crop maturity	Germany 2005 EFSA, 2005

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

Summary of metabolism in rotational crop studies reported in the EU

Total radioactive residues in food items from lettuce, sugar beet, sunflower, soybeans, sorghum and wheat, grown in soil treated with ¹⁴C-rimsulfuron at an application rate of 52 g/ha and aged for either 30 days, 120 days or 10 months prior to planting, were below the LOQ of 0.05 mg parent equivalent/kg. Only in wheat straw, total radioactive residues amounted to 0.38-0.46 mg parent equivalent/kg when the crop was sown after 30 days ageing, with metabolite IN-70941 present at 0.07 mg/kg as main compound identified. IN-70942 was identified in wheat and soybean straw. IN-E9260 and IN-H1043 were tentatively identified in water soluble wheat straw extracts.

Summary of new plant metabolism studies

No new confined rotational crop studies or data are submitted in support of this application.

Conclusion on metabolism in rotational crops

There is no reasonable expectation of concentration of rimsulfuron or its metabolites/degradation products in the succeeding crop food and feed items after application of rimsulfuron under the normal agricultural practices. Metabolism in primary and succeeding crops are similar. No residue definition is needed and no restriction for cultivation of rotational crops needs to be applied.

zRMS comments:

zRMS agrees with information provided by the Applicant above.

According to the soil degradation studies evaluated in the framework of the peer review, DT₉₀ value of rimsulfuron was expected to be lower than 100 days but relevant soil metabolites (IN-70941, IN-70942, IN-E9260) were shown to be more persistent (EFSA, 2005). According to the European guidelines on rotational crops (EC, 1997c), further investigation of residues in rotational crops is relevant.

In EFSA Journal 2012;10(10):2911 it is stated that “*The metabolism of rimsulfuron in rotational crops – lettuce, sugar beet, soya bean, sunflower, sorghum, wheat – has been evaluated (Germany, 2003). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available. Total radioactive residues in consumable parts of all crops planted at each plant-back intervals were below the LOQ of 0.05 mg eq/kg. In wheat straw, TRR reached 0.38-0.46 mg eq/kg when the crop was sown after 30 days ageing. Metabolite IN-70941 was the main identified compound (0.07 mg/kg).*

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.”

No additional data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data: EFSA, 2005

Regulation (EU) No 283/2013 states that if the level of residues is less than 0.01 mg/kg, a study to establish the hydrolytic stability under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation is not required. Therefore, a study was not triggered since residues in commodities to be processed were <0.01 mg/kg.

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

Conclusion on nature of residues in processed commodities

Nature of the residue studies in processed commodities are not needed.

zRMS comments:

As quantifiable residues of rimsulfuron are not expected in edible part of 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.

7.2.2.4 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, sugar beets, sunflower, sorghum, and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
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	Rimsulfuron (EFSA, 2005)
Plant residue definition for risk assessment	Rimsulfuron (EFSA, 2005)
Conversion factor from enforcement to RA	Not applicable

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

Available data: EFSA, 2005

Livestock (goat and hen) metabolism studies relevant to the uses of rimsulfuron were submitted and evaluated in the Rimsulfuron DAR, Volume 3, Annex B.7, July 2005. No new data are submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animals	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	2- ¹⁴ C-pyrimidine	1	0.37 mg/kg bw/day (9.9 mg/kg/day feed)	3	Milk	twice daily	Germany, 2005; EFSA, 2005
						Urine and faeces	daily	
	Tissues	at sacrifice 24 hours after the final dose						
	2- ¹⁴ C-pyridine	1	0.30 mg/kg bw/day (12.1 mg/kg/day feed)	3	Milk	twice daily	Germany, 2005; EFSA, 2005	
Urine and faeces					daily			
Tissues	at sacrifice 24 hours after the final dose							
Laying Poultry	Hens	2- ¹⁴ C-pyrimidine	5	0.96 mg/kg bw/day (9.6 mg/kg/day feed)	5	Eggs		daily
						Excreta	daily	
	Tissues	at sacrifice 6 hours after the final dose						
	2- ¹⁴ C-pyridine	5	0.89 mg/kg bw/day (12.0 mg/kg/day feed)	5	Eggs	daily	Germany, 2005; EFSA, 2005	
Excreta					daily			
Tissues	at sacrifice 6 hours after the final dose							

The metabolic pathway in ruminant (goat) and mono-gastric animals (rat and hen) was similar. Therefore, no pig metabolism study is required.

There was no significant fish dietary burden resulting from the maize grain and a fish metabolism study was not conducted or required.

Summary of animal metabolism studies reported in the EU

As no significant residues are expected to be present in maize or potato products intended for livestock consumption, livestock metabolism studies are not in principle required. Livestock (goat and hen) studies were however submitted and evaluated, but no residue definition for animal products needs to be proposed.

Metabolism studies were conducted in lactating goat and laying hens with orally administered rimsulfuron radiolabelled either in the pyridine or pyrimidine ring. Daily doses were approximately 10 mg/kg feed, representing highly exaggerated dose levels. In both animals, minimal transfer of rimsulfuron and its metabolites was observed to the edible animal matrices and tissues. Identification of residues was carried out on the excreta. Two metabolic pathways were identified, based on contraction or cleavage of the sulfonylurea bridge, leading to metabolite patterns which are qualitatively similar to rats and plants.

As mentioned above, given the very low potential exposure of animals to rimsulfuron, no livestock feeding studies were required.

Summary of new animal metabolism studies

No new livestock metabolism studies or data are submitted in support of this application.

Conclusion on metabolism in livestock

The metabolic pathways in ruminant (goat) and mono-gastric animals (rat and hen) was similar. Therefore, no pig metabolism study is required. Based on the uses reported by the RMS, no significant intakes were calculated for the different type of livestock animals. Consequently, it was concluded by

EFSA that no residue definition for products of animal origin are needed.

zRMS comments:

zRMS agrees with information provided by the Applicant above.
 A residue definition for animals is not needed for the current proposed use. No additional data are 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	There were no quantifiable residues in milk and eggs (<0.02 mg/kg).
Animal residue definition for monitoring	A residue definition for livestock animals is not required; intakes below 0.1 mg/kg diet/day (EFSA 2005)
Animal residue definition for risk assessment	A residue definition for livestock animals is not required; intakes below 0.1 mg/kg diet/day (EFSA 2005)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes A pig metabolism study is not required as the metabolic pathway in the goat, rat and hen is similar. Further, dietary intakes for the pig are not significant.
Fat soluble residue	No

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

The EU MRL was set on the basis of residue data generated with a WG rimsulfuron formulation containing 250 g/kg, applied at a cGAP of 20 g a.s./ha.

One new study, DuPont-49732, on the magnitude of residue have been submitted by the applicant in the framework of this application. The data were generated to support the proposed use of GF-3969, which includes use of maize grain and stover as animal feed items.

The studies are summarized in the table below. These data show that application of GF-3969 according to the proposed cGAP will not exceed the current EU MRL for rimsulfuron.

The detailed assessment of the studies are presented in Appendix 2.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of GF-3969 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: rimsulfuron RA = according to risk assessment residue definition: rimsulfuron	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance	
Maize grain	EFSA, 2012a	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.02 kg a.s./ha, up to BBCH 10-16, PHI not applicable, outdoor E: 18x <0.05 RA: 18x <0.05 [Note: 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.]	NA					
	New trials (DuPont-49732)	N-EU	Trials GAP: 1 x 0.020 kg rimsulfuron/ha, BBCH 19, PHI not applicable, outdoor E: 6x <0.01 RA: 6x <0.01						
	Overall supporting data for cGAP	N-EU	E: 24x <0.01 RA: 24x <0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.01	Yes	
Maize forage (silage)	EFSA, 2012a	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.02 kg a.s./ha, up to BBCH 10-16, PHI not applicable, outdoor E: 6x <0.05 RA: 6x <0.05 [Note: 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.]	NA					
	New trials (DuPont-49732)	N-EU	Trials GAP: 1 x 0.020 kg rimsulfuron/ha, BBCH 19, PHI not applicable, outdoor E: 6x <0.01 RA: 6x <0.01						
	Overall supporting data for cGAP	N-EU	E: 24x <0.01 RA: 24x <0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	-	-	
Maize stover (straw)	New trials (DuPont-49732)	N-EU	Trials GAP: 1 x 0.020 kg rimsulfuron/ha, BBCH 19, PHI not applicable, outdoor E: 6x <0.01 RA: 6x <0.01	NA					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition: rimsulfuron RA = according to risk assessment residue definition: rimsulfuron	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	Overall supporting data for cGAP	N-EU	E: 6x <0.01 RA: 6x <0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	-	-

* Source of EU MRL: Reg. (EU) No 617/2014
 NA: Not applicable

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 both indoor and outdoor uses.

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

The uses are considered acceptable.

zRMS comments:

New study on the magnitude of residue have been submitted by the Applicant in the framework of this application.

Table 7.1: Summary of intended GAP in maize for GF-3969.

Type of GAP	Method	Number of applications	Application rate per treatment (g as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Intended GAP - maize	Hydraulic sprayer overall	1-2 (split)	rimsulfuron 20 g a.s./ha thifensulfuron methyl 12.5 a.s./ha (split application possible without exceeding the total maximum of 135 g product/ha)	7	BBCH 18	-

Eleven field trials (6 trials in N-EU and 5 trials in S-EU) were conducted to determine residues of rimsulfuron and thifensulfuron methyl in commodities derived from maize treated with DPX-TNS43 (a blend of rimsulfuron 25SG/thifensulfuron methyl 50SG/mesotrione 50WG plus isoxadifen-ethyl 50WG (safener; not active)) during the 2017 and 2018 growing seasons in EU. Trend 90 (0.2% (v/v)) adjuvant was added to the tank mix. DPX-TNS43 was applied once on maize at growth stage BBCH 19 at a nominal rate of 20 g ai/ha for rimsulfuron and 15 g ai/ha for thifensulfuron methyl.

Northern Europe:

Rimsulfuron residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.

Residues in maize whole plant samples ranged from not detected (<0.003mg/kg) to 0.021 mg/kg at 14±1 DALA.

The addition of Trend 90 (0.2% (v/v)) adjuvant to the DPX-TNS43 formulation did not affect the residue levels of a.s..

While the number of residue trials was not compliant with the data requirements for maize, the reduced number of residue trials was considered acceptable for rimsulfuron and thifensulfuron methyl because all residues were below the LOQ and a no residue situation was expected.

Available results show that the in force MRL for rimsulfuron on maize/corn of 0.01* mg/kg (Reg. (EU) No 617/2014) will not be exceeded. Therefore the use of GF3969 can be considered as supported on maize in Europe.

No additional data are required.

(*) Limit of analytical determination

7.2.4 Magnitude of residues in livestock

Input values for the livestock dietary burden calculation are from the Article 12 review for rimsulfuron (EFSA, 2012a). Maximum and median calculated intakes were calculated using the animal model 2017 and results are shown in Table 7.2 10. The proposed use of GF-3969 is not expected to raise the dietary burden.

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure which include 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: Rimsulfuron				
Maize grain	0.01	STMR (EFSA 2012a)	0.01	STMR (EFSA 2012a)
Maize silage	0.01	STMR (EFSA 2012a)	0.01	STMR (EFSA 2012a)
Potatoes	0.01	STMR (EFSA 2012a)	0.01	HR (EFSA 2012a)

Table 7.2-10: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.002	0.002	0.05	0.05	Dairy cattle	Potato	process waste	No
Cattle (dairy only)	0.002	0.002	0.04	0.04	Dairy cattle	Potato	process waste	No
Sheep (all diets)	0.002	0.002	0.05	0.05	Ram/Ewe	Potato	process waste	No
Sheep (ewe only)	0.002	0.002	0.05	0.05	Ram/Ewe	Potato	process waste	No
Swine (all diets)	0.001	0.001	0.05	0.05	Swine (finishing)	Corn, field	gluten feed	No
Poultry (all diets)	0.002	0.002	0.03	0.03	Turkey	Corn, field	hominy meal	No
Poultry (layer only)	0.002	0.002	0.03	0.03	Poultry layer	Corn, field	hominy meal	No

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

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data: EFSA, 2005; DAR, 2005

Since the calculated dietary burdens for all types of livestock were found to be below the trigger value of 0.004 mg/kg bw/day, further investigation on the nature of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

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

Conclusion on feeding studies

The requested uses do not modify the theoretical maximum daily intake for livestock and there is no risk for livestock commodity MRL to be exceeded.

zRMS comments:

Information given by the Applicant is sufficient. In RAR for rimsulfuron, Vol. 1 (2018) it is concluded that *“Feeding studies shall be provided where metabolism studies indicate that residues at levels above 0.01 mg/kg may occur in tissues, milk and eggs taking into account the residue levels in potential feeding stuffs, obtained at the real dose rate, calculated on the dry weight basis. Feeding studies should be performed in cases where the residue, that is to say the active substance, its metabolites or breakdown products, as defined in the residue definition for risk assessment, tends to accumulate. For rimsulfuron, there are no quantifiable residues (<0.05 mg/kg) of the active substance in any maize, potato, tomato, and chicory matrices at harvest as shown in the supervised residue trials. In addition, considering the metabolism studies, it can be concluded that residues in maize grain at maturity and maize kernels plus cobs at maturity, potato tubers, and tomato fruit will be below the enforcement LOQ of 0.01 mg/kg. Estimated livestock dietary burdens assuming residues in maize forage and stover at 0.05 mg/kg and residues in maize grain, potato tubers and tomato fruit at 0.01 mg/kg are less than 0.004 mg/kg bw/day. Therefore no metabolism or feeding studies were needed or required.”*

The trigger value for feeding studies (0.004 mg/kg bw/day) was not exceeded in any case and livestock feeding studies are not required. It should be noted that no risk for livestock commodity MRL to be exceeded.

7.2.5 Magnitude of residues in processed commodities (industrial processing and/or household preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Available data for all crops under consideration

Regulation (EU) No 283/2013 states that if the level of residues is less than 0.1 mg/kg, processing studies are not needed unless the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is <10% of the ADI or if the estimated daily intake is <10% of the ARfD for any European consumer group diet. Since there are no quantifiable residues of rimsulfuron found in any maize food commodity at the time of harvest, the TMDI is <10% of the ADI and there is no ARfD allotted, no processing studies are necessary.

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

7.2.5.2 Conclusion on processing studies

Regulation (EU) No 283/2013 states that if the level of residues is less than 0.1 mg/kg, processing studies are not needed unless the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is <10% of the ADI or if the estimated daily intake is <10% of the ARfD for any European consumer group diet. Since there are no quantifiable residues of rimsulfuron found in any maize food commodity at the time of harvest, the TMDI is <10% of the ADI and there is no ARfD allotted, no processing studies are necessary.

zRMS comments:

zRMS agrees with information provided by the Applicant above. No additional data are required.

7.2.6 Magnitude of residues in representative succeeding crops

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT₉₀ value of rimsulfuron was expected to be lower than 100 days but relevant soil metabolites (IN-70941, IN-70942 and IN-E9260) were shown to be more persistent (EFSA, 2005). According to the European guidelines on rotational crops (EC, 1997c), further investigation of residues in rotational crops is relevant.

Considering the overdosing factor and resulting data dealing with nature of residues (see Section 7.2.2.1), no study dealing with magnitude of residues in succeeding crops is needed (EFSA, 2012a). The provided studies are sufficient to demonstrate the absence of residues in rotational crops, provided that rimsulfuron is applied in compliance with the corn/maize GAP proposed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data: EFSA, 2005

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

The available data demonstrate the absence of residues in rotational crops, provided that rimsulfuron is applied in compliance with the corn/maize GAP proposed.

zRMS comments:

Information given by the Applicant is sufficient. The crop under consideration can be grown in rotation. According to the EFSA Scientific Report (2005) 45, 1-61, Conclusion on the peer review of rimsulfuron „*There is no reasonable expectation of concentration of rimsulfuron or its metabolites/degradation products in the succeeding crop food and feed items after application of rimsulfuron under the normal agricultural practices.*”

In EFSA Journal 2012;10(10):2911 it is concluded that “*Rimsulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg.*”

No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted. No additional data are required.

7.2.7 Other/ special studies (KCA 6.10, 6.10.1)

In accordance with the technical guidelines for setting MRLs in honey (SANTE/11956/2016 rev. 9; 14 Sep 2018), maize is considered a non-melliferous crop, which is not attractive to bees and/or does not provide enough pollen, nectar, propolis and/or honeydew to enable honeybees to yield honey from the crops. Therefore, residues in honey are not expected from the use under consideration.

zRMS comments:

Information given by the Applicant is sufficient.

In RAR for rimsulfuron, 2018 it is concluded that “*Maize is listed as “not attractive” to honey bees for nectar but “highly attractive” to honey bees for pollen (EFSA Journal 2013; 11(7):3295). Hence, any possibility of rimsulfuron residues in bee products for human consumption must be the result of residues in maize pollen collected by honey bees which might be transferred to honey. Since rimsulfuron is applied to maize early in the season, no later than BBCH 18 (8-leaves unfolded), well before BBCH 61 (flowering) and since the rate of degradation of rimsulfuron in plants is extremely rapid with <20% of rimsulfuron residues remaining in whole maize plant after 15 days (metabolism study in maize), any rimsulfuron residues remaining at flowering are likely to be minimal such that the transfer of residues to pollen and subsequently honey will be extremely small.*”

No additional data are required.

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see Section 7.1.2).

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

7.2.8.1 Input values for the consumer risk assessment

The input values in the following table were used to estimate consumer risk using the EFSA PRIMo (revision 3.1) and UK CRD's ten consumer model (version 1.1). All assessments follow the Tier I approach and are based on published MRL values (for all commodities). The dietary models assume that all crops with MRLs included in the diet have been treated with the active ingredient and there is no dissipation of residues. **The acute dietary assessments are performed only for the consumption of commodities for which GAPs are notified.**

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Rimsulfuron		
FRUITS, FRESH OR FROZEN: (except Tree nuts)	0.01*	* Indicates that the MRL is set at the limit of analytical quantification (EU Pesticides Database, accessed March 16, 2020)
Tree nuts	0.02*	
VEGETABLES, FRESH OR FROZEN (Except herbs and edible flowers)	0.01*	
Herbs and edible flowers	0.02*	
PULSES	0.01*	
OILSEEDS AND OILFRUITS	0.02*	
CEREALS	0.01*	
TEAS, COFFEE, HERBAL INFUSIONS, COCOA & CAROBS	0.05*	
HOPS	0.05*	
SPICES (except horseradish)	0.05*	
Horseradish	0.070	
SUGAR PLANTS	0.01*	
PRODUCTS OF ANIMAL ORIGIN (except Liver, Edible Offals, Other products, Honey)	0.02*	
Liver, Edible Offals, Other products; Honey and other apiculture products	0.05*	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rimsulfuron				
Maize	0.01*	EU MRL (Reg.EU No 617/2014)	0.01*	EU MRL (Reg.EU No 617/2014)
Products of Animal Origin indicated below				
Bovine, Sheep, Goat Muscle/meat/fat/kidney	0.02*	EU MRL (Reg.EU No 617/2014)	0.02*	EU MRL (Reg.EU No 617/2014)
Bovine, Sheep, Goat Liver/edible offals (other than liver & kidney)/ other products	0.05*		0.05*	
Milk	0.02*		0.02*	
All other Commodities	EU MRL (Reg.EU No 617/2014)		Acute risk assessment was undertaken only for the commodities under consideration.	
* Indicates that the MRL is set at the lower limit of analytical quantitation				

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

The highest Theoretical Maximum Daily Intake (TMDI) predicted using EFSA PRIMo is 2% of the ADI for the NL Toddler. The highest contribution is from cattle milk. ~~In the UK, infants are the most exposed population at 1% of the ADI based on EFSA PRIMo exposure estimates.~~

~~Estimates of potential dietary exposure were also calculated using the UK CRD's ten consumer model (version 1.1). The highest predicted total National TMDI (NTMDI) is 3% of the ADI for the UK infant.~~

~~These estimates indicate that no health effects due to chronic exposure are expected in UK consumers.~~

The acute risk assessment was undertaken only for the crops under consideration. Children have the highest International Estimated Short-Term Intake (IESTI) for unprocessed commodities at 0.1% of the ARfD for the consumption of cattle milk, and for processed commodities at 0.01% of the ARfD for the consumption of maize/oil.

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	2% (based on NL Toddler)
NTMDI (% ADI) according to UK Model	3% (UK Infant)
IESTI (% ARfD) according to EFSA PRIMo	No acute reference dose was set therefore IESTI is not required.
NESTI (% ARfD)	Not required.
IESTI (% ARfD) according to EFSA PRIMo ^a	<p>Unprocessed Commodities: 0.1% based on consumption of milk</p> <p>Processed Commodities: 0.01% based on consumption of maize/oil</p>

^a Based on all listed EU MRLs.

The proposed uses of rimsulfuron in the formulation GF-3969 do not represent unacceptable chronic and acute risks for the consumer.

zRMS comments:

The calculation of the TMDI using EFSA model (version 3.1) and MRLs values for all plant and animals commodities (according to the Reg. (EU) No 617/2014) led to a utilisation of the ADI of 2% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is milk: cattle with 1% of the ADI. The intended use will not result in a consumer chronic exposure exceeding the ADI.

Acute risk assessment not required as an ARfD is not necessary (EFSA, 2005).

EFSA concluded in EFSA Journal 2018;16(5):5258 that „The acceptable daily intake (ADI) of rimsulfuron is 0.1 mg/kg bw per day with no change in the ADI value compared to SANCO/10528/2005-rev.2 (European Commission, 2006), based on decreased body weight and body weight gain, decreased food efficiency and increased in relative testes weight in the rat 2-year study by applying an uncertainty factor (UF) of 100. The acute reference dose (ARfD), which was not set in the review report assessment (European Commission, 2006) following the previous evaluation, is 1.7 mg/kg bw based on decreased food consumption, and mortality observed in the developmental study in the rabbit and applying an UF of 100.”

Additionally, the evaluator performed an acute consumer risk assessment using STMR/HR (0.01 mg/kg) for maize and MRLs for animal commodities and using a new value of ARfD of 1.7 mg/kg bw.

Acute risk assessment / children		Acute risk assessment / adults / general population		Acute risk assessment / children		Acute risk assessment / adults / general population																																																																																																																																																																																																																																																																																																																																	
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The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.				ESTI 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 cases 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.																																																																																																																																																																																																																																																																																																																																			
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0.01%	0.02 / 0.02	Equine: Musclemeat	0.02 / 0.02	0.12																																																																																																																																																																																																																																																																																																																																			
0.01%	0.02 / 0.02	Sheep: Musclemeat	0.02 / 0.02	0.11																																																																																																																																																																																																																																																																																																																																			
0.00%	0.02 / 0.02	Bovine: Kidney	0.02 / 0.02	0.08																																																																																																																																																																																																																																																																																																																																			
0.00%	0.02 / 0.02	Milk: Sheep	0.02 / 0.02	0.07																																																																																																																																																																																																																																																																																																																																			
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0.05%	0.02 / 0.02	Milk: Cattle	0.02 / 0.02	0.77																																																																																																																																																																																																																																																																																																																																			
0.02%	0.02 / 0.02	Milk: Goat	0.02 / 0.02	0.37																																																																																																																																																																																																																																																																																																																																			
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0.01%	0.05 / 0.05	Poultry: Liver	0.05 / 0.05	0.24																																																																																																																																																																																																																																																																																																																																			
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0.05%	0.02 / 0.02	Milk: Goat	0.02 / 0.02	0.48																																																																																																																																																																																																																																																																																																																																			
0.02%	0.05 / 0.05	Bovine: Liver	0.05 / 0.05	0.40																																																																																																																																																																																																																																																																																																																																			
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0.02%	0.02 / 0.02	Poultry: Musclemeat	0.02 / 0.02	0.34																																																																																																																																																																																																																																																																																																																																			
0.01%	0.02 / 0.02	Eggs: Chicken	0.02 / 0.02	0.25																																																																																																																																																																																																																																																																																																																																			
0.01%	0.02 / 0.02	Swine: Musclemeat	0.02 / 0.02	0.24																																																																																																																																																																																																																																																																																																																																			
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0.01%	0.05 / 0.05	Swine: Other products	0.05 / 0.05	0.16																																																																																																																																																																																																																																																																																																																																			
0.01%	0.05 / 0.05	Sheep: Liver	0.05 / 0.05	0.14																																																																																																																																																																																																																																																																																																																																			
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Total number of commodities exceeding the ARfD/ADI in children and adult diets (ESTI calculation)		Total number of commodities exceeding the ARfD/ADI in children and adult diets (ESTI new calculation)		Total number of commodities exceeding the ARfD/ADI in children and adult diets (ESTI new calculation)		Total number of commodities exceeding the ARfD/ADI in children and adult diets (ESTI new calculation)																																																																																																																																																																																																																																																																																																																																	
<p>The highest International Estimated Short-Term Intake (IESTI) is at 0.1% and 0.05% of the ARfD for the consumption of Milk: Cattle by children and by adults respectively.</p> <p>The proposed use of rimsulfuron in the product GF-3969 do not represent unacceptable acute and chronic risks for the consumer.</p> <p>No further information is deemed necessary in support of evaluation of GF-3969.</p>																																																																																																																																																																																																																																																																																																																																							

7.3 Thifensulfuron methyl

General data on thifensulfuron methyl are summarized in the table below (last updated 19 December 2020).

Table 7.3-1: General information on thifensulfuron methyl

Active substance (ISO Common Name)	Thifensulfuron methyl
IUPAC	methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbonylsulfamoyl)thiophene-2-carboxylate
Chemical structure	
Molecular formula	C ₁₂ H ₁₃ N ₅ O ₆ S ₂
Molar mass	387.39 g/mol
Chemical group	Sulfonylurea
Mode of action (if available)	Selective, absorbed through foliage and roots. Inhibits plant amino acid synthesis - acetohydroxyacid synthase AHAS
Systemic	Yes
Company (ies)	FMC* Notifiers for Thifensulfuron-methyl: DuPont and EU TSM AIR 2 Task Force (representing Cheminova A/S and Rotam Agrochemical Europe Ltd).
Rapporteur Member State (RMS)	Austria is designated, previous RMS was United Kingdom
Approval status	Approved Commission Implementing Regulation (EU) 2016/1424 of 25 August 2016

Restriction	None In this overall assessment Member States shall pay particular attention to: — the protection of groundwater; — the protection of non-target plants and aquatic organisms.
Review Report	SANTE/10150/2016; SANCO/7577/VI/97
Current MRL regulation	Regulation (EC) No 396/2005 Regulation (EC) 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 2015
EFSA Journal: conclusion on article 12	Yes, EFSA 2012
Current MRL applications on intended uses	EFSA-Q-2008-636 Commodities Status: Reasoned opinion available (EFSA Journal 2012;10(8):2863 [38 pp.]

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

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain	high-starch content	42 months (thifensulfuron methyl) 14 months (thifensulfuron methyl and IN-L9225)	EFSA Journal 2015;13(7):4201
Corn grain	high-starch content	24 months (thifensulfuron methyl)	EFSA Journal 2015;13(7):4201
Cabbage	high-water content	24 months (thifensulfuron methyl and IN-L9225)	EFSA Journal 2015;13(7):4201
Cotton seed	high-starch content	14 months (thifensulfuron methyl and IN-L9225)	EFSA Journal 2015;13(7):4201
Dry beans	high protein content	24 months (thifensulfuron methyl and IN-L9225)	EFSA Journal 2015;13(7):4201
Wheat straw	dry	14 months (thifensulfuron methyl and IN-L9225)	EFSA Journal 2015;13(7):4201
Cotton gin trash	high-oil content	14 months (thifensulfuron methyl and IN-L9225)	EFSA Journal 2015;13(7):4201
Soybean seed	High-oil content	14 months (thifensulfuron methyl and IN-L9225)	EFSA Journal 2015;13(7):4201
Varied	All commodity categories	18 months (IN-A4098*)	EFSA Journal 2017;15(7):4912

* IN-A4098 is a triazine-amine metabolite that is common to several active ingredients. A recent public EFSA conclusion on the active tribuenuron-methyl concluded that IN-A4098 was stable for 18 months in all commodity categories (the

'varied' matrices: wheat forage, hay, sunflower seeds, dried beans, wheat grain and orange (Tribenuron methyl, RAR Volume 3, Annex B.7, April 2017)).

Conclusion on stability of residues during storage

The data show that residues of thifensulfuron methyl and metabolites IN-L9225 and IN-A4098 are stable for at least 14 months in various agricultural commodities stored under frozen conditions. The commodities tested were selected across five crop groupings (high water, high starch, high protein, high oil and dry) to represent a wide variety of crops and are representative for the crops concerned by this application - wheat grain, corn grain, cabbage, cotton seed, dry beans, wheat straw and cotton gin trash. These conditions are consistent with the storage of actual field samples.

Stability data for thifensulfuron methyl and its metabolites in animal products is not provided. Based on the results of the metabolism studies, the anticipated residues of the parent thifensulfuron methyl and its metabolites in edible tissues, milk and eggs at the reasonable worst-case dietary burden remain <0.01 mg/kg and therefore feeding studies were not triggered.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Stability of analyte residues in sample extracts is verified by fortification recovery data summarised with each study. At least one or two fortifications were run with each set of analytical samples. These fortifications were run concurrently with the samples in every set and were stored and treated in every way as the treated specimens in that set.

zRMS comments:

zRMS agrees with information provided by the Applicant above.

Corn/maize seed belongs to high starch content matrices, maize silage belongs to high water content matrices. The potential degradation of residues during storage of the residues trials samples was assessed in the framework of the peer review. Storage stability of thifensulfuron-methyl was demonstrated for a period of 42 months and 24 months at -20 °C in high starch commodities (wheat grain and corn respectively).

The data show that residues of thifensulfuron methyl and metabolites IN-L9225 and IN-A4098 are stable for at least 14 months in various agricultural commodities stored under frozen conditions.

As the trial samples were stored for a maximum period of 14 months between sampling and analysis, it is concluded that the residue data are valid with regard to storage stability.

No additional data are required.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Plant metabolism studies relevant to the uses of thifensulfuron methyl have been evaluated within the EU AIR2 Approval Renewal and are summarised in the Thifensulfuron methyl RAR, Volume 3, Annex B.7, March 2015. The relevant endpoints are listed in the EFSA Conclusion on Thifensulfuron methyl (EFSA 2015). Wheat, corn, and soybean studies as well as goat and poultry metabolism studies (EFSA 2015) were conducted with [triazine-2-¹⁴C] and [thiophene-2-¹⁴C]thifensulfuron methyl as test substances. Characterisation of significant ¹⁴C residues and the elucidation of the metabolic pathway of [¹⁴C]thifensulfuron methyl in representative crops and livestock animals were carried out. The corresponding study summaries were included in Thifensulfuron methyl RAR, Volume 3, Annex B.7, 2014 updated on March 2015.

The study design for thifensulfuron methyl plant metabolism studies conducted under field and greenhouse conditions are summarised in Table 7.3-3 below.

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G ^a	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Pulses and oilseeds	Soybean	[thiophene-2- ¹⁴ C] thifensulfuron methyl	Foliar, G	0.016	1	0 ^b , 7, 30, 100	Samples: 0, 7, 30 DAT: whole plants 100 DAT: seed (beans), pods and foliage (stalks)	UK, 2014 EFSA, 2015 (AMR 572-86)
		[thiophene-2- ¹⁴ C] thifensulfuron methyl	Foliar, G	0.008 (+0.25 % surfactant) ^c	1	0 ^b , 7, 30, 100	Samples: 0, 7, 30 DAT: whole plants 100 DAT: seed (beans), pods and foliage (stalks)	UK, 2014 EFSA, 2015 (AMR 572-86)
		[triazine-2- ¹⁴ C]thifensulfuron methyl	Foliar, G	0.016	1	0 ^b , 7, 30, 100	Samples: 0, 7, 30 DAT: whole plants 100 DAT: seed (beans), pods and foliage (stalks)	UK, 2014 EFSA, 2015 (AMR 547-86, Revision No. 1)
		[triazine-2- ¹⁴ C]thifensulfuron methyl	Foliar, G	0.008 (+0.25 % surfactant) ^c	1	0 ^b , 7, 30, 100	Samples: 0, 7, 30 DAT: whole plants 100 DAT: seed (beans), pods and foliage (stalks)	UK, 2014 EFSA, 2015 (AMR 547-86, Revision No. 1)

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G ^a	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	[thiophene-2- ¹⁴ C] thifensulfuron methyl	Foliar, F	0.074	1	0 ^b , 4, 8, 21, 28, 63	Samples: 0, 4, 8, 21, 28 DAT: whole plants 63 DAT: grain, forage and straw fractions.	UK, 2014 EFSA, 2015 (AMR 498-86 and AMR 783-87)
		[triazine-2- ¹⁴ C]thifensulfuron methyl	Foliar, F	0.080	1	0 ^b , 4, 8, 21, 28, 63	Samples: 0, 4, 8, 21 and 28 DAT: whole plants 63 DAT: grain forage and straw fractions.	UK, 2014 EFSA, 2015 (AMR 513-86 and AMR 794-87)
	Maize (corn)	[thiophene-2- ¹⁴ C] thifensulfuron methyl	Foliar, F	0.036	1	0 ^b , 3, 10, 30, 72, 113	Samples: 0, 3, 10, 30, 72 DAT: whole plants 113 DAT: grain and foliage fractions	UK, 2014 EFSA, 2015 (AMR 532-86)
		[triazine-2- ¹⁴ C]thifensulfuron methyl	Foliar, F	0.039	1	0 ^b , 3, 10, 30, 72, 113	Samples: 0, 3, 10, 30, 72 DAT: whole plants 113 DAT: grain and foliage fractions	UK, 2014 EFSA, 2015 (AMR 532-86)

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

b Refers to sample taken immediately after the spray dried.

c Surfactant (Ortho X-77[®])

Summary of plant metabolism studies reported in the EU

Crops (wheat, maize, and soybeans) in the plant metabolism studies were similarly treated at immature stages (at application rates of 8-74 g a.s./ha) with either [thiophene-2-¹⁴C] or [triazine-2-¹⁴C]thifensulfuron methyl. Mature wheat, maize (corn), and soybeans were harvested 63, 113, and 100

days (respectively) after application. No significant residues of thifensulfuron methyl or its individual metabolites were detected in the mature grain (wheat or corn) or the soybean seeds (beans). Metabolism of thifensulfuron methyl in the three crops was similar, yielding the same degradation compounds. In immature and/or mature foliage, parent underwent de-esterification to form thifensulfuron acid (IN-L9225; 10-16% TRR in wheat straw; 28-31% TRR in soybean leaves). Hydrolysis of the sulfonyleurea structure gave thiophene ring metabolites (*e.g.* 2-acid-3 sulfonamide, IN-L9223, 59% TRR in maize straw) and triazine ring metabolites such as *O*-demethyl triazine amine (IN-B5528, 11% TRR in soybean leaves; 50% TRR in maize straw) and triazine amine (IN-A4098, 13% TRR in soybean leaves). Thifensulfuron methyl was present at harvest at *ca.* 11-15% TRR in wheat straw, <10% TRR in soybean leaves with surfactant use and 44% TRR in soybean leaves without surfactant use. Thifensulfuron methyl was not identified in maize commodities at harvest. Other foliage residues included *-O*-demethyl thifensulfuron methyl (IN-L9226), 2-ester-3-sulfonamide (IN-A5546), triazine urea (IN-V7160) - Trace amounts (<0.01 mg/kg) of *O*-demethyl triazine urea (IN-31804), 2-acid-3-sulfonic acid (IN-N9134) and thiophene sulfonimide (IN-W8268) were detected in corn or soybean foliage.

Summary of new plant metabolism studies

No new plant metabolism studies or data are submitted in support of this application.

Conclusion on metabolism in primary crops

The metabolism of thifensulfuron methyl in plants (wheat, maize and soybeans) was rapid. Metabolism of thifensulfuron methyl in wheat, maize and soybean was similar, yielding the same degradation compounds. Most of the radioactivity was recovered in the leaves with the residues in the grain or seeds being low regardless of the treatment regimes. Based on the available data in plants, the residue definition for risk assessment for fodder crops is proposed as sum of thifensulfuron methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron methyl, and provisionally IN-A4098 to be considered separately pending the toxicological profile of this compound. The residue definition for risk assessment for other plant commodities (food commodities) is proposed as thifensulfuron methyl and provisionally IN-A4098 to be considered separately pending on the toxicological profile of this compound. The plant residue definition for monitoring is proposed as thifensulfuron methyl only, since fodder crops.

zRMS comments:

zRMS agrees with information provided by the Applicant above.
 Metabolism of thifensulfuron-methyl was investigated for foliar application on cereals (wheat and maize) and soybean using [thiophene-2-14C] and [triazine-2-14C] labelled thifensulfuron-methyl.
 EFSA concludes that “Based on the available data in plants, the residue definition for risk assessment for fodder crops is proposed as sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl, and provisionally IN-A4098 to be considered separately pending the toxicological profile of this compound to be fully addressed. The residue definition for risk assessment for other plant commodities (food commodities) is proposed as thifensulfuron-methyl and provisionally IN-A4098 to be considered separately pending on the toxicological profile of this compound. The plant residue definition for monitoring is proposed as thifensulfuron-methyl only, since fodder crops are currently not affected by MRL setting. Metabolism data were available for two primary crop groups (cereals and pulses), and following current guidance it is not possible to set a general residue definition.” (EFSA, 2015).

Plant residue definition for monitoring	For oilseeds and cereals (weed-control use): Thifensulfuron-methyl (parent only) Although currently no EU MRLs are set for feed commodities, for possible future applicability it is proposed for animal feed items (grass / alfalfa): Sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl
Plant residue definition for risk assessment	For oilseeds and cereals (weed-control use): Thifensulfuron-methyl and provisionally triazine amine (IN-A4098)

	For Animal feed items (grass / alfalfa): Sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl and provisionally triazine amine (IN-A4098)
Conversion factor (monitoring to risk assessment)	None

No additional data are required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Metabolism in rotational crop studies relevant to the uses of thifensulfuron methyl have been evaluated within the EU AIR2 Approval Renewal and are summarised in the Thifensulfuron methyl RAR, Volume 3, Annex B.7, March 2015. The relevant endpoints are listed in the EFSA Conclusion on Thifensulfuron methyl (EFSA 2015).

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details				Reference	
			Method, F or G ^a	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		Remarks
EU data								
Root and tuber vegetables	beetroot	[thiophene-2- ¹⁴ C] thifensulfuron methyl	Soil spraying, G	86-94	30, 120	At harvest	Root and foliage were sampled	UK, 2014 EFSA, 2015 (AMR 256-84)
		[triazine-2- ¹⁴ C]thifensulfuron methyl	Foliar treatment ^b , G	36	45, 75	At harvest		UK, 2014 EFSA, 2015 (AMR 582-86)
Pulses and oilseeds	Sunflower Pea	[thiophene-2- ¹⁴ C] thifensulfuron methyl	Soil spraying, G	86-94	30, 120	At harvest	Foliage, seeds, and pods/seed heads were sampled.	UK, 2014 EFSA, 2015 (AMR 256-84)
		[triazine-2- ¹⁴ C]thifensulfuron methyl	Foliar treatment ^b , G	36	45, 75	At harvest		UK, 2014 EFSA, 2015 (AMR 582-86)
Cereals	wheat	[thiophene-2- ¹⁴ C] thifensulfuron methyl	Soil spraying, G	33.6	90, 241	At harvest	—	UK, 2014 EFSA, 2015 (AMR 858-87)
		[triazine-2- ¹⁴ C]thifensulfuron methyl	Soil spraying, G	33.6	90, 241	At harvest		UK, 2014 EFSA, 2015 (AMR 858-87)

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

^b Application on wheat which was ploughed under the soil prior to planting of crops.

Summary of metabolism in rotational crop studies reported in the EU

Three confined rotational crop studies were evaluated in the RAR to determine residues of thifensulfuron methyl in succeeding crops (peas, beet root, sunflower and wheat).

Radiolabelled residues did not accumulate in rotational crops (beets, peas and sunflowers) grown in soil treated 30 and 120 days earlier with thiophene-labelled thifensulfuron methyl at 86-96 g a.s./ha. The level of radiolabelled residues was <0.01 mg/kg in mature crop fractions. No significant residues (<0.01 mg/kg) were observed in edible portions (beetroot, peas, pea pod, sunflower seeds and heads) of crops planted 45 or 75 days following treated (36 g a.s./ha) wheat cultivation and incorporation into soil. Parent, thifensulfuron methyl was not detected in any edible crop parts.

Additionally, there were no significant residues in mature grain (from thiophene and triazine radiolabels) from crops planted 90 and 241 days following soil treatment. Thifensulfuron methyl, parent, was not detected in any edible crop parts. Low residues were detected in ¹⁴C-triazine labelled straw, but no compound was greater than 0.03 mg/kg. Good comparability was demonstrated with primary crop metabolism studies. Metabolites 2-acid-3-sulfonamide, triazine amine, triazine urea and *O*-demethyl triazine amine were detected in plant tissues. Metabolites found in rotational crops not in the primary crop were only found in low amounts and evaluated to be of no toxicological significance. Overall, the majority of the radioactivity was concluded to be incorporated into natural compounds and minor unidentified fractions.

Summary of new plant metabolism studies

No new confined rotational crop studies or data are submitted in support of this application.

Conclusion on metabolism in rotational crops

In summary, the metabolism of thifensulfuron methyl in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary (EFSA 2015).

zRMS comments:

The presented above information regarding nature of residue in rotational crops is in line with data presented during EU review.

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Foliar treatment – cereals (wheat and maize) and oilseed (soybean)
Rotational crops	Beet root, sunflower, pea and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, the metabolites identified in primary crops and rotational crops are in a high degree the same. Metabolites found in rotational crops but not in the primary crop are only found in minor amounts and evaluated to be of no toxicological significance.

No additional data are required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Regulation (EU) No 283/2013 states that if the level of residues is less than 0.01 mg/kg, a study to establish the hydrolytic stability under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation is not required. Therefore, a study was not triggered since residues in commodities to be processed were <0.01 mg/kg.

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

Conclusion on nature of residues in processed commodities

Nature of the residue studies in processed commodities are not needed.

zRMS comments:

As quantifiable residues of thifensulfuron methyl are not expected in edible part of 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.

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

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

Endpoints	
Plant groups covered	Foliar treatment – cereals (wheat and maize) and oilseed (soybean)
Rotational crops covered	Beet root, sunflower, pea and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, the metabolites identified in primary crops and rotational crops are in a high degree the same. Metabolites found in rotational crops but not in the primary crop are only found in minor amounts and evaluated to be of no toxicological significance.
Processed commodities	Not required as residues are <0.1 mg/kg.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	For oilseeds and cereals (weed-control use): Thifensulfuron methyl (parent only) Although currently no EU MRLs are set for feed commodities, for possible future applicability it is proposed for animal feed items (grass/alfalfa): Sum of thifensulfuron methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron methyl (EFSA 2015)
Plant residue definition for risk assessment	For oilseeds and cereals (weed-control use): Thifensulfuron methyl and provisionally triazine amine (IN-A4098) For Animal feed items (grass / alfalfa): Sum of thifensulfuron methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron methyl and provisionally triazine amine (IN-A4098) (EFSA 2015)
Conversion factor from enforcement to RA	None (EFSA 2015)

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

Available data

Livestock (goat and hen) metabolism studies with thifensulfuron methyl relevant to the uses of thifensulfuron methyl have been evaluated within the EU AIR2 Approval Renewal and are summarised in the Thifensulfuron methyl RAR, Volume 3, Annex B.7, 2014, updated on March 2015. The relevant endpoints are listed in the EFSA Conclusion on thifensulfuron methyl (EFSA 2015).

No new data submitted in the framework of this application.

Table 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[thiophene-2- ¹⁴ C]	2 (one per radiolabel)	1.25 mg/kg	7	Milk	twice daily	UK, 2014 EFSA, 2015
						Urine and	daily	

		thifensulfuron methyl [triazine-2- ¹⁴ C] thifensulfuron methyl		bw/day (28 mg/kg/day feed)		faeces		(AMR 326-85)
						Tissues (fat, liver, kidney and muscle)	at sacrifice	
Poultry	Hen	[thiophene-2- ¹⁴ C] thifensulfuron methyl [triazine-2- ¹⁴ C] thifensulfuron methyl	10 (5 per radiolabel)	3.33 mg/kg bw/da (50 mg/kg/day feed)	5	Eggs	daily	UK, 2014 EFSA, 2015 (AMR 2022-91)
						Excreta	daily	
		10 (5 per radiolabel)	0.05 mg/kg feed/day	14	Tissues (abdominal fat, thigh and breast muscle, skin, liver)	At sacrifice, 6 hours after last dose		

a Based on information reported in the DAR (goat received 28 mg/kg of labelled thiophene-2-¹⁴C or triazine-2-¹⁴C in the diet and a daily ration of 1.8 kg) and assumption that the body weight of a goat is 70.1 kg.

No metabolism data in pigs are submitted for evaluation since the metabolism of thifensulfuron methyl in poultry, ruminants (goat) and rats are sufficiently similar that additional metabolism data in pigs are not required. This conclusion remains the case at approval renewal (EFSA 2015).

Summary of animal metabolism studies reported in the EU

A goat metabolism study was conducted with [triazine-2-¹⁴C] and [thiophene-2-¹⁴C]thifensulfuron methyl for 7 consecutive days of oral dosing at a level equivalent to *ca.* 28-mg thifensulfuron methyl/kg total daily dietary intake (*ca.* 1.25 mg thifensulfuron methyl/kg bw/day). Most of the administered dose was recovered in the excreta (urine 53-64%; feces 28-33%). There was minimal transfer of [¹⁴C]thifensulfuron methyl residues to milk, fat, liver, kidney, and muscle tissues. Approximately 0.3 to 0.9% of the dose was eliminated in milk with total radioactive residues (TRR) in milk ranging from 0.08 to 0.16 mg/kg. Most of the residue in the milk was intact parent. Minor milk components included triazine amine (IN-A4098), *O*-demethyl thifensulfuron methyl (IN-L9226), thifensulfuron acid (IN-L9225), *O*-demethyl triazine amine (IN-B5528), 2-ester-sulfonamide (IN-A5546), 2-acid-3-sulfonamide (IN-L9223) and thiophene sulfonimide (IN-W8268). Total radioactive residues in tissues were low (≤ 0.07 mg/kg). The principal component in all tissues was parent. Minor components in the tissues included 2-ester-3-sulfonamide, thiophene sulfonimide and triazine amine.

A poultry metabolism study was conducted at 0.05 and 50 mg thifensulfuron methyl/kg feed /day (3.33 mg thifensulfuron methyl/kg bw/day) with [triazine-2-¹⁴C] and [thiophene-2-¹⁴C]thifensulfuron methyl. Hens were dosed once daily for 14 and 5 consecutive days, respectively. The concentration of radioactivity in eggs and tissues from the low dose groups were below the limit of detection. For the high dose groups, most of the administered dose was recovered in the excreta (70-79%). Minimal transfer of thifensulfuron methyl equivalent residues to eggs, and tissues (liver, muscle and fat) was observed accounting for <1% of the dose. Levels of radioactivity in eggs from the high dose groups were highest on Day 5 with concentrations of 0.30 mg thifensulfuron methyl equivalents/kg for the triazine-labelled eggs and 0.02 mg/kg for the thiophene-label. Average tissue concentrations were 0.46, 0.28, and 0.29 mg/kg for triazine-labelled liver, thigh muscle and breast muscle, respectively, and 0.21, 0.01, and 0.01 mg/kg for the corresponding thiophene-labelled tissues. An apparent plateau in egg residues (*ca.* 0.26 mg/kg) was observed on days 3 through 5. Similar metabolic profiles were observed in the excreta, eggs and tissues. Components in eggs and tissues included thifensulfuron methyl, triazine urea (IN-V7160, which was the highest observed component in liver), triazine amine, and hydroxymethyl triazine amine (IN-L9622). The thiophene-labelled metabolite, 2-ester-3-sulphonic acid (IN-T7090), was only observed at low levels in hen liver. The metabolic fate of thifensulfuron methyl in the laying hen was consistent with that observed in the laboratory rat and lactating goat.

Summary of new animal metabolism studies

No new livestock metabolism studies or data are submitted in support of this application.

Conclusion on metabolism in livestock

The major metabolic pathway in ruminants and poultry involved hydrolysis of the ester group, resulting in the formation of thifensulfuron acid. Oxidative *O*-demethylation occurred to a limited extent. The major residue in milk, muscle and tissues was thifensulfuron methyl. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. Since log P_{ow} thifensulfuron methyl is less than 3 (DAR, France, 1996), EFSA concludes that the residue in commodities of animal origin is not fat soluble.

Based on livestock metabolism data and assuming a similar behaviour of the thifensulfuron acid (IN-L9225) in animals, the residue definition for risk assessment in livestock matrices was derived as sum of thifensulfuron methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron methyl, and provisionally IN-A4098 to be considered separately pending the toxicological profile of this compound.

zRMS comments:

zRMS agrees with information provided by the Applicant above.
 EFSA concluded in EFSA Journal 2015;13(7):4201 that “*Livestock metabolism was studied with thifensulfuron-methyl in goat and hen. Based on these data and assuming a similar behaviour of the thifensulfuron acid (IN-L9225) in the animals, the residue definition for risk assessment in livestock matrices was derived as sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl, and provisionally IN-A4098 to be considered separately pending on the toxicological profile of this compound. IN-A4098 also appeared as a livestock metabolite of thifensulfuron-methyl, and therefore a livestock exposure assessment for IN-A4098 residues in feeding stuffs is to be conducted to estimate the actual residue levels of IN-A4098 in animal commodities from both internal and external exposure to IN-A4098 (data gap).*”
 No further information is deemed necessary in support of evaluation of GF-3969.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2-3 days in milk
	3-5 days in eggs
Animal residue definition for monitoring	Thifensulfuron methyl (parent only) (EFSA 2015)
Animal residue definition for risk assessment	Sum of thifensulfuron methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron methyl and provisionally triazine amine (IN-A4098) (EFSA 2015)
Conversion factor	None (EFSA 2015)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

The EU MRL was set on the basis of residue data generated with a WG thifensulfuron methyl formulation. While the number of residue trials was not compliant with the data requirements for maize, the reduced number of residue trials was considered acceptable for thifensulfuron methyl because all residues were below the LOQ and a no residue situation was expected (EFSA, 2012b).

One new study on the magnitude of residue has been submitted by the applicant in the framework of this application. The study is summarized in the table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of GF-3969 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize grain	EFSA, 2012b	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 15 g a.s./ha, BBCH 12-18, PHI not applicable, outdoor E: 4x <0.05 RA: 4x <0.05 [Note: Considering the 2N metabolism study in maize, it is concluded that residues will be below the enforcement LOQ of 0.01 mg/kg.]	NA				
	New trials (DuPont-49732)	N-EU	Trials GAP: 1 x 0.015 kg a.s./ha, BBCH 19, PHI not applicable, outdoor E: 6x <0.01 RA: 6x <0.01					
	Overall supporting data for cGAP	N-EU	E: 10x <0.01 RA: 10x <0.01 [Note: Considering the 2N metabolism study in maize, it is concluded that residues will be below the enforcement LOQ of 0.01 mg/kg.]	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.01	Yes
Maize forage (silage)	EFSA, 2012b	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 15 g a.s./ha, BBCH 12-18, PHI not applicable, indoor E: 4x <0.05 RA: 4x <0.05	NA				
	New trials (DuPont-49732)	N-EU	Trials GAP: 1 x 0.015 kg a.s./ha, BBCH 19, PHI not applicable, outdoor E: 6 x <0.01 RA: 6 x <0.01					
	Overall supporting data for cGAP	N-EU	E: 6 x <0.01, 4x <0.05 RA: 6 x <0.01, 4x <0.05	E: <0.01 RA: <0.01	E: <0.05 RA: <0.05	0.05	-	-
Maize stover (straw)	New trials (DuPont-49732)	N-EU	Trials GAP: 1 x 0.015 kg a.s./ha, BBCH 19, PHI not applicable, outdoor E: 6 x <0.01 RA: 6 x <0.01	NA				
	Overall supporting data	N-EU	E: 6 x <0.01 RA: 6 x <0.01	E: <0.01 RA: <0.01	E: <0.01 RA: <0.01	0.01	-	-

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	STM (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	for cGAP							

* Source of EU MRL: Reg. (EU) No 617/2014; NA: not applicable

7.3.3.2 Conclusion on the magnitude of residues in plants

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

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

The uses are considered acceptable.

zRMS comments:

New study on the magnitude of residue have been submitted by the Applicant in the framework of this application.

Table 7.2: Summary of intended GAP in maize for GF-3969.

Type of GAP	Method	Number of applications	Application rate per treatment (g as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Intended GAP - maize	Hydraulic sprayer overall	1-2 (split)	rimsulfuron 20 g a.s./ha thifensulfuron methyl 12.5 a.s./ha (split application possible without exceeding the total maximum of 135 g product/ha)	7	BBCH 18	-

Eleven field trials (6 trials in N-EU and 5 trials in S-EU) were conducted to determine residues of rimsulfuron and thifensulfuron methyl in commodities derived from maize treated with DPX-TNS43 (a blend of rimsulfuron 25SG/thifensulfuron methyl 50SG/mesotrione 50WG plus isoxadifen-ethyl 50WG (safener; not active)) during the 2017 and 2018 growing seasons in EU. **Trend 90 (0.2% (v/v)) adjuvant was added to the tank mix.** DPX-TNS43 was applied once on maize at growth stage BBCH 19 at a nominal rate of 20 g ai/ha for rimsulfuron and 15 g ai/ha for thifensulfuron methyl.

Northern Europe:

Thifensulfuron methyl residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.

Residues in maize whole plant samples ranged from not detected (<0.003mg/kg) to 0.10 mg/kg at 14±1 DALA.

IN L9225 residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.

IN-A4098 residues were not detected in any field-grown maize whole plant, forage/silage, stover or grain samples taken at maturity.

The addition of Trend 90 (0.2% (v/v)) adjuvant to the DPX-TNS43 formulation did not affect the residue levels of a.s..

While the number of residue trials was not compliant with the data requirements for maize, the reduced number of residue trials was considered acceptable for rimsulfuron and thifensulfuron methyl because all residues were below the LOQ and a no residue situation was expected.

Available results show that the in force MRL for thifensulfuron methyl on maize/corn of 0.01* mg/kg (Reg. (EU) No 617/2014) will not be exceeded. Therefore the use of GF3969 can be considered as supported on maize in Europe.

No additional data are required.

(* Limit of analytical determination)

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

An assessment of the theoretical maximum daily intakes by domestic animals (pig, poultry, dairy and beef cattle) from the consumption of feed commodities of cereals, maize, alfalfa/clover, and grasses which may contain residues of thifensulfuron methyl plus thifensulfuron acid (IN-L9225) residues, expressed as thifensulfuron methyl, has been made in the Thifensulfuron methyl RAR, Volume 3, Annex B.7, March 2015. The calculated poultry intake is less than 0.1 mg/kg feed. The calculated pig, dairy and beef cattle intakes exceed 0.1 mg/kg feed. However, the doses applied during the goat and hen metabolism studies are 9x the highest calculated pig or cattle intake and 3330x the highest poultry intake. Based on the results of the metabolism studies, the anticipated residues of the parent thifensulfuron methyl and metabolites in edible tissues, milk and eggs at the reasonable worst-case dietary burden remain <0.01 mg/kg. See details in the Thifensulfuron methyl RAR, Volume 3, Annex B.7, March 2015.

The input values include the median and highest residue values from the current proposed use and previously evaluated maize uses for thifensulfuron methyl (EFSA, 2012b). The proposed use of GF-3969 is not expected to raise the dietary burden.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Thifensulfuron methyl				
Maize grain	0.01	STMR (proposed use)	0.01	HR (proposed use)
Maize forage (silage)	0.01	STMR (proposed use)	0.05	HR (proposed use)
Alfalfa (fresh and silage)	0.05	STMR	0.05	HR
Clover (fresh and silage)	0.05	STMR	0.05	HR
Grass (fresh and silage)	0.05	STMR	0.13	HR
Alfalfa hay	0.2	STMR x 4	0.2	HR x 4
Clover hay	0.2	STMR x 4	0.2	HR x 4
Grass hay	0.2	STMR x 4	0.52	HR x 4
Wheat grain	0.01	STMR	0.01	HR
Barley grain	0.01	STMR	0.01	HR
Rye grain	0.01	STMR	0.01	HR
Oat grain	0.01	STMR	0.01	HR
Wheat bran	0.01	STMR	0.01	HR
Rye bran	0.01	STMR	0.01	HR
Wheat straw	0.05	STMR	0.05	HR
Barley straw	0.05	STMR	0.05	HR
Rye straw	0.05	STMR	0.05	HR
Oat straw	0.05	STMR	0.05	HR
Sobean (incl. meal)	0.01	STMR	0.01	HR

The intake calculations for thifensulfuron methyl in livestock have been performed using the EFSA calculator (~~2017 model~~ Animal model 2017) considering the current proposed use and those included in the Article 12 review and are presented in the following table:

Table 7.3-10: Results of the dietary burden calculation for the proposed use

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.001	0.004	0.04	0.11	Dairy cattle	Corn, field	forage/silage	No
Cattle (dairy only)	0.001	0.004	0.03	0.09	Dairy cattle	Corn, field	forage/silage	No
Sheep (all diets)	0.001	0.001	0.02	0.02	Lamb	Corn, field	gluten feed	No
Sheep (ewe only)	0.001	0.001	0.02	0.02	Ram/Ewe	Corn, field	gluten feed	No
Swine (all diets)	0.001	0.001	0.02	0.04	Swine (breeding)	Corn, field	forage/silage	No
Poultry (all diets)	0.002	0.002	0.02	0.03	Poultry layer	Corn, field	forage/silage	No
Poultry (layer only)	0.002	0.002	0.02	0.03	Poultry layer	Corn, field	forage/silage	No

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

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Table 7.3-11b: Results of the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.006	0.015	0.16	0.38	Dairy cattle	Grass	hay	Yes
Cattle (dairy only)	0.006	0.015	0.16	0.38	Dairy cattle	Grass	hay	Yes
Sheep (all diets)	0.007	0.018	0.22	0.55	Ram/Ewe	Grass	hay	Yes
Sheep (ewe only)	0.007	0.018	0.22	0.55	Ram/Ewe	Grass	hay	Yes
Swine (all diets)	0.002	0.004	0.09	0.16	Swine (breeding)	Grass	hay	Yes
Poultry (all diets)	0.003	0.003	0.05	0.05	Poultry layer	Clover	hay	No
Poultry (layer only)	0.003	0.003	0.05	0.05	Poultry layer	Clover	hay	No

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

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The metabolism of thifensulfuron-methyl was investigated in lactating goats dosed with 0.71 mg/kg bw per d of thifensulfuron-methyl corresponding to approximately 25 times the maximum exposure of meat ruminants. The study demonstrated that the transfer of residues in milk and tissues at this rate was relatively low. Parent thifensulfuron-methyl was the major component found in milk, muscle, and tissues. The highest concentration for both labels was detected in kidneys (0.16 ppm), milk (0.14 ppm), liver (0.05 ppm), and muscle (0.03 ppm). At the maximum dietary burden for sheep (all diets), residues in ruminant tissues would be below LOQ. No feeding study is required (UK, 2014; EFSA, 2015).

zRMS comments:

Dietary burden calculation performed using the EFSA calculator (Animal model 2017) for thifensulfuron methyl is confirmed to be correct. The trigger value for feeding studies (0.004 mg/kg bw/day) was not exceeded in any case **for the proposed uses**.
No additional data are required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

The trigger value for feeding studies (0.004 mg/kg bw/day) was not exceeded in any case and livestock feeding studies are not required.

No new livestock dietary burden calculations were triggered and no new data were submitted in the framework of this application.

Conclusion on feeding studies

The requested uses do not trigger new livestock dietary burden calculations, and there is no risk for animal MRL to be exceeded.

zRMS comments:

Information given by the Applicant is sufficient.
Since the calculated dietary burdens for all types of livestock were found to be below the trigger value of 0.004 mg/kg bw/day, further investigation on feeding studies is not necessary. It should be noted that no risk for livestock commodity MRL to be exceeded.
No additional data are required.

7.3.5 Magnitude of residues in processed commodities (industrial processing and/or household preparation) (KCA 6.5.2-6.5.3)

The Commission Directive 96/68/EC states that processing studies are not necessary “if no significant (>0.1 mg/kg) or no analytically determinable residues occur in the plant product being processed”.

The DAR evaluation considered that processing studies were not necessary as no significant (<0.01 ppm in cereal grains) and no analytically determinable residues occurred in the plant or plant product being processed.

7.3.5.1 Available data for all crops under consideration

A study to establish the hydrolytic stability of thifensulfuron methyl under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation was not triggered since residues in commodities to be processed were <0.1 mg/kg.

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

7.3.5.2 Conclusion on processing studies

No quantifiable thifensulfuron methyl residues (<0.01 to <0.02 mg/kg) were found in any human food commodity at the time of harvest (Thifensulfuron methyl RAR, Volume 3, Annex B.7, March 2015). Therefore, no processing studies are necessary.

The EFSA Conclusion on thifensulfuron methyl (EFSA, 2015) confirms processing studies are not applicable.

zRMS comments:

zRMS agrees with information provided by the Applicant above. As the residues in maize grains were below the 0.1 mg/kg trigger, and the metabolism studies indicate that positive residues are not expected, studies to investigate the effects of processing are not considered necessary.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see Section 7.3.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

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

Table 7.3-12: 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			Reference/ Remarks
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	
EU data					
Cereal crop / bare soil	0.60 g a.s./ha	Leafy crops	Spinach	14-30 ^a , 120-132 ^b , 300- 365 ^c	RAR, UK, July 2014 (DuPont-28582)
Cereal crop / bare soil	0.60 g a.s./ha	Root crops	Radish	14-30 ^a , 120-132 ^b , 300- 365 ^c	
Cereal crop / bare soil	0.60 g a.s./ha	Cereal crops	Spring wheat, sorghum	14-30 ^a , 120-132 ^b , 300- 365 ^c	

a Interval simulating circumstances of crop failure or closely related crops

b Interval simulating conditions reflecting the anticipated agricultural use of the pesticide for a typical harvest interval

c Interval simulating conditions for crops rotated the following year

Conclusion on rotational crops studies

Though the metabolism studies previously assessed the possibility of residues expressed in the following crops and concluded that the occurrence of such residues was unlikely, the notifier has included the assessed rotational crop study for completeness and to further support the case for a no residues situation in following crops. The metabolite IN-A4098 was found in very low amounts and was more prevalent (but still at low amounts) at earlier replanting intervals. According to the RAR (UK, 2014), residues of IN-A4098 in rotational crops ranged from ND – 0.015 mg/kg. The majority of timepoints were ND or <LOQ (<0.01 mg/kg) for IN-A4098, while two samples for spinach were >LOQ. Immature spinach at PBI 292-312 days included IN-A4098 residue at 0.015 mg/kg. Mature spinach at PBI 14-26 days included IN-A4098 residue at 0.011 mg/kg. On this basis there is a low likelihood that residues of this metabolite (and residues of other metabolites) would be found. Therefore, The residue definition for rotational crops is provisionally parent plus IN-A4098 and is proposed to remain as parent only for rotational crops and does not need to be reconsidered, in view of this low expectation of any significant residues being found (of parent or metabolites) in rotational crops.

In March 2020, the PPR Panel published its Opinion on triazine amine (IN-A4098) in which it concluded that there is no concern for the potential of triazine amine to induce gene mutations and clastogenicity. With regard to aneugenicity, the PPR Panel did not highlight any concern for aneugenic potential, however recommended that in order to complete the database and definitively conclude, an in vitro micronucleus test should be submitted. The Committee agreed that the conditions of approval do not need to be modified, however, an in vitro micronucleus study should be submitted by the

applicant (FMC) during the renewal assessment to complete the database on aneugenicity and confirm that triazine amine is not of concern.

FMC is in the position that the conclusion from EFSA has already cleared IN-A4098 genotox profile, and In vitro micronucleus test is only needed for final confirmation.

FMC confirmed that In vitro micronucleus for IN-A4098 study was submitted to support AIR 5 metsulfuron methyl data (in September 2020) and it clearly confirms EFSA conclusion on metabolite IN-A4098 with negative results.

Wodds, I. (2020): IN-A4098: In Vitro Mammalian Cell Micronucleus Test in Human Peripheral Lymphocytes. Report No: FMC-54579.

zRMS comments:

Information given by the Applicant is sufficient. The presented above information regarding magnitude of residues in representative succeeding crops is in line with data presented during EU review. The crop under consideration can be grown in rotation. No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted. No further information is deemed necessary in support of evaluation of GF-3969.

7.3.7 Other/ special studies (KCA 6.10, 6.10.1)

In accordance with the technical guidelines for setting MRLs in honey (SANTE/11956/2016 rev. 9; 14 Sep 2018), maize is considered a non-melliferous crop, which is not attractive to bees and/or does not provide enough pollen, nectar, propolis and/or honeydew to enable honeybees to yield honey from the crops. Therefore, residues in honey are not expected from the use under consideration.

zRMS comments:

Information given by the Applicant is sufficient. See zRMS comments in the point. 7.2.7. No additional data are required.

7.3.8 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 Section 7.1.2).

7.3.8.1 Input values for the consumer risk assessment

The input values in the following table were used to estimate consumer risk using the EFSA PRIMo Rev 3.1 and UK CRD's ten consumer model (version 1.1). All assessments follow the Tier I approach and are based on published MRL values (for all commodities) and assume no dissipation of residues. The acute dietary assessments are performed only for the consumption of commodities for which GAPs are notified.

Table 7.3-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Thifensulfuron methyl				
FRUITS, FRESH or FROZEN; TREE NUTS	0.01*	* Indicates that the MRL is set at the limit		Acute risk assessment was undertaken only for the crops under consideration.

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
VEGETABLES, FRESH or FROZEN (except herbs and edible flowers)	0.01*	of analytical quantification (EU Pesticides Database, accessed 23 rd March, 2020)		
Herbs and edible flowers	0.02*			
Pulses	0.01*			
Oilseed and oil fruits	0.01*			
Cereals	0.01*			
Maize / corn	0.01*		0.01*	MRL for maize/corn (EU Pesticides Database, accessed 23 rd March, 2020)
Teas, coffee, herbal infusions, cocoa	0.05*			
HOPS	0.05*			Acute risk assessment was undertaken only for the crops under consideration.
Spices (except horseradish)	0.05*			
Horseradish	0.070			
Sugar plants	0.01*			
Commodities from terrestrial animals including milk and birds eggs	0.01*			
Honey and other apiculture products	0.05*			

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

The highest Theoretical Maximum Daily Intake (TMDI) is 12% of the ADI for the Netherlands toddler. The highest contribution (6% ADI) is from cattle milk. The acute risk assessment was undertaken only for the crops under consideration. Children have the highest International Estimated Short-Term Intake (IESTI) for unprocessed commodities at 0.01% of the ARfD for the consumption of maize, and for processed commodities at 0.01% of the ARfD for the consumption of maize/oil.

Estimates of potential dietary exposure were also calculated using the UK CRD's ten consumer model (version 1.1). The highest predicted total National Estimate of Dietary Intake (NEDI) is 15% of the ADI for UK infants. The acute dietary assessment performed using the UK model for the consumption of commodities for which GAPs are notified (maize) estimates the highest National Estimate of Short-Term Intake (NESTI) to be <0.01% of the ARfD for all population groups.

These estimates indicate that no health effects due to chronic and acute dietary exposure are expected in UK consumers.

Table 7.3-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo ^a	12% (based on NL toddler)
NTMDI (% ADI) according to UK Model ^a	15% (based on UK infant)
IESTI (% ARfD) according to EFSA PRIMo ^b	<u>Unprocessed Commodities:</u> 0.01% based on consumption of maize by UK infant <u>Processed Commodities:</u> 0.01% based on consumption of maize/oil by NL toddler
NESTI (% ARfD) according to UK Model ^b	<0.01% based on consumption of maize by all population groups.

a Based on all listed EU MRLs.

b Based on crops under consideration, *i.e.* maize

The proposed uses of thifensulfuron methyl in the formulation GF-3969 do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:

The calculation of the TMDI using EFSA model (version 3.1) and MRLs values for all plant and animals commodities (according to the Reg. (EU) No 617/2014) led to a utilisation of the ADI of 12% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is milk: cattle with 6% of the ADI. The intended use will not result in a consumer chronic exposure exceeding the ADI.

The acute consumer risk assessment was performed only for the crops under consideration using MRLs values (0.01 mg/kg according to the Reg. (EU) No 617/2014) for maize.

EFSA PRIMo Rev. 3.1 calculates a maximum utilisation of the ARfD of 0.01% in case of maize/corn for children and for adults.

The proposed use of thifensulfuron methyl in the product GF-3969 do not represent unacceptable acute and chronic risks for the consumer.

No further information is deemed necessary in support of evaluation of GF-3969.

7.4 Isoxadifen-ethyl (safener)

zRMS comments:

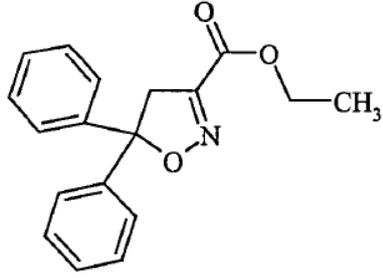
Isxadifen-ethyl

It should be pointed out that formulation GF-3969 contains 111.1 g/kg of safener, isxadifen-ethyl. Isoxadifen-ethyl is not considered as an active substance and at present MRLs are not set in the EU for safeners.

The Applicant provided the data for safener reviewed by Germany. According to Regulation 1107/2009, data for safener should be evaluated in line with requirements relevant for active substances and EU agreed and peer-reviewed endpoints should be generated. Such evaluation, however, is outside the scope of the product registration and should be carried out at the EU level in order to derive uniform endpoints that may be used in evaluation of various formulations. For this reason studies provided for isxadifen-ethyl were not validated by the zRMS.

General data on isxadifen-ethyl are summarized in the table below.

Table 7.4-1: General information on isoxadifen-ethyl

Active substance (ISO Common Name)	Isoxadifen-ethyl
IUPAC	5,5-diphenyl-2-isoxazoline-3-carboxylic acid ethylester
Chemical structure	
Molecular formula	C ₁₈ H ₁₇ NO ₃
Molar mass	295.36 g/mol
Chemical group	Safener
Mode of action (if available)	Increased herbicide metabolism in corn It protects corn from damage caused by herbicides taken up via the roots or the leaves. It is applied in co-formulation with the herbicide(s) at pre-emergence or post-emergence.
Systemic	Yes
Company (ies)*	Not relevant
Rapporteur Member State (RMS)	Germany The safener has been evaluated by Germany as RMS of the active ingredient foramsulfuron under the framework of Directive 91/414/EEC
Approval status	Not relevant
Restriction	None
Review Report	EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl. M-263999-01-1.
Current MRL regulation	Not relevant
Peer review of MRLs according to Article 12 of Reg. No 396/2005 EC performed	Not relevant
EFSA Journal: Conclusion on the peer review	Not relevant
EFSA Journal: conclusion on article 12	Not relevant
Current MRL applications on intended uses	None

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

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data: Germany, 2002; Austria, 2006

Storage stability data are reported in the German evaluation (2002) of isoxadifen-ethyl. Representative frozen samples and principal extracts of straw from the rice metabolism study were checked for storage stability and shown to be stable for more than 2 years (27-29 months). One new stability study performed on cereal crops has been submitted and evaluated by Austria in 2006.

Table 7.4-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Isoxadifen-ethyl			
Rice (straw)	High starch and/ or protein content and low water and fat content	27-29 months	EU peer reviewed Germany, 2002*
Rice (grain)	High starch content	912 days at -10°C to -20°C	Not EU peer reviewed Evaluated by Austria, 2006**
Corn (forage)	High water content	1199 days at -10°C to -20°C	
Isoxadifen			
Rice (grain)	High starch content	912 days at -10°C to -20°C	Not EU peer reviewed Evaluated by Austria, 2006**
Corn (forage)	High water content	1199 days at -10°C to -20°C	
AE F162241			
Corn (forage)	High water content	1199 days at -10°C to -20°C	Not EU peer reviewed Evaluated by Austria, 2006**
AE C637375			
Rice (grain)	High starch content	912 days at -10°C to -20°C	Not EU peer reviewed Evaluated by Austria, 2006**

* EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl M-263999-01-1)

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Maximum storage period of samples from European supervised field trials

Compound	Crop	Sample material	Maximum storage period (days)	Duration covered (days)	Reference
Northern EU					
Isoxadifen-ethyl (AE F122006), isoxadifen and AE F162241	Maize/ Corn	Ear, corn	499	1199 days for forage (corn) and 912 days for grain	EU peer reviewed Germany, 2002*
		Kernel	485		
		Green material	585		
		Rest of plant	501		
Isoxadifen-ethyl (AE F122006), isoxadifen and AE F162241	Maize/ Corn	Ear, corn	512	1199 days for forage (corn) and 912 days for grain	EU peer reviewed Germany, 2002*
		Kernel	492		
		Green material	595		
		Rest of plant	510		
Isoxadifen-ethyl (AE F122006), isoxadifen and AE F162241	Maize/ Corn	Ear, corn	300	1199 days for forage (corn) and 912 days for grain	EU peer reviewed Germany, 2002*
		Kernel	270		
		Shoot	391		
		Rest of plant	300		
		Kernel	372		
		Shoot	272		
		Rest of plant	321		

* Study reported in EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl M-263999-01-1)

Conclusion on stability of residues during storage

The three tested analytes (isoxadifen-ethyl, isoxadifen and AE C63735) exhibited good stability during frozen storage in rice grain for a period of 912 days.

In corn forage, isoxadifen (AE F129431) showed no significant decline during frozen storage while isoxadifen-ethyl declined slightly with an estimated half-life of 3.7 years. It should be noted that isoxadifen-ethyl degraded to isoxadifen (AE F129431), which is accounted for by the method and when added to the isoxadifen-ethyl residues gave full accountability of the isoxadifen-ethyl residues over the course of the study. The minor metabolite AE F162241 had an estimated half-life of approximately 2.2 years.

Samples taken from the field residue trials that were already evaluated (Germany, 2002) were stored maximal 595 days prior to analysis. The storage periods are covered by the storage stability study performed on rice and corn matrices.

7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data: Germany, 2002; Austria, 2006

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

The relevant information on the stability in the final or any intermediate step can be derived from the fortification experiments performed during method validation. Every analytical batch does contain at least one concurrent recovery which is handled and stored in parallel to the residue samples. If the recoveries in the fortified samples are within acceptable ranges, stability is considered as sufficiently proven.

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: Germany, 2002; Austria, 2006

No new data are submitted in the framework of this application. The metabolism of isoxadifen-ethyl in primary crops was investigated in maize and rice. The corresponding data are summarised in the Annex II dossier for isoxadifen-ethyl and were evaluated by Germany in 2002 and in evaluation by Austria in

2006.

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								
Cereal/ grass crops	Rice	[phenyl-UL- ¹⁴ C] – isoxadifen-ethyl	Foliar treatment, G	0.167 or 1.670 at 4th tiller stage (62 days after planting)	1	DAT 202, at maturity	Rice flooded 26 days after planting	EU peer-reviewed Germany, 2002*
	Corn	[phenyl-UL- ¹⁴ C] – isoxadifen-ethyl	Foliar treatment, F	0.0514 or 0.4662 at BBCH 31 (53 days after planting)	1	DAT 101 DAT 144	Forage grain, stover (at maturity)	EU peer-reviewed Germany, 2002*, Austria, 2006 **

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

* EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl M-263999-01-1)

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Summary of plant metabolism studies reported in the EU

EU peer-reviewed Germany 2002: “Treatment of rice with isoxadifen-ethyl at 167 g/ha resulted in only limited residues in the final harvest commodities; 0.713 mg equiv./kg in the straw and 0.049 mg equiv./kg in the grain. The very low residues in the grain indicate that translocation of isoxadifen-ethyl is not a significant process.

The metabolic pathway in rice involves initial hydrolysis of the parent ester to give the acid (AE F129431; the principal straw metabolite). The pathway may then proceed via hydroxylation of the phenyl ring (AE F162241; significant in rice straw) or by opening of the heterocyclic ring (AE C637375; the principal grain metabolite), followed by hydrolysis to the amide (AE C642961). Despite every effort being made to maximize residues for identification, residue levels, particularly in grain, were very low and the major metabolite in grain (AE C637375) represented less than 0.008 mg/kg at the 1 X rate. The remainder in grain and straw was composed of many minor polar metabolites. The major metabolites detected in plants (AE F129431, AE F162241 and AE C637375) were also identified in animal metabolism studies.

Treatment of corn with isoxadifen-ethyl at 51.4 g/ha resulted in only limited residues in the forage and final harvest commodities: 0.215 mg equiv./kg in forage, 0.017 mg equiv./kg in grain, 0.317 mg equiv./kg in stover. The very low residues in the grain indicate that translocation of isoxadifen-ethyl is not a significant process.

The metabolic pathway in corn involves initial hydrolysis of the parent ester to give the acid (AE F129431, the principal metabolite in forage, grain and stover). The pathway then proceeds via hydroxylation of the phenyl ring (AE F162241, also significant in forage and stover). Despite every effort to maximise residues for identification, residue levels, particularly in grain, were very low and the major metabolite in grain (AE F129431) represented less than 0.008 mg/kg at the 1X rate. The remainder in forage, grain and stover was composed of several minor metabolites, none of which were significant (<7% TRR). The major metabolites detected in corn (AE F129431 and AE F162241) were also identified in the rice metabolism study and in animal metabolism studies.”

Conclusion on metabolism in primary crops

Metabolism, distribution and expression of residues have been investigated in rice and corn after foliar

spray applications of parent isoxadifen-ethyl at rates representative for the intended uses.

In the 2002 German national evaluation, a preliminary residue definition for risk assessment and monitoring comprised of the parent compound only. Isoxadifen-ethyl is rapidly hydrolysed to form isoxadifen free acid (AE F129431) in plants, the latter representing the major portion of the residue. Also, under deep-freezing storage conditions, isoxadifen-ethyl tends to degrade to isoxadifen (AE F129431) overtime. Thus, Bayer CropScience is proposing to add to the residue definition in plants for risk assessment and monitoring includes beside the active ingredient also isoxadifen free acid (AE F129431).

The available metabolism studies adequately cover the intended uses on corn.

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data: Germany, 2002; Austria, 2006

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								
Not required							EU peer reviewed Germany, 2002** Austria, 2006***	

* Outdoor/field application (F) or glasshouse/protected/indoor application (G) Or climatic chamber simulating outdoor conditions

** EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl. M-263999-01-1)

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Conclusion on metabolism in rotational crops

EU peer-reviewed Germany 2002: “Studies on the behaviour in soil did not indicate that significant residues of isoxadifen-ethyl and/or its metabolites and degradation products might remain in soil or in plant material up to the sowing or planting of succeeding crops. Therefore, no residues above the LOQ resulting from soil uptake are to be anticipated and a theoretical consideration of the nature and level of the residue in succeeding crops is not required.

Metabolism in soil studies showed that less than 10% of isoxadifen-ethyl and metabolites remain in soil after 100 days. No residues at or above the limit of quantification could arise in succeeding crops from these low soil residues.

Therefore, a rotational crop field study is not required.”

7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

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

Table 7.4-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Not required		EU peer reviewed Germany, 2002* Austria, 2006**

* EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl. M-263999-01-1)

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Conclusion on nature of residues in processed commodities

EU peer-reviewed Germany 2002:

“Metabolism studies conducted with isoxadifen-ethyl at an application rate of 466.2 g/ha (31N rate) in maize showed residues of 0.226 mg/kg TRR (total radioactive residue) in the edible agricultural commodity kernels. Upon identification of the residue no single component was identified which accounted for more than 28.0% of the TRR.

In the field residue trials, no isoxadifen-ethyl derived residues above 0.01 mg/kg (LOQ, limit of quantification) were found in maize kernels following application of up to 2 times 60 g/ha. Consequently, no residues of the parent or metabolites are to be expected in maize grain at levels above the trigger value of 0.1 mg/kg under normal field conditions.

Therefore, no processing studies were necessary.”

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

Table 7.4-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (maize/ corn, rice)
Rotational crops covered	N/A
Metabolism in rotational crops similar to metabolism in primary crops?	N/A
Processed commodities	N/A
Residue pattern in processed commodities similar to pattern in raw commodities?	N/A
Plant residue definition for monitoring	Isoxadifen-ethyl and the metabolite isoxadifen (AE F129431), expressed as isoxadifen-ethyl (maize/ corn)
Plant residue definition for risk assessment	Isoxadifen-ethyl and the metabolite isoxadifen (AE F129431), expressed as isoxadifen-ethyl (maize/ corn)
Conversion factor from enforcement to RA	CF = 1*

N/A: not applicable

* For isoxadifen, the conversion for molecular weights is neglected (Molecular weight of isoxadifen-ethyl = 294.4 g/mole and molecular weight of isoxadifen = 267.3 g/mole)

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

Available data: Germany, 2002; Austria, 2006

No new data are submitted in the framework of this application. The corresponding data are summarised in the Annex II dossier for isoxadifen-ethyl and were evaluated by Germany in 2002 and evaluated by Austria in 2006.

Table 7.4-7: 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	Lactating cow	[phenyl-UL- ¹⁴ C] – isoxadifen-ethyl	1 cow	0.323 (corresponding to 160.66 mg a.s./day, or to 11.52 mg a.s./kg DM feed/day)	7 days	Urine, faeces	Daily	EU peer reviewed Germany, 2002* Austria, 2006**
						Milk	Twice daily	
						Blood	Twice daily after day 1	
						Liver, kidney, heart, lungs, fat (renal, subcutaneous and omental), muscle (psoas, loin and hindquarter), rumen, abomasal fluid, bile	At necropsy	
Laying poultry	Hens	[phenyl-UL- ¹⁴ C] – isoxadifen-ethyl	6 hens	0.826 (corresponding to 1.59 mg a.s./day or 11.20 mg a.s./kg DM feed/day)	14 days	Excreta	Daily	EU peer-reviewed Germany, 2002* Austria, 2006**
						Cage wash	Daily	
						Eggs	Twice daily	
						Liver, fat (renal and subcutaneous), skin, skeletal muscle, undeveloped eggs	At necropsy	

* EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl M-263999-01-1)

** AGES Evaluation of Laudis – 2006 – Document AGES 2127/06

Summary of animal metabolism studies reported in the EU

EU peer-reviewed Germany 2002:

“Six laying hens were orally dosed with [U-¹⁴C-phenyl]-AE F122006 for 14 consecutive days with a mean daily dose of 1.59 mg per bird per day, equivalent to approximately 11 mg/kg in the diet.

In egg yolks and whites, isoxadifen-ethyl residues were detectable 72 hours after the initial dose, with the concentration of the residues in the yolks reaching a plateau of 0.017 ± 0.004 µg equivalents/g by day 7 of dosing. The concentration of residues in the egg whites were an order of magnitude lower.

The levels of radioactive residues in the hen tissues at necropsy were low with the highest concentration being found in the muscle (0.213 µg/g). The residues in the skin and fat samples were an order of magnitude lower.

In all tissues analysed, the major component of the residue was the free acid AE F129431 (5,5-diphenyl-2-isoxazoline-3-carboxylic acid). There were small amounts of the parent compound in the yolks, liver, muscle and excreta whilst the hydroxylation product AE F162241 (5-(4-hydroxyphenyl)-5-phenyl-2-isoxazoline-3-carboxylic acid) was only detected in the yolks, liver and excreta.

Following the first dose of isoxadifen-ethyl, elimination was rapid with 77% of the radioactivity being excreted within 24 hours. The mean overall daily recovery was 86.74% over the 14-day study period. The metabolic profile in the excreta was similar to that seen in the rat with the major metabolites present being AE F129431 together with lesser amounts of AE F162241.”

“A dairy cow was orally dosed with [U-¹⁴C-phenyl] isoxadifen-ethyl for 7 consecutive days with a mean daily dose of 160.66 mg, equivalent to 11.52 mg/kg in the diet.

Residues of isoxadifen-ethyl were detectable in the milk by 24 hours after the first dose but remained at extremely low concentrations (0.001 µg equivalents/g) throughout the study. Levels of radioactive residues in the edible tissues of the cow at necropsy were generally low, the highest residue levels were found in the kidney (0.147 µg equivalents/g) followed by the heart (0.083 µg equivalents/g). The residue levels in the muscle were the lowest at 0.004 µg equivalents/g (psoas) and 0.003 µg equivalents/g (loin and hindquarters).

AE F129431 (5,5-diphenyl-2-isoxazoline-3-carboxylic acid) was the only metabolite identified in the liver, kidney and heart, and was the main metabolite in the fat samples and the minor metabolite in milk. Unchanged isoxadifen-ethyl was only observed in the fat tissues and in the milk where it was the main residue present.

The mean daily recovery of the dosed isoxadifen-ethyl was 22.7% in the faeces and 24.6% in the urine, giving total daily recovery of 47.3% in the excreta. The free acid AE F129431 was found to account for over 98% of the radioactivity in the urine.”

Pigs:

EU peer-reviewed Germany 2002:

“The metabolism studies in rats, ruminants and poultry did not indicate significant differences in the nature and distribution of residues in the three species. Therefore studies on metabolism, distribution and expression of residues in pigs are not required.”

Nature of residue in fish

No metabolism study or feeding study in fish was conducted.

In document SANCO/11187/2013 (31 January 2013 rev. 3) it is stated:

The potential of pesticide residues to accumulate in fish tissue is determined to a significant extent by the lipophilicity of the active substance (expressed as the n-octanol-water partition coefficient, P_{ow}). The accumulation of compounds of relatively low lipophilicity ($\log P_{ow} < 3$) via the diet is known to be negligible as far as reported residues in fish are taken into account. Fish metabolism studies are therefore required only for active substances where the $\log P_{ow}$ is greater than or equal to three.

The octanol-water partition coefficient of isoxadifen-ethyl ($\log P_{ow} = 3.8$) exceeds the trigger value of 3 but isoxadifen-ethyl is rapidly decomposed in environmental matrices, resulting in products of high polarity.

The half-life of isoxadifen-ethyl ranges from <0.1 days to 3.6 days in soil, or from 0.2 to 1.5 days in water/sediment systems. The abiotic hydrolysis DT_{50} at pH 7 was 2.3 days. The predominant breakdown product is the carboxylic acid AE F129431, $\log P_{ow}$ of which ranges from -0.18 (pH 4) to -1.77 (pH 10).

As isoxadifen-ethyl is applied at a very early stage no residues of the active ingredient are to be expected in any commodity used as fish feed. Consequently, the $\log P_{ow}$ of the residues of isoxadifen-ethyl in

fish feed is far below 3 and a metabolism study in fish is not needed.

Conclusion on metabolism in livestock

Sufficient data have been provided to acknowledge the metabolism of isoxadifen-ethyl in ruminant and poultry which indicate that significant residues may not occur in food of animal origin after use of the safener isoxadifen-ethyl at exaggerated rates. Therefore, a residue definition in animal commodities is not needed since residues of isoxadifen-ethyl are not anticipated in food of animal origin.

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

Table 7.4-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Ruminants
	Poultry
Time needed to reach a plateau concentration	24 h in milk*
	7 days for egg yolk, not applicable for egg white**
Animal residue definition for monitoring	N/A
Animal residue definition for risk assessment	N/A
Conversion factor	N/A
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

* Residue levels in milk did not rise above 0.001 mg equivalents AE F122006/kg throughout the study which lasted 7 days

** The maximum concentration in egg whites of 0.002 mg equivalents/kg tissue was seen on day 3 and 14 only.

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

This is not applicable as isoxadifen-ethyl is a safener.

7.4.3.2 Conclusion on the magnitude of residues in plants

This is not applicable as isoxadifen-ethyl is a safener.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

In the following, the animal dietary burdens are estimated considering the European diet in the OECD feedstuff tables and OECD approaches presented in the Guidance Document on Residues in Livestock, No. 73. Only maize grain was considered as feed item. The input values considered in the dietary burden calculation are summarised below and the livestock dietary intakes are given in the following table.

Table 7.4-9: Input values for the dietary burden calculation (considering all the uses authorized in the EU and Import tolerances), Art. 12 procedure is not yet implemented

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of isoxadifen-ethyl and isoxadifen, expressed as isoxadifen-ethyl				
Maize grain	0.02	STMR (Germany, 2002)*	0.02	HR (Germany, 2002)*

* EU peer-reviewed, Germany, 2002 (Summary of the German national evaluation of the safener - isoxadifen-ethyl M-263999-01-1)

Table 7.4-10: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.001	0.001	0.03	0.03	Dairy cattle	Corn, field	gluten feed	No
Cattle (dairy only)	0.001	0.001	0.02	0.02	Dairy cattle	Corn, field	gluten feed	No
Sheep (all diets)	0.001	0.001	0.02	0.02	Lamb	Corn, field	gluten feed	No
Sheep (ewe only)	0.001	0.001	0.02	0.02	Ram/Ewe	Corn, field	gluten feed	No
Swine (all diets)	0.001	0.001	0.02	0.02	Swine (finishing)	Corn, field	milled bypds	No
Poultry (all diets)	0.002	0.002	0.02	0.02	Turkey	Corn, field	milled bypds	No
Poultry (layer only)	0.002	0.002	0.02	0.02	Poultry layer	Corn, field	milled bypds	No

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

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data: Germany, 2002; Austria, 2006

Since the calculated dietary burdens for all types of livestock were found to be below the trigger value of 0.004 mg/kg bw/day, further investigation on the nature of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

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

Conclusion on feeding studies

The requested uses do not modify the theoretical maximum daily intake for livestock and there is no risk for livestock commodity MRL to be exceeded.

Conclusion on feeding studies

Livestock feeding studies are considered not necessary. It is also not necessary to set MRLs in food of animal origin.

7.4.5 Magnitude of residues in processed commodities (industrial processing and/or household preparation) (KCA 6.5.2-6.5.3)

As stated in the German evaluation of 2002 and in AGES evaluation of Laudis from 2006 – Document AGES 2127/06, investigations of the effect of industrial and/or household processing are not obligatory in view of the very low residues in maize grains which are not expected to be higher than 0.01 mg/kg.

No studies were submitted and no studies are required.

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

Investigations of the effect of industrial and/or household processing were not conducted and are not obligatory in view of the very low residues in maize grains.

7.4.6 Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application.

7.4.6.1 Field rotational crop studies (KCA 6.6.2)

Available data: Germany, 2002

As stated in the German evaluation of 2002, “studies on the behaviour in soil did not indicate that significant residues of isoxadifen-ethyl and/or its metabolites and degradation products might remain in soil or in plant material up to the sowing or planting of succeeding crops.

Therefore, no residues above the LOQ resulting from soil uptake are to be anticipated and a theoretical consideration of the nature and level of the residue in succeeding crops is not required”.

Metabolism in soil studies showed that less than 10% of isoxadifen-ethyl and metabolites remain in soil after 100 days. Therefore, studies to evaluate the residue behaviour in succeeding crop are not required.

Conclusion on rotational crops studies

Studies to evaluate the residue behaviour in succeeding crop are not required.

7.4.7 Other/ special studies (KCA 6.10, 6.10.1)

The available data for the safener sufficiently address aspects of the residue situation that might arise from the use of GF-3969. 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 Section 7.1.2).

7.4.8.1 Input values for the consumer risk assessment: Isoxadifen-ethyl

In Europe, the safener isoxadifen-ethyl is used only on rice, maize, sweet corn, and poppy. Residues are not anticipated in food of animal origin (2002 German Evaluation). The MRLs proposed here are based on the sum of the LOQ (0.01 mg/kg) of isoxadifen-ethyl and the LOQ (0.01 mg/kg) of isoxadifen, except for sweet corn. The MRL proposed for sweet corn are based on the worst-case scenario for residues of isoxadifen-ethyl (0.05 mg/kg) and isoxadifen (0.05 mg/kg). The proposed national MRLs for isoxadifen-ethyl have not been established for the safener in the EU as it does not fall under the Regulation (EC) 396/2005; the supervised residue trials were used to propose MRLs used solely for risk assessment purposes.

The input values in the following table were used to estimate consumer risk using the EFSA PRIMo (revision 3.1) and UK CRD’s ten consumer model (version 1.1). The dietary models assume there is no dissipation of residues. The acute dietary assessments are performed only for the consumption of commodities for which GAPs are notified (maize).

Table 7.4-11: Input values for the consumer risk assessment: Isoxadifen-ethyl

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: isoxadifen-ethyl, isoxadifen				
Sweet corn	0.10	Sum of LOQs	Acute risk assessment was undertaken only with regard to the crops on the GAP under consideration.	
Poppy seed	0.02			
Rice rain	0.02			
Maize grain	0.02		0.02	Only maize considered for acute risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Honey*	0.02			

* No residues of isoxadifen-ethyl and its metabolite isoxadifen are to be expected in honey since the safener is applied at BBCH 18 and not sprayed in flowering crops. Therefore, honey is only included into the risk assessment for the purpose of completeness since maize is potentially visited by bees for pollen and/or for nectar according to EFSA Journal 2013;11(7):3295.

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

The highest Theoretical Maximum Daily Intake (TMDI) predicted using EFSA PRIMo is 0.5% of the ADI for the NL Toddler. The highest contribution is from maize/corn. In the UK, infants are the most exposed population at 0.1% of the ADI based on EFSA PRIMo exposure estimates. The acute dietary estimates were performed using EFSA PRIMo for the consumption of commodities for which GAPs are notified (maize). The highest International Estimated Short-Term Intake (IESTI) for unprocessed commodities is at 0.03% of the ARfD for the consumption of maize/corn by UK infants, while for processed commodities, the highest IESTI is 0.1% of the ARfD for the consumption of maize/oil by NL toddlers.

Estimates of potential dietary exposure were also calculated using the UK CRD's ten consumer model (version 1.1). The highest predicted total National TMDI (NTMDI) is 1% of the ADI for the UK toddler. The acute dietary assessment performed using the UK model for the consumption of commodities for which GAPs are notified (maize) estimates the highest NESTI to be 1.1% of the ARfD for the consumption of maize by infants.

These estimates indicate that no health effects due to chronic and acute dietary exposure are expected in UK consumers.

Table 7.4-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.5% (based on NL Toddler)
NTMDI (% ADI) according to UK Model	1% (based on UK toddler)
IESTI (% ARfD) according to EFSA PRIMo	Unprocessed Commodities: 0.03% based on consumption of maize/corn by UK Infants Processed Commodities: 0.1% based on consumption of maize/oil by NL Toddler
NESTI (% ARfD) according to UK Model	1.1% based on consumption of maize infants.

The proposed uses of isoxadifen-ethyl as a safener in the formulation GF-3969 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.

The product is a mixture of two active substances (rimsulfuron and thifensulfuron methyl) and a safener (isoxadifen-ethyl). An acute reference dose has been allocated only for one of the active substances (thifensulfuron methyl); therefore, a combined acute exposure is not required.

7.5.1 Acute consumer risk assessment from combined exposure

The product is a mixture of two active substances and a safener, ~~but for only one of them has an acute reference dose been allocated.~~

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.3.1) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.5-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Unprocessed Commodities: Consumption of maize by Children	Thifensulfuron methyl	0.0001
	Rimsulfuron	0.00004
	Isoxadifen-ethyl	0.0003
	Cumulative risk (HI)	0.0004 0.00044
Processed Commodities: Consumption of maize/oil by Children	Thifensulfuron methyl	0.0001
	Rimsulfuron	0.0001
	Isoxadifen-ethyl	0.0010
	Cumulative risk (HI)	0.001 0.0012

The Hazard Index is <1. Thus combined exposure to all active substances in GF-3969 is not expected to present a consumer risk. No further refinement of the assessment is required.

7.5.2 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.

Chronic intake calculations for rimsulfuron show a maximum exposure of 2% of the ADI. Chronic intake calculations for thifensulfuron methyl show a maximum exposure of 12% of the ADI. These low exposures indicate that any interaction between the active substances resulting in a unique or greater toxicological response is highly unlikely.

zRMS comments:

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

7.6 References

AGES Evaluation of Laudis – 2006 – Document AGES 2127/06. Austria 2006.

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

EFSA (European Food Safety Authority), 2015. Conclusion regarding the peer review of the pesticide risk assessment of the active substance thifensulfuron methyl, EFSA Scientific Report (2015) 13(7):4201.

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007.

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

EFSA (European Food Safety Authority), 2012b. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thifensulfuron methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(8):2863.

EFSA (European Food Safety Authority), 2017. Peer review of the pesticide risk assessment of the active substance tribenuron-methyl. EFSA Journal 2017;15(7):4912

Germany, 2002. Summary of the German national evaluation of the safener isoxadifen-ethyl.

Germany, 2005. Draft Assessment Report (DAR). Initial risk assessment provided by the Rapporteur Member State Germany for the existing active substance rimsulfuron of the second stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC, Volume 3, Annex B.7, July 2005.

Slovenia, 2018. Renewal Assessment Report under Regulation (EC) 1107/2009: Rimsulfuron. February 2018.

United Kingdom, 2014. Thifensulfuron-methyl: Report and proposed decision of the United Kingdom made to the European Commission under Regulation 1141/2010 for first renewal of approval. July 2014 (updated March 2015)

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on – all documents

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCA, 6.3.1/01	Spence, C.	2020	Magnitude of residues in/on maize following foliar application of DPX-TNS43, a blend of paste extruded granules (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG Active)-EU, initiated 2017 DuPont-49732 Charles River Laboratories (UK) GLP: Yes Published: No	N	DuPont	Y

List of data submitted by the applicant and relied on – vertebrate studies

No vertebrate studies submitted

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

No studies previously submitted and relied upon

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

No studies previously submitted and relied upon

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

Unless specifically indicated, all reports in this section are submitted to address mandatory data requirements for the approval of the plant protection product.

A 2.1 Rimsulfuron

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new or additional studies have been submitted

A 2.1.1.1.2 Storage stability of residues in animal products

No new or additional studies have been submitted

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new or additional studies have been submitted

A 2.1.2.1.2 Nature of residue in rotational crops

No new or additional studies have been submitted

A 2.1.2.1.3 Nature of residues in processed commodities

No new or additional studies have been submitted

A 2.1.2.2 Nature of residues in livestock

No new or additional studies have been submitted

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Maize

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Germany, 2005)	1-2	5-20 g a.s./ha	n.a.	BBCH 18	n.a.
cGAP EU (Art. 12, EFSA, 2012a)	1-2	20 g a.s./ha	7	BBCH 18 (S-EU) BBCH 16 (N-EU)	n.a.
Intended cGAP* (1)	1	rimsulfuron 20 g a.s./ha	n.a.	BBCH 18	n.a.
Intended cGAP* (14)	1-2	rimsulfuron ** 20 g a.s./ha	7	BBCH 18	n.a.

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

** Split application possible without exceeding the total maximum of 135 g product/ha (20 g rimsulfuron/ha)

n.a.- not applicable

A 2.1.3.1.1 Study 1, DuPont-49732

Comments of zRMS:	<p>The study included six supervised residue trials conducted under field conditions in Northern Europe during the 2017 season and five trials conducted in Southern Europe during the 2017 and 2018 seasons.</p> <p>Northern Europe: This study determined rimsulfuron and thifensulfuron methyl (DPX-E9636 and DPX-M6316) and the metabolites of thifensulfuron methyl (IN-A4098 and IN-L9225) residues in/on maize (cereal crops), following treatment with DPX-TNS43 (a blend of rimsulfuron 25SG/thifensulfuron methyl 50SG/mesotrione 50WG plus isoxadifen-ethyl 50WG (safener; not active)). Trend 90 (0.2% (v/v)) adjuvant was added to the tank mix. One application applied at growth stage BBCH 19 were made at a nominal rate of 20 g ai/ha for rimsulfuron and 15 g ai/ha for thifensulfuron methyl. Treated plots were sampled at 14±1, 28±3, BBCH 83-85 (forage harvest timing for silage production) and at commercial maturity for grain and stover.</p> <p><u>Rimsulfuron</u> residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity. Residues in maize whole plant samples ranged from not detected (<0.003mg/kg) to 0.021 mg/kg at 14±1 DALA.</p> <p><u>Thifensulfuron methyl</u> residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity. Residues in maize whole plant samples ranged from not detected (<0.003mg/kg) to 0.10 mg/kg at 14±1 DALA.</p> <p><u>IN-L9225</u> residues are low in field-grown maize forage values ranging from detectable at LOD (0.003 mg/kg) to 0.012 mg/kg at 14±1 DALA. IN L9225 residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.</p> <p><u>IN-A4098</u> residues were not detected in any field-grown maize whole plant, forage/silage, stover or grain samples taken at maturity.</p> <p>No residues above the LOQ were found in the control specimens. Specimens were analyzed for residues of rimsulfuron using a method based on DuPont Method No. 13412 Revision 1/Supplement 1. The analysis of thifensulfuron methyl and the metabolites IN-L9225 and IN- A4098 was performed using a method based on DuPont Method No. DuPont-28527. The determined Limit of Quantification (LOQ) was 0.010 mg/kg for both active substances and metabolites. The maximum storage interval from sampling to extraction was 14 months. The residue data are valid with regard to storage stability. The study is acceptable.</p> <p><u>Remark:</u> In SANTE/2019/12752 it is stated that „Residue field trials need to be performed at different geographical sites/locations to reflect the variability in production system, soil conditions and/or weather conditions. The different sites must be at least 20 km far from one another.” Therefore the trials conducted in England and separated by at least 100 km from each other can be considered as independent trials.</p>
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Reference:	KCA 6.3.1/01
Report:	Spence, C., (2020); Magnitude of residues in/on maize following foliar application of DPX-TNS43, a blend of paste extruded granules (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG Active)-EU, initiated 2017
DuPont Report No.:	DuPont-49732
Testing Facility Report No.:	682133
Guidelines	OECD 509 (2009), SANCO/3029/99
Deviations:	None
GLP:	Yes
Acceptability:	Yes

I. MATERIALS AND METHODS

A blend formulation of rimsulfuron, DPX-TNS43 (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG + 4.55% Isoxadifen ethyl 50WG safener), was used for these trials. DPX-TNS43 is no longer under development. No further information is supplied related to mesotrione and isoxadifen, as they are not relevant to the proposed rimsulfuron registration.

This study determined rimsulfuron and thifensulfuron methyl (DPX-E9636 and DPX-M6316) and the metabolites of thifensulfuron methyl (IN-A4098 and IN-L9225) residues in/on maize (cereal crops), in Europe following treatment with DPX-TNS43 (a blend of rimsulfuron 25SG/thifensulfuron methyl 50SG/mesotrione 50WG plus isoxadifen-ethyl 50WG (safener; not active)). The number, location, test type and test system (maize with the variety being common of the representative growing areas) per growing season used in this study are given as follows.

Growing season	Test No.	Regulatory Region	Country	Location, Region	Test Type ^a	Crop/Variety ^b
2017	1	Northern EU	UK, England	Lincoln, Lincolnshire	MOR	Maize / Beethoven
2017	2	Northern EU	UK, England	Leeds, West Yorkshire	MOR	Maize / Ambrosini
2017	5	Northern EU	Germany	Babenhhausen, Hessen	MOR	Maize / Scenic
2017	7	Northern EU	Poland	Urbanowice, Opole	MOR	Maize / Valterinio
2017	8	Northern EU	The Netherlands	Groesbeek, Gelderland	MOR	Maize / Liberator
2017	9	Northern EU	Hungary	Kiskunlacháza, Közép-Magyarország	MOR	Maize / LG 34.75
2018	11	Southern EU	South France	Charantonnay, Auvergne-Rhône-Alpes	MOR	Maize / DK4079
2017	14	Southern EU	North Spain	Bellví, Catalunya	MOR	Maize / ES Flato
2018	15	Southern EU	Italy	Graffignana, Lombardia	MOR	Maize / P1921
2017	17	Southern EU	Greece	Paleos Milotopos, Central Macedonia	MOR	Maize / DKC 6728
2017	18	Southern EU	Greece	Nae Magnisia, Central Macedonia	MOR	Maize / DKC 7050

a MOR = magnitude of residue (one treatment plot for all sampling intervals)

b Varieties used were common of the representative growing areas

Note: Trials 3, 4, 6, 10, 12, 13 and 16 were terminated and will not be reported. Trial 13 was terminated as the trial was lost due to co-operator error. The study was designed with 18 trials being commissioned (9 in the northern residue zone; 9 in the southern residue zone), with as many as possible being started in 2017 and the remainder to be conducted in 2018. Six northern residue zone trials were completed from the 2017 season, a sufficient number to meet the required number of trials for the northern residue zone. There was no need for the 2018 northern residue zone trials. No samples from Trials 3, 4 or 6 were analysed. All data have been retained but none from trials not required / analysed have been reported. For the southern residue zone, three trials were completed from the 2017 season in the southern zone (Spain; 2 in Greece). Two 2018 trials were selected for completion to meet the required number of southern residue zone trials. The remaining southern residue zone trials were not completed. Two trials were selected from the 5 trials performed in

2018. The trials selected give the study the best geographical spread as well as the shortest pre-harvest intervals (PHI). The PHIs for South Spain (Trial 10) and South France (Trial 11) are only 1 day apart, therefore Trial 11 was completed as a new location not already analysed and containing a short PHI. The final trial to be completed was selected from the two trials conducted in Italy to give the study the best representative geographical spread. Trial 15 was completed instead of Trial 16 as Trial 15 has a shorter PHI. No samples from Trials 10, 12 and 16 were analysed.

This was the targeted design of each type of test conducted.

Test Type ^a	Formulation	Number of Appl ^b	Rate per Appl (g a.s./ha)	RTI ^c (days)	Spray Conc (g a.s./hL)	Spray Volume (L/ha)	DALA ^d
2017							
MOR	DPX-TNS43 blend	1	137.5*	na	na	100-400	Whole plant: 14±1, 28±3, Silage / Forage at BBCH 83-85, and Stover/ Grain at Commercial Maturity
2018							
MOR	DPX-TNSnd43 blend	1	137.5*	na	na	100-400	Silage / Forage at BBCH 83-85 and Stover/ Grain at Commercial Maturity

a MOR = magnitude of residue (one treatment plot for all sampling intervals)

b Application A1 targeted at BBCH 19

c RTI = retreatment interval (days)

d DALA = Days After Last Application corresponding to sampling (treated plot)

* 102.5 g mesotrione a.s./ha + 20 g rimsulfuron a.s./ha + 15 g thifensulfuron methyl a.s./ha

na = not applicable

The use patterns are described below.

Table A 2: Study use pattern

Test Identification (City, Region, Country, Year, Zone)	EP ^a	Method/ Timing	Vol (L/ha)	Application ^c		RTT ^b Days	Total Rate (g a.s./ha)	Tank Mix Adjuvants
				g a.s./ha	g a.s./hL			
Test 01 Lincoln , Lincolnshire UK, England 2017 (NEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	304	Mesotrione: 103.95 Rimsulfuron: 20.33 Thifensulfuron methyl: 14.94 Isoxadifen-ethyl: 7.56	Mesotrione: 34.19 Rimsulfuron: 6.69 Thifensulfuron methyl: 4.91 Isoxadifen-ethyl: 2.49	-	DPX-TNS43 Blend: 139.99	Trend 90 (0.2% v/v)
Test 02 Leeds, West Yorkshire UK, England 2017 (NEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	301	Mesotrione: 102.96 Rimsulfuron: 20.08 Thifensulfuron methyl: 14.94 Isoxadifen-ethyl: 7.56	Mesotrione: 34.21 Rimsulfuron: 6.67 Thifensulfuron methyl: 4.96 Isoxadifen-ethyl: 2.51	-	DPX-TNS43 Blend: 138.74	Trend 90 (0.2% v/v)
Test 05 Babenhausen Hessen Germany 2017 (NEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	297	Mesotrione: 101.48 Rimsulfuron: 19.83 Thifensulfuron methyl: 14.94 Isoxadifen-ethyl: 7.56	Mesotrione: 34.17 Rimsulfuron: 6.68 Thifensulfuron methyl: 5.03 Isoxadifen-ethyl: 2.55	-	DPX-TNS43 Blend: 136.66	Trend 90 (0.2% v/v)

Test Identification (City, Region, Country, Year, Zone)	EP ^a	Application ^c					RTI ^b Days	Total Rate (g a.s./ha)	Tank Mix Adjuvants
		Method/ Timing	Vol (L/ha)	g a.s./ha		g a.s./hL			
Test 07 Urbanowice, Opole, Poland 2017 (NEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	287	Mesotrione: 98.02 Rimsulfuron: 19.09 Thifensulfuron methyl: 14.29 Isoxadifen-ethyl: 7.23	Mesotrione: 34.16 Rimsulfuron: 6.65 Thifensulfuron methyl: 4.98 Isoxadifen-ethyl: 2.52	-	DPX-TNS43 Blend: 131.4	Trend 90 (0.2% v/v)	
Test 08 Groesbeek, Gelderland, The Netherlands 2017 (NEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	313	Mesotrione: 107.0 Rimsulfuron: 20.8 Thifensulfuron methyl: 15.5 Isoxadifen-ethyl: 7.9	Mesotrione: 34.2 Rimsulfuron: 6.7 Thifensulfuron methyl: 5.0 Isoxadifen-ethyl: 2.5	-	DPX-TNS43 Blend: 143.4	Trend 90 (0.2% v/v)	
Test 09 KiskunlacházaKözép- Magyarország Hungary 2017 (NEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	300	Mesotrione: 102.4 Rimsulfuron: 19.83 Thifensulfuron methyl: 14.9 Isoxadifen-ethyl: 7.56	Mesotrione: 34.2 Rimsulfuron: 6.6 Thifensulfuron methyl: 5.0 Isoxadifen-ethyl: 2.5	-	DPX-TNS43 Blend: 137.13	Trend 90 (0.2% v/v)	

Test Identification (City, Region, Country, Year, Zone)	EP ^a	Application ^c					RTI ^b Days	Total Rate (g a.s./ha)	Tank Mix Adjuvants
		Method/ Timing	Vol (L/ha)	g a.s./ha		g a.s./hL			
Test 11 Charantonnay Auvergne- Rhône-Alpes, South France 2018 (SEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	305	Mesotrione: 103.95 Rimsulfuron: 20.33 Thifensulfuron methyl: 15.44 Isoxadifen-ethyl: 7.56	Mesotrione: 34.08 Rimsulfuron: 6.67 Thifensulfuron methyl: 5.06 Isoxadifen-ethyl: 2.48	-	DPX-TNS43 Blend: 140.41	Trend 90 (0.2% v/v)	
Test 14 Bellvis, Catalunya, North Spain 2017 (SEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	292	Mesotrione: 99.50 Rimsulfuron: 19.58 Thifensulfuron methyl: 14.44 Isoxadifen-ethyl: 7.56	Mesotrione: 34.08 Rimsulfuron: 6.71 Thifensulfuron methyl: 4.95 Isoxadifen-ethyl: 2.59	-	DPX-TNS43 Blend: 134.58	Trend 90 (0.2% v/v)	
Test 15 Graffignana, Lombardia, Italy 2018 (SEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	307	Mesotrione: 104.94 Rimsulfuron: 20.33 Thifensulfuron methyl: 15.44 Isoxadifen-ethyl: 7.56	Mesotrione: 34.18 Rimsulfuron: 6.62 Thifensulfuron methyl: 5.03 Isoxadifen-ethyl: 2.46	-	DPX-TNS43 Blend: 141.26	Trend 90 (0.2% v/v)	

Test Identification (City, Region, Country, Year, Zone)	EP ^a	Application ^c					RTI ^b Days	Total Rate (g a.s./ha)	Tank Mix Adjuvants
		Method/ Timing	Vol (L/ha)	g a.s./ha		g a.s./hL			
Test 17 Paeleos Milotopos, Central Macedonia, Greece 2017 (SEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	300.67	Mesotrione: 102.69 Rimsulfuron: 20.00 Thifensulfuron methyl: 15.04 Isoxadifen-ethyl: 7.52	Mesotrione: 34.15 Rimsulfuron: 6.65 Thifensulfuron methyl: 5.00 Isoxadifen-ethyl: 2.5	-	DPX-TNS43 Blend: 137.73	Trend 90 (0.2% v/v)	
Test 18 Nea Magnisia, Central Macedonia, Greece 2017 (SEU)	DPX- TNS43 blend	Foliar Broadcast/ BBCH 19	300.67	Mesotrione: 102.69 Rimsulfuron: 20.00 Thifensulfuron methyl: 15.04 Isoxadifen-ethyl: 7.52	Mesotrione: 34.15 Rimsulfuron: 6.65 Thifensulfuron methyl: 5.00 Isoxadifen-ethyl: 2.5	-	DPX-TNS43 Blend: 137.73	Trend 90 (0.2% v/v)	

a EP = End-use Product

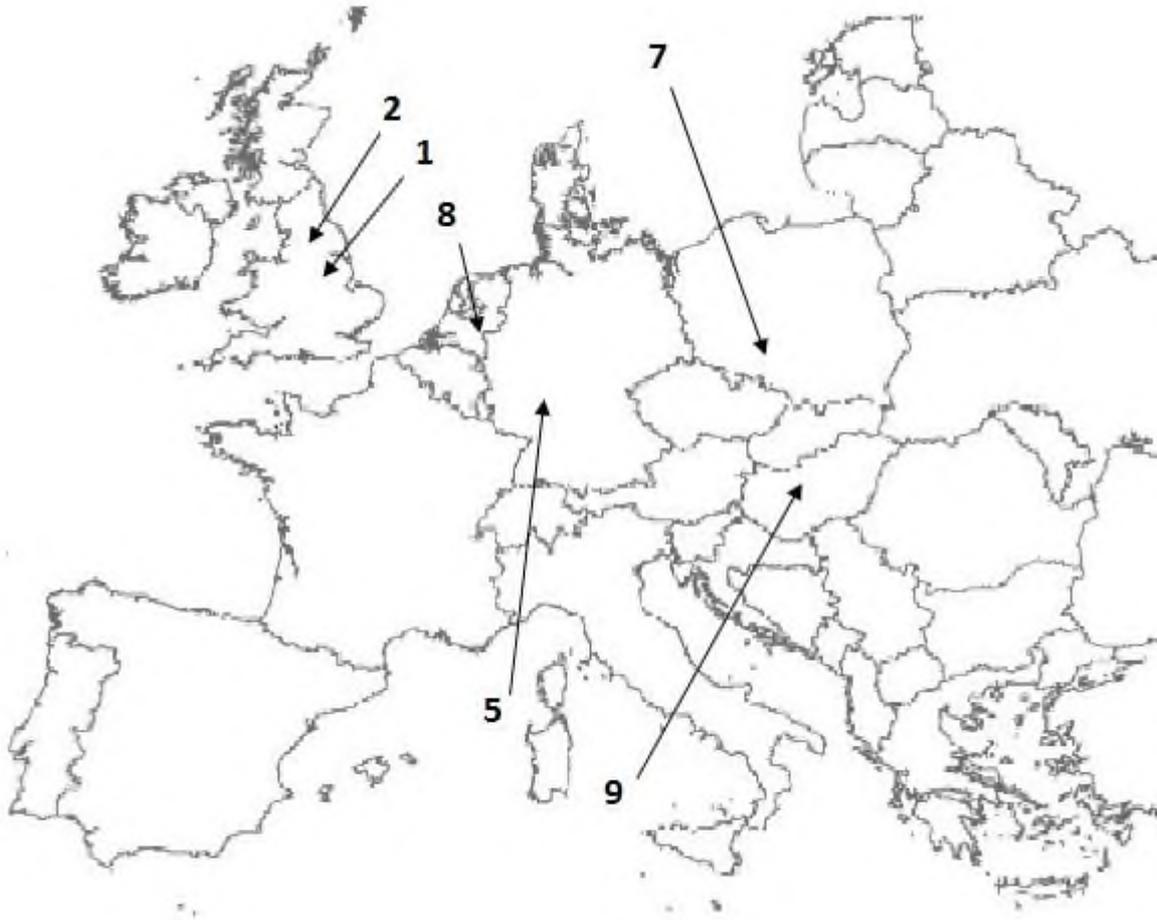
b RTI = Retreatment Interval

c Isoxadifen-ethyl was used as a safener product and not an active ingredient

Note: Trials 3, 4, 6, 10, 12, 13 and 16 were terminated and will not be reported. Please see footnote in Materials and Methods for full details.

A summary of the residue tests conducted is given below. Locations of the test sites are given as follows.

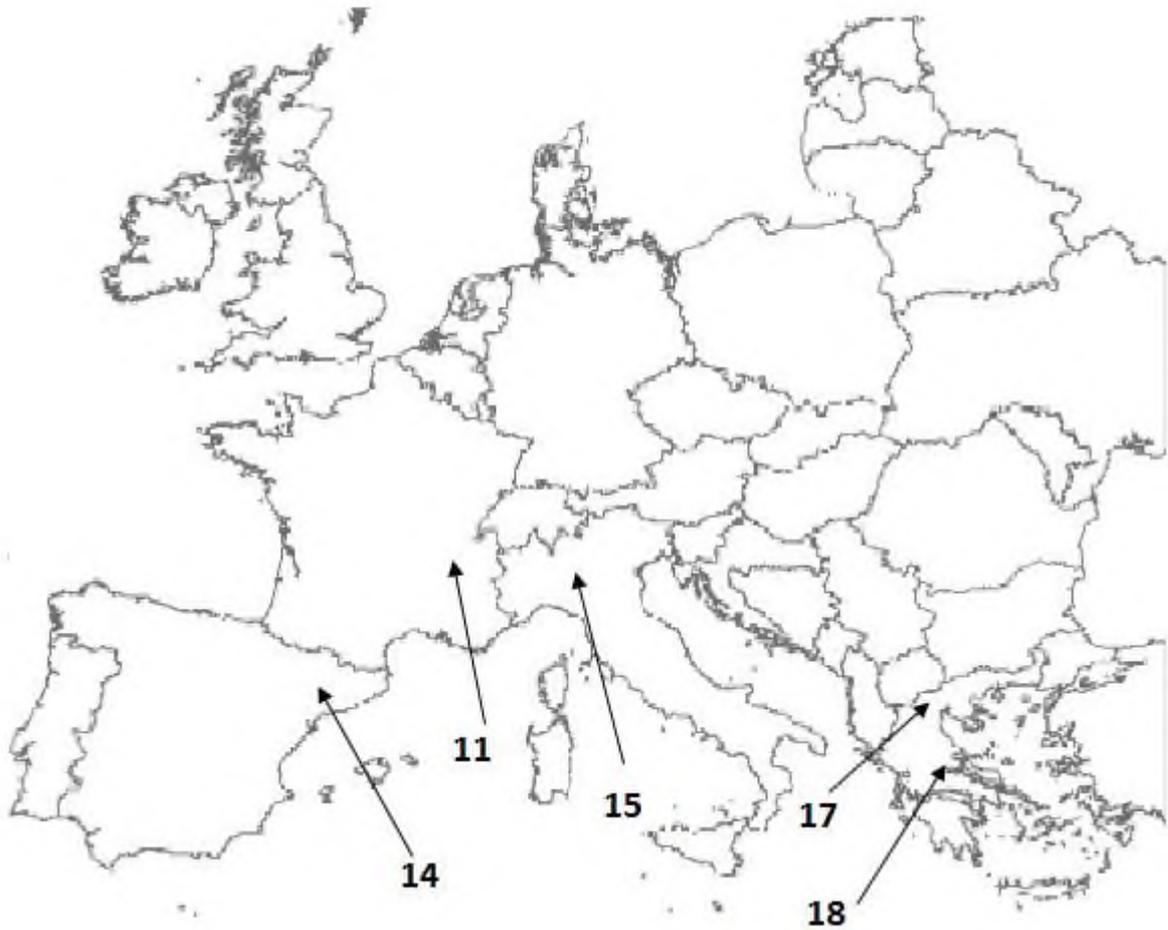
Figure A 1 **Map of European Test Site Locations**



(For illustrative purposes only)

Growing season	Test No.	Country	Location, Region
2017	1	UK, England	Lincoln, Lincolnshire
2017	2	UK, England	Leeds, West Yorkshire
2017	5	Germany	Babenhausen, Hessen
2017	7	Poland	Urbanowice, Opole
2017	8	The Netherlands	Groesbeek, Gelderland
2017	9	Hungary	Kiskunlacháza, Közép-Magyarország

Figure A 1 **Map of European Test Site Locations (continued)**



Growing season	Test No.	Country	Location, Region
2018	11	South France	Charantonnay, Auvergne-Rhône-Alpes
2017	14	Spain	Bellví, Catalunya
2018	15	Italy	Graffignana, Lombardia
2017	17	Greece	Paleos Milotopos, Central Macedonia
2017	18	Greece	Nea Magnisia, Central Macedonia

Note: Trials 3, 4, 6, 10, 12, 13 and 16 were terminated and not reported. Please see footnote in Materials and Methods for full details.

A residue data summary (in mg/kg) is provided below.

To generate these data, the following analysis and recovery information pertains.

Analysis method:

Method ID	DuPont 13412, Revision No. 1/Supplement No. 1 - Multiresidue Analytical Method for the Determination of Sulphonylurea Herbicides in Oily, Watery, Acidic and Dry Crops using SPE Purification and LC-MS/MS Detection
Analyte(s)	Rimsulfuron (DPX-E9636)
Extraction Solvent/Technique	The procedure for the analysis of rimsulfuron in maize samples involved extraction of 10-g samples with 90 mL of acetonitrile/potassium phosphate (pH 7) (75:25, v/v) solution using a homogenizing probe. The extraction process was repeated, and the final volume made up to 200 mL with Acetonitrile.
Cleanup Strategies	Following centrifugation, 10-mL extract aliquots were partitioned with hexane to remove oils and co-extractants. The hexane is removed and discarded and then 5 mL of the remaining extract is evaporated until only aqueous remains. The samples were diluted to 10 mL using water and then purified using SPE ENV cartridges. After loading the cartridges, a 10-mL hexane wash was applied. Rimsulfuron was eluted with ammonium hydroxide in methanol into a centrifuge tube containing ammonium acetate solution. The eluates were evaporated at ~35°C to remove the methanol component and then quantitatively transferred into a clean centrifuge tube using a rinse of 0.5 mL acetonitrile followed by 50 mM ammonium acetate to bring the final volume to 5 mL. The purified extracts were analyzed by LC/MS/MS.
Chromatography	HPLC System: Shimadzu Prominence, Data Acquisition Software: Analyst 1.6.2 for LC/MS/MS Mass Spectrometer: AB Sciex Instruments API5000 Column: Luna 3-µm Phenyl Hexyl, 4.6 mm × 150 mm
Detection	For detection of the analyte, electrospray ionization (ESI) was used in the positive polarity mode. Two parent-to-daughter ion transitions of Rimsulfuron (quantifier 432→182 and confirmatory 432→325) were monitored during LC/MS/MS analysis.
LOQ	0.010 mg/kg

Method ID	DuPont-28527, “Analytical Method for the Determination of Thifensulfuron Methyl and Metabolites in Crops Using LC/MS/MS”
Analyte(s)	Thifensulfuron Methyl (DPX-M6316) and metabolites IN-L9225 and IN-A4098
Extraction Solvent/Technique	The procedure for the analysis of thifensulfuron methyl (DPX-M6316), IN-L9225 and IN-A4098 in maize samples involved extraction with a solution of acetone and water. For all maize samples (whole plant, silage, stover and grain) a 5-mL aliquot of the extract was evaporated to approximately 1-mL and diluted to 10-mL with water.
Cleanup Strategies	The crops extracts were purified using Supelco Envi Chrom-P solid phase extraction cartridges. Aliquots of purified extracts were evaporated under a stream of nitrogen until the volume was less than 1-mL. The extracts were diluted with acetonitrile and water and an aliquot of the extracts was transferred to an auto-sampler vial for LC/MS/MS analysis.
Chromatography	HPLC System: Shimadzu Prominence, Data Acquisition Software: Analyst 1.6.2 for LC/MS/MS Mass Spectrometer: AB Sciex Instruments API5000 Column: Omnisphere C18, 5 µm, 4.6 mm × 150 mm
Detection	For detection of the analyte, electrospray ionization (ESI) was used in the positive polarity mode. Two parent-to-daughter ion transitions of thifensulfuron methyl (quantifier 388→167 and confirmatory 388→141), IN-L9225 (quantifier 374→167 and confirmatory 374→141), and IN-A4098 (quantifier 141→57 and confirmatory 141→85) were monitored during LC/MS/MS analysis.
LOQ	0.010 mg/kg for all analytes

Storage stability:

Treated samples for this study were stored at *ca* -20°C for less than approximately 14 months between sampling and analysis.

Fortified controls were included with each analytical set and the recovery data for concurrent fortifications show good stability for the analytes in sample extracts.

Table A 3: Residue data from maize trials with DPX-TNS43 blend

Test Identification (City, Region, Country, Year/ Zone)	EP ^a	Crop/ Variety	Commodity or Matrix	Total Rate * (g a.s./ha)	DALA ^b /PHI (days)	Residues, ppm (mg/kg) ^c			
						Rimsulfuron	Thifensulfuron methyl	IN-L9225	IN-A4098
1 Lincoln Lincolnshire UK, England 2017 (NEU)	DPX- TNS43 blend*	Maize / Beethoven	Whole Plant	DPX-TNS43 Blend: 139.99 Mesotrione: 103.95 Rimsulfuron: 20.33 Thifensulfuron methyl: 14.94	15	ND	ND	0.003	ND
			Forage/Silage		27	ND	ND	ND	ND
			Stover		119	ND	ND	ND	ND
			Grain		151	ND	ND	ND	ND
2 Leeds West Yorkshire UK, England 2017 (NEU)	DPX- TNS43 blend*	Maize / Ambrosini	Whole Plant	DPX-TNS43 Blend: 138.74 Mesotrione: 102.96 Rimsulfuron: 20.08 Thifensulfuron methyl: 14.94	14	ND	ND	0.009	ND
			Forage/Silage		28	ND	ND	0.004	ND
			Stover		106	ND	ND	ND	ND
			Grain		141	ND	ND	ND	ND
5 Babenhausen Hessen Germany 2017 (NEU)	DPX- TNS43 blend*	Maize / Scenic	Whole Plant	DPX-TNS43 Blend: 136.66 Mesotrione: 101.48 Rimsulfuron: 19.83 Thifensulfuron methyl: 14.94	14	0.021	0.008	0.009	ND
			Forage/Silage		28	ND	ND	ND	ND
			Stover		72	ND	ND	ND	ND
			Grain		120	ND	ND	ND	ND
7 Urbanowice Opole Poland 2017 (NEU)	DPX- TNS43 blend*	Maize / Valterinio	Whole Plant	DPX-TNS43 Blend: 131.4 Mesotrione: 98.02 Rimsulfuron: 19.09 Thifensulfuron methyl: 14.29	13	ND	ND	0.012	ND
			Forage/Silage		28	ND	ND	0.004	ND
			Stover		66	ND	ND	ND	ND
			Grain		105	ND	ND	ND	ND
8 Groesbeek Gelderland The Netherlands 2017 (NEU)	DPX- TNS43 blend*	Maize / Liberator	Whole Plant	DPX-TNS43 Blend: 143.4 Mesotrione: 107.0 Rimsulfuron: 20.8 Thifensulfuron methyl: 15.5	13	ND	ND	0.010	ND
			Forage/Silage		25	ND	ND	0.004	ND
			Stover		83	ND	ND	ND	ND
			Grain		144	ND	ND	ND	ND

Test Identification (City, Region, Country, Year/ Zone)	EP ^a	Crop/ Variety	Commodity or Matrix	Total Rate * (g a.s./ha)	DALA ^b /PHI (days)	Residues, ppm (mg/kg) ^c			
						Rimsulfuron	Thifensulfuron methyl	IN-L9225	IN-A4098
	DPX- TNS43 blend*	Maize / LG 34.75	Whole Plant		15	ND	ND	0.010	ND
			Forage/Silage		28	ND	ND	0.004	ND
			Stover		59	ND	ND	ND	ND
					106	ND	ND	ND	ND

Test Identification (City, Region, Country, Year/ Zone)	EP ^a	Crop/ Variety	Commodity or Matrix	Total Rate * (g a.s./ha)	DALA ^b /PHI (days)	Residues, ppm (mg/kg) ^c			
						Rimsulfuron	Thifensulfuron methyl	IN-L9225	IN-A4098
9 Kiskunlacháza, Közép-Magyarország Hungary 2017 (NEU)			Grain	DPX-TNS43 Blend: 137.13 Mesotrione: 102.4 Rimsulfuron: 19.83 Thifensulfuron methyl:14.9	106	ND	ND	ND	ND
11 Charantonnay Auvergne- Rhône- Alpes South France 2018 (SEU)	DPX- TNS43 blend*	Maize / DK4079	Forage/Silage	DPX-TNS43 Blend: 140.41 Mesotrione: 103.95 Rimsulfuron: 20.33 Thifensulfuron methyl: 15.44	85	ND	ND	ND	ND
			Stover		98	ND	ND	ND	0.004
			Grain		98	ND	ND	ND	ND
14 Bellvis Catalunya North Spain 2017 (SEU)	DPX- TNS43 blend*	Maize / ES Flato	Whole Plant	DPX-TNS43 Blend: 134.58 Mesotrione: 99.50 Rimsulfuron: 19.58 Thifensulfuron methyl: 14.44	14	0.003	ND	0.007	ND
			Forage/Silage		28	ND	ND	ND	ND
			Stover		56	ND	ND	ND	ND
			Grain		111	ND	ND	ND	ND
15 Graffignana Lombardia Italy 2018 (SEU)	DPX- TNS43 blend*	Maize / P1921	Forage/Silage	DPX-TNS43 Blend: 141.26 Mesotrione: 104.94 Rimsulfuron:20.33 Thifensulfuron methyl: 15.44	71	ND	ND	ND	ND
			Stover		104	ND	ND	ND	ND
			Grain		104	ND	ND	ND	ND
17 Paleos Milotopos Central Macedonia Greece 2017 (SEU)	DPX- TNS43 blend*	Maize / DKC 6728	Whole Plant	DPX-TNS43 Blend: 137.73 Mesotrione:102.69 Rimsulfuron:20.00 Thifensulfuron methyl: 15.04	14	ND	ND	0.003	ND
			Forage/Silage		29	ND	ND	ND	ND
			Stover		63	ND	ND	ND	ND
			Grain		90	ND	ND	ND	ND
18 Nea Magnisia Central Macedonia Greece 2017 (SEU)	DPX- TNS43 blend*	Maize / DKC 7050	Whole Plant	DPX-TNS43 Blend: 137.73 Mesotrione: 102.69 Rimsulfuron: 20.00 Thifensulfuron methyl: 15.04	13	0.007	0.010	0.007	ND
			Forage/Silage		28	0.004	0.005	0.004	ND
			Stover		70	ND	ND	ND	ND
			Grain		101	ND	ND	ND	ND ^p
					101	ND	ND	ND	ND

a EP = End-use Product

b DALA = Days after last application (Days between last application and sampling); PHI = Pre-harvest interval

c The designation “ND” is used for treated samples for which the residue was <LOD (below the limit of detection); <0.003 mg/kg. For calculations, one-half LOD (0.0015 mg/kg) was used for samples with no detectable (ND) residues.

- d Values <LOQ (0.005 mg/kg) were generated in the primary quantitation transition however, no peak was detected in the secondary confirmatory transition. Therefore these residues are not considered to be related to the IN-A4098 analyte and no residue is detected.
- * Note: DPX-TNS43 is a blend of Mesotrione 50WG/ Rimsulfuron 25SG/ Thifensulfuron methyl 50SG/ plus Isoxadifen ethyl 50WG (safener; not active) – with the total rate being derived from the three active rates of mesotrione, rimsulfuron and thifensulfuron methyl.

Table A 4: Summary of residue data from maize trials with DPX-TNS43 blend

Commodity	EP ^a	Total Application Rate (g a.s./ha)	DALA/PHI (days)	Residue Levels in ppm (mg/kg)*						
				n ^b	Min. ^b	Max. ^b	HAFT ^b	Median ^b (STMdR)	Mean ^b (STMR)	Std. Dev. ^b
Rimsulfuron										
Maize Whole Plant	DPX-TNS43 blend**	131.4-143.4	13-15	9	ND	0.021	0.021	ND	0.004	0.006
			25-29	9	ND	0.004	0.004	ND	ND	0.001
Maize Forage/Silage		131.4-143.4	56-119	11	ND	ND	ND	ND	ND	NA
Maize Stover			90-151	11	ND	ND	ND	ND	ND	NA
Maize Grain			90-151	11	ND	ND	ND	ND	ND	NA
Thifensulfuron methyl										
Maize Whole Plant	DPX-TNS43 blend**	131.4-143.4	13-15	9	ND	0.01	0.01	ND	0.003	0.003
			25-29	9	ND	0.005	0.005	ND	ND	0.001
Maize Forage/Silage		131.4-143.4	56-119	11	ND	ND	ND	ND	ND	NA
Maize Stover			90-151	11	ND	ND	ND	ND	ND	NA
Maize Grain			90-151	11	ND	ND	ND	ND	ND	NA
IN-L9225										
Maize Whole Plant	DPX-TNS43 blend**	131.4-143.4	13-15	9	0.003	0.012	0.012	0.009	0.008	0.003
			25-29	9	ND	0.004	0.004	0.004	0.003	0.001
Maize Forage/Silage		131.4-143.4	56-119	11	ND	ND	ND	ND	ND	NA
Maize Stover			90-151	11	ND	ND	ND	ND	ND	NA
Maize Grain			90-151	11	ND	ND	ND	ND	ND	NA
IN-A4098										
Maize Whole Plant	DPX-TNS43 blend**	131.4-143.4	13-15	9	ND	ND	ND	ND	ND	NA
			25-29	9	ND	ND	ND	ND	ND	NA
Maize Forage/Silage		131.4-143.4	56-119	11	ND	ND	ND	ND	ND	NA
Maize Stover			90-151	11	ND	0.004	0.004	ND	ND	0.001
Maize Grain			90-151	11	ND	ND	ND	ND	ND	NA

* The designation “ND” is used for treated samples for which the residue was <LOD (below the limit of detection); <0.003 mg/kg. For calculations, one-half LOD (0.0015 mg/kg) was used for samples with no detectable (ND) residues. NA = Not Applicable.

a EP = End-use Product

b N = Number of individual samples,

Min = Minimum individual sample residue,

Max = Maximum individual sample residue,

HAFT = Highest Average residue from one Field Trial (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),

Median = Median of individual sample residues,

Mean = Mean of individual sample residues,

Std Dev = Standard deviation of mean

** Note: DPX-TNS43 is a blend of Mesotrione 50WG/ Rimsulfuron 25SG/ Thifensulfuron methyl 50SG/ plus Isoxadifen ethyl 50WG (safener; not active) – with the total rate being derived from the three active rates of mesotrione, rimsulfuron and thifensulfuron methyl.

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table A 5: Summary of concurrent recoveries of rimsulfuron, thifensulfuron methyl and thifensulfuron methyl metabolites from maize

Analyte	Matrix	Fortification Level in ppm (mg/kg)	Sample Size (n)	Recoveries (%)	Mean \pm std. dev. (RSD) (%)
Rimsulfuron	Maize Whole Plant	0.01	6	94, 96, 91, 88, 89, 77	89 \pm 7 (8)
		0.10	6	101, 102, 99, 93, 80, 87	94 \pm 9 (9)
	Maize Stover	0.01	4*	88, 90, 94, 99	93 \pm 5 (5)
		0.10	4*	97, 99, 76, 93	91 \pm 10 (11)
	Maize Grain	0.01	4*	87, 89, 99, 97	92 \pm 6 (7)
		0.10	4*	86, 88, 63, 100	85 \pm 15 (18)
Thifensulfuron methyl	Maize Whole Plant	0.01	9	94, 80, 84, 82, 76, 72, 72, 105, 99	85 \pm 12 (14)
		0.10	9	84, 87, 89, 88, 82, 86, 80, 108, 101	89 \pm 9 (10)
	Maize Stover	0.01	7	83, 77, 72, 71, 75, 103, 96	82 \pm 13 (15)
		0.10	7	89, 82, 79, 78, 80, 100, 105	88 \pm 11 (12)
	Maize Grain	0.01	7	100, 85, 87, 81, 80, 95, 100	90 \pm 9 (10)
		0.10	7	98, 87, 86, 89, 82, 100, 106	92 \pm 9 (9)
IN-L9225	Maize Whole Plant	0.01	9	86, 76, 74, 84, 80, 79, 77, 94, 95	83 \pm 8 (9)
		0.10	9	84, 84, 90, 84, 85, 86, 85, 114, 107	91 \pm 11 (12)
	Maize Stover	0.01	7	90, 77, 79, 79, 80, 87, 80	82 \pm 5 (6)
		0.10	7	91, 84, 84, 80, 83, 93, 99	87 \pm 7 (8)
	Maize Grain	0.01	7	87, 90, 90, 85, 84, 93, 95	89 \pm 4 (5)
		0.10	7	99, 93, 93, 88, 90, 104, 111	97 \pm 8 (8)
IN-A4098	Maize Whole Plant	0.01	9	86, 81, 74, 93, 97, 98, 96, 89, 88	89 \pm 8 (9)
		0.10	9	83, 90, 81, 87, 78, 91, 85, 104, 105	89 \pm 9 (11)
	Maize Stover	0.01	7	87, 85, 82, 78, 85, 78, 78	82 \pm 4 (5)
		0.10	7	93, 85, 89, 86, 89, 98, 97	91 \pm 5 (6)
	Maize Grain	0.01	7	93, 98, 98, 103, 98, 96, 92	97 \pm 4 (4)
		0.10	7	98, 100, 96, 88, 94, 99, 102	97 \pm 5 (5)

*n <5: This is considered to have no impact on the quality of the overall study as results are within acceptable range. Additionally, maize grain and maize stover (dry commodities) have acceptable combined recoveries (n=8) at both fortification levels.

II. RESULTS AND DISCUSSION

The residue studies presented in the dossier were carried out in the indicated regulatory region(s) and provide data relevant to conditions in those regions.

All of the analytical work associated with the studies was performed at Charles River Laboratories Edinburgh Ltd. All of the analyses were carried out between the following dates, the date that the first field specimen was extracted and the date that the last field specimen was analyzed: 28 Dec 2017 and 16 May 2019.

Northern EU and Southern EU

The magnitude of residue data demonstrate the following:

- Rimsulfuron residues in field-grown maize following foliar application are low and most samples exhibited no detectable residues. Residues in maize whole plant samples ranged from not detected (<0.003 mg/kg) to 0.021 mg/kg at 14 \pm 1 DALA. Rimsulfuron residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28 \pm 3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.
- Thifensulfuron methyl residues in field-grown maize following foliar application are low and most samples exhibited no detectable residues. Residues in maize whole plant samples ranged from not detected (<0.003 mg/kg) to 0.10 mg/kg at 14 \pm 1 DALA. Thifensulfuron methyl residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28 \pm 3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.
- IN-L9225 residues are low in field-grown maize forage values ranging from detectable at LOD (0.003 mg/kg) to 0.012 mg/kg at 14 \pm 1 DALA. IN-L9225 residues were less than LOQ (<0.01

mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.

- IN-A4098 residues were not detected in any field-grown maize whole plant, forage/silage, or grain samples taken at maturity.
- IN-A4098 residues were not detected (<0.003 mg/kg) in stover samples from all trials with the exception of Trial 11. Residues <0.010 mg/kg (ranging from 0.003 mg/kg to 0.004 mg/kg) were detected in both the control and treated specimens from Trial 11.
- As rimsulfuron and thifensulfuron methyl and metabolite residues in field-grown maize are low following foliar applications, no statistically significant decline curves can be calculated.

All sets of data show a consistent residue profile when DPX-TSN43 is applied in accordance with GAP. Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 0.10 mg/kg with rimsulfuron, thifensulfuron methyl, IN-L9225 or IN-A4098 were analyzed concurrently with the treated samples to verify method performance. Recoveries for all analyte/matrix combinations ranged from 63-114%. Mean values (□ standard deviation) per analyte/matrix combination ranged from 85 □ 6% to 97 □ 4% for 8 to 18 fortifications per analyte/matrix combination. Therefore, the analytical methods used perform well for the determination of rimsulfuron, thifensulfuron methyl and metabolites in treated crops.

III. CONCLUSION

Overall consistent residue behaviour was found in Northern EU and Southern EU for application and sampling conducted according to GAP, providing data appropriate for setting tolerances/MRLs.

(Spence, C., 2020)

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new or additional studies have been submitted

A 2.1.5 Magnitude of residues in processed commodities (industrial processing and/or household preparation)

No new or additional studies have been submitted

A 2.1.5.1 Processing studies on a core set of representative processes

No new or additional studies have been submitted

A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted

A 2.1.7 Other/special studies

No new or additional studies have been submitted

A 2.2 Thifensulfuron methyl

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

No new or additional studies have been submitted

A 2.2.1.1.2 Storage stability of residues in animal products

No new or additional studies have been submitted

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

No new or additional studies have been submitted

A 2.2.2.1.2 Nature of residue in rotational crops

No new or additional studies have been submitted

A 2.2.2.1.3 Nature of residues in processed commodities

No new or additional studies have been submitted

A 2.2.2.2 Nature of residues in livestock

No new or additional studies have been submitted

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Maize

Table A 6: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, UK, 2014)	1	15 g a.s./ha	n.a.	BBCH 18	n.a.
cGAP EU (Art. 12, EFSA, 2012b)	1	15 g a.s./ha	n.a.	BBCH 18	n.a.
Intended cGAP* (1)	1	thifensulfuron 12.5 g a.s./ha	n.a.	BBCH 18	n.a.
Intended cGAP* (14)	1-2	thifensulfuron ** 12.5 g a.s./ha	7	BBCH 18	n.a.

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

** Split application possible without exceeding the total maximum of 135 g product/ha (12.5 g thifensulfuron /ha)

n.a.- not applicable

A 2.2.3.1.1 Study 1, DuPont-49732

Comments of zRMS:	<p>The study included six supervised residue trials conducted under field conditions in Northern Europe during the 2017 season and five trials conducted in Southern Europe during the 2017 and 2018 seasons.</p> <p>Northern Europe: This study determined rimsulfuron and thifensulfuron methyl (DPX-E9636 and DPX-M6316) and the metabolites of thifensulfuron methyl (IN-A4098 and IN-L9225) residues in/on maize (cereal crops), following treatment with DPX-TNS43 (a blend of rimsulfuron 25SG/thifensulfuron methyl 50SG/mesotrione 50WG plus isoxadifen-ethyl 50WG (safener; not active)). Trend 90 (0.2% (v/v)) adjuvant was added to the tank mix. One application, applied at growth stage BBCH 19 were made at a nominal rate of 20 g ai/ha for rimsulfuron and 15 g ai/ha for thifensulfuron methyl. Treated plots were sampled at 14±1, 28±3, BBCH 83-85 (forage harvest timing for silage production) and at commercial maturity for grain and stover.</p> <p>Rimsulfuron residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.</p>
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	<p>Residues in maize whole plant samples ranged from not detected (<0.003mg/kg) to 0.021 mg/kg at 14±1 DALA.</p> <p>Thifensulfuron methyl residues were less than LOQ (<0.01 mg/kg) in whole plant samples at 28±3 DALA, in maize forage/silage taken at BBCH 83-85, and in stover or grain samples taken at maturity.</p> <p>Residues in maize whole plant samples ranged from not detected (<0.003mg/kg) to 0.10 mg/kg at 14±1 DALA.</p> <p>No residues above the LOQ were found in the control specimens.</p> <p>Specimens were analyzed for residues of rimsulfuron using a method based on DuPont Method No. 13412 Revision 1/Supplement 1.</p> <p>The analysis of thifensulfuron methyl and the metabolites IN-L9225 and IN- A4098 was performed using a method based on DuPont Method No. DuPont-28527.</p> <p>The determined Limit of Quantification (LOQ) was 0.010 mg/kg for both active substances.</p> <p>The maximum storage interval from sampling to extraction was 14 months. The residue data are valid with regard to storage stability.</p> <p>The study is acceptable.</p> <p><u>Remark:</u> In SANTE/2019/12752 it is stated that „Residue field trials need to be performed at different geographical sites/locations to reflect the variability in production system, soil conditions and/or weather conditions. The different sites must be at least 20 km far from one another.” Therefore the trials conducted in England and separated by at least 100 km from each other can be considered as independent trials.</p>
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Reference:	KCA 6.3.1/01
Report:	Spence, C., (2020); Magnitude of residues in/on maize following foliar application of DPX-TNS43, a blend of paste extruded granules (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG Active)-EU, initiated 2017
DuPont Report No.:	DuPont-49732
Testing Facility Report No.:	682133
Guidelines	OECD 509 (2009), SANCO/3029/99
Deviations:	None
GLP:	Yes
Acceptability:	Yes

The study DuPont-49732 used a formulation containing rimsulfuron and thifensulfuron methyl and the full summary is provided in Section A 2.1.3.1.1 in this document.

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new or additional studies have been submitted

A 2.2.5 Magnitude of residues in processed commodities (industrial processing and/or household preparation)

No new or additional studies have been submitted

A 2.2.5.1 Processing studies on a core set of representative processes

No new or additional studies have been submitted

A 2.2.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted

A 2.2.7 Other/special studies

No new or additional studies have been submitted

A 2.3 Isoxadifen-ethyl (safener)

A 2.3.1 Stability of residues

A 2.3.1.1 Stability of residues during storage of samples

A 2.3.1.1.1 Storage stability of residues in plant products

No new or additional studies have been submitted

A 2.3.1.1.2 Storage stability of residues in animal products

No new or additional studies have been submitted

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

A 2.3.2.1 Nature of residue in plants

A 2.3.2.1.1 Nature of residue in primary crops

No new or additional studies have been submitted

A 2.3.2.1.2 Nature of residue in rotational crops

No new or additional studies have been submitted

A 2.3.2.1.3 Nature of residues in processed commodities

No new or additional studies have been submitted

A 2.3.2.2 Nature of residues in livestock

No new or additional studies have been submitted

A 2.3.3 Magnitude of residues in plants

A 2.3.3.1 Maize

No new or additional studies have been submitted

A 2.3.4 Magnitude of residues in livestock

A 2.3.4.1 Livestock feeding studies

No new or additional studies have been submitted

A 2.3.5 Magnitude of residues in processed commodities (industrial processing and/or household preparation)

No new or additional studies have been submitted

A 2.3.5.1 Processing studies on a core set of representative processes

No new or additional studies have been submitted

A 2.3.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted

A 2.3.7 Other/special studies

No new or additional studies have been submitted

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):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2005	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)

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	No of diets exceeding the ADI : ---			3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
				Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)				
TMDI/IEDI calculation (based on average food consumption)	2%	NL toddler	1.91	1%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn	2%
	1%	UK infant	1.04	0.8%	Milk: Cattle	0.0%	Potatoes	0.0%	Eggs: Chicken	1%
	1.0%	NL child	0.97	0.5%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	1.0%
	0.9%	FR toddler 2 3 yr	0.90	0.6%	Milk: Cattle	0.0%	Apples	0.0%	Wheat	0.9%
	0.9%	DE child	0.87	0.4%	Milk: Cattle	0.1%	Apples	0.0%	Wheat	0.9%
	0.9%	FR child 3 15 yr	0.85	0.5%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots	0.9%
	0.7%	UK toddler	0.69	0.4%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.7%
	0.6%	DK child	0.59	0.3%	Milk: Cattle	0.1%	Rye	0.0%	Swine: Muscle/meat	0.6%
	0.6%	GEMS/Food G11	0.58	0.2%	Milk: Cattle	0.1%	Soybeans	0.0%	Potatoes	0.6%
	0.6%	ES child	0.56	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.6%
	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%
	0.5%	RO general	0.53	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.5%
	0.5%	GEMS/Food G15	0.52	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.5%
	0.5%	DE women 14-50 yr	0.52	0.2%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.5%
	0.5%	GEMS/Food G08	0.52	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Soybeans	0.5%
	0.5%	DE general	0.51	0.2%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.5%
	0.5%	GEMS/Food G10	0.51	0.1%	Milk: Cattle	0.1%	Soybeans	0.0%	Wheat	0.5%
	0.5%	FR infant	0.47	0.3%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.5%
	0.5%	GEMS/Food G06	0.45	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Potatoes	0.5%
	0.4%	NL general	0.43	0.2%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.4%
	0.4%	IE adult	0.42	0.1%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat	0.4%
	0.4%	FI adult	0.35	0.3%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.4%
	0.3%	FR adult	0.30	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat	0.3%
	0.3%	ES adult	0.29	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.3%
	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%
	0.2%	PT general	0.22	0.1%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.2%
	0.2%	UK vegetarian	0.18	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%
	0.2%	UK adult	0.18	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%
0.2%	FI 3 yr	0.18	0.0%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.2%	
0.2%	IT toddler	0.17	0.1%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.2%	
0.1%	FI 6 yr	0.14	0.0%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.1%	
0.1%	IE child	0.12	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	
0.1%	IT adult	0.12	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.1%	
0.1%	PL general	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.1%	

Conclusion:

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

Rimsulfuron – UK Model

Active substance:	Rimsulfuron		ADI:	0.1	mg/kg bw/day		Source:	EFSA 2005				
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TOTAL INTAKE based on 97.5th percentile										
	Adult	Infant	Toddler	4-6 Years	7-10 Years	11-14 Years	15-18 Years	Vegetarian	Elderly (Own Home)	Elderly (Residential)
mg/kg bw/day	0.00046	0.00258	0.00202	0.00127	0.00095	0.00063	0.00055	0.00047	0.00039	0.00052
% of ADI	<1%	3%	2%	1%	<1%	<1%	<1%	<1%	<1%	<1%

Commodity	STMR	P	COMMODITY INTAKES									
	(mg/kg)		(mg/kg bw/day)									
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.02		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.02		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.02		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.02		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Coconuts	0.02		0.00000	0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Hazelnuts	0.02		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.02		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00001	0.00000	L/C
Pistachios	0.02		0.00001	L/C	0.00001	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.02		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Peanuts	0.02		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Apples	0.01		0.00003	0.00008	0.00015	0.00009	0.00008	0.00004	0.00004	0.00003	0.00002	0.00001
Pears	0.01		0.00001	0.00003	0.00007	0.00004	0.00002	0.00002	0.00001	0.00002	0.00002	0.00001
Apricots	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000

Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Salsify	0.01		L/C									
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C								
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.01		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001
Peppers	0.01		0.00000	L/C	0.00001	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Aubergines	0.01		0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Cauliflower	0.01		0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Chinese cabbage	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	L/C
Kohl Rabi	0.01		L/C									
Cress	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01		0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Watercress	0.01		0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C

Chicory	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	0.02		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Beans with pods	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01		0.00000	L/C								
Globe artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01		0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001
Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.02		0.00006	0.00013	0.00014	0.00014	0.00011	0.00008	0.00007	0.00009	0.00006	0.00008
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
dried (instant) Potatoes	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Crisps	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Potato chips	0.01		0.00002	0.00003	0.00006	0.00004	0.00003	0.00003	0.00003	0.00002	0.00002	0.00001
Tea (dried leaves)	0.05		0.00001	0.00004	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Hops (dried 0.25% of beer)	0.05		0.00000	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	0.00000	0.00000
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000

Millet	0.01		L/C	L/C	0.00000	L/C						
Buckwheat	0.01		L/C									
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.02		0.00003	0.00003	0.00006	0.00006	0.00004	0.00003	0.00003	0.00003	0.00003	0.00002
Meat fat	0.02		0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.02		0.00004	0.00008	0.00008	0.00007	0.00006	0.00004	0.00004	0.00001	0.00004	0.00003
All types of kidney	0.02		0.00001	0.00001	0.00003	0.00001	0.00000	0.00000	0.00001	L/C	0.00001	0.00001
All types of Liver	0.05		0.00002	0.00011	0.00012	0.00002	0.00002	0.00003	0.00001	L/C	0.00003	0.00002
Other types of offal	0.05		0.00003	0.00008	0.00011	0.00005	0.00005	0.00005	0.00002	0.00001	0.00004	0.00004
Eggs	0.02		0.00002	0.00009	0.00007	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00003
Milk	0.02		0.00016	0.00195	0.00112	0.00059	0.00036	0.00024	0.00019	0.00019	0.00017	0.00024
Sugar beet	0.01		0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015
Refined sugar	0.01		0.00002	0.00005	0.00008	0.00005	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value \geq 0.000005 is rounded to 0.00001)
 L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Thifensulfuron methyl



European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Thifensulfuron-methyl			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.01	ARID (mg/kg bw):	2
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2015	Year of evaluation:	2015

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI :								Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	12%	NL toddler	1.24	6%	Milk: Cattle	1%	Apples	0.7%	Maize/corn	12%	0.7%
	7%	NL child	0.66	2%	Milk: Cattle	0.8%	Sugar beet roots	0.6%	Apples	7%	0.0%
	6%	DE child	0.64	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	6%	0.0%
	6%	UK infant	0.61	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat	6%	0.1%
	6%	FR toddler 2 3 yr	0.56	3%	Milk: Cattle	0.3%	Apples	0.3%	Wheat	6%	0.0%
	6%	FR child 3 15 yr	0.55	2%	Milk: Cattle	0.5%	Wheat	0.4%	Sugar beet roots	6%	0.0%
	4%	UK toddler	0.45	2%	Milk: Cattle	0.4%	Wheat	0.3%	Potatoes	4%	0.0%
	4%	GEMS/Food G11	0.42	0.8%	Milk: Cattle	0.4%	Potatoes	0.4%	Soyabeans	4%	0.0%
	4%	DK child	0.41	1%	Milk: Cattle	0.6%	Rye	0.4%	Wheat	4%	0.0%
	4%	GEMS/Food G07	0.38	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes	4%	0.0%
	4%	GEMS/Food G06	0.38	0.7%	Wheat	0.4%	Tomatoes	0.2%	Milk: Cattle	4%	0.1%
	4%	GEMS/Food G15	0.38	0.7%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	0.1%
	4%	GEMS/Food G08	0.38	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes	4%	0.0%
	4%	RO general	0.38	1%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	0.1%
	4%	ES child	0.38	1%	Milk: Cattle	0.4%	Wheat	0.3%	Cocoa beans	4%	0.0%
	4%	SE general	0.37	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.4%	Potatoes	4%	0.0%
	4%	DE women 14-50 yr	0.37	1%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Apples	4%	0.0%
	4%	GEMS/Food G10	0.37	0.5%	Milk: Cattle	0.4%	Wheat	0.3%	Soyabeans	4%	0.1%
	4%	DE general	0.36	1%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Apples	4%	0.0%
	4%	FI adult	0.35	3%	Coffee beans	0.1%	Potatoes	0.1%	Rye	4%	0.0%
	3%	IE adult	0.33	0.4%	Milk: Cattle	0.4%	Sweet potatoes	0.2%	Wheat	3%	0.0%
	3%	NL general	0.30	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Potatoes	3%	0.0%
	3%	FR infant	0.29	2%	Milk: Cattle	0.2%	Potatoes	0.2%	Apples	3%	0.0%
	2%	FR adult	0.22	0.4%	Milk: Cattle	0.2%	Wine grapes	0.2%	Wheat	2%	0.0%
	2%	PT general	0.21	0.5%	Potatoes	0.4%	Wheat	0.2%	Wine grapes	2%	0.0%
	2%	ES adult	0.21	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges	2%	0.0%
	2%	FI 3 yr	0.18	0.5%	Potatoes	0.1%	Bananas	0.1%	Wheat	2%	0.0%
	2%	IT toddler	0.16	0.7%	Wheat	0.2%	Other cereals	0.1%	Tomatoes	2%	0.0%
	2%	DK adult	0.16	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	0.0%
	2%	LT adult	0.16	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Apples	2%	0.0%
	1%	UK vegetarian	0.15	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	0.0%
	1%	FI 6 yr	0.14	0.4%	Potatoes	0.1%	Cocoa beans	0.1%	Wheat	1%	0.0%
	1%	UK adult	0.14	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	0.0%
	1%	IT adult	0.12	0.4%	Wheat	0.1%	Tomatoes	0.1%	Apples	1%	0.0%
	1.0%	PL general	0.10	0.3%	Potatoes	0.2%	Apples	0.1%	Tomatoes	1.0%	0.0%
	0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.0%

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

Thifensulfuron methyl – UK model

Active substance:	Thifensulfuron methyl	ADI:	0.01	mg/kg bw/day	Source:	EFSA 2015				
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TOTAL INTAKE based on 97.5th percentile										
	Adult	Infant	Toddler	4-6 Years	7-10 Years	11-14 Years	15-18 Years	Vegetarian	Elderly (Own Home)	Elderly (Residential)
mg/kg bw/day	0.00038	0.00155	0.00140	0.00092	0.00072	0.00048	0.00042	0.00038	0.00029	0.00038
% of ADI	4%	15%	14%	9%	7%	5%	4%	4%	3%	4%

Commodity	STMR	P	COMMODITY INTAKES									
	(mg/kg)		(mg/kg bw/day)									
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hazelnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Peanuts	0.01		0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Apples	0.01		0.00003	0.00008	0.00015	0.00009	0.00008	0.00004	0.00004	0.00003	0.00002	0.00001
Pears	0.01		0.00001	0.00003	0.00007	0.00004	0.00002	0.00002	0.00001	0.00002	0.00002	0.00001

Apricots	0.01	0.00000	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Peaches	0.01	0.00001	0.00001	0.00003	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Plums	0.01	0.00001	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Cherries	0.01	0.00000	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Table grapes	0.01	0.00001	0.00002	0.00005	0.00002	0.00003	0.00001	0.00001	0.00001	0.00002	0.00001	0.00000
Wine grapes	0.01	0.00010	0.00001	0.00001	0.00001	0.00000	0.00001	0.00004	0.00010	0.00007	0.00001	0.00001
Strawberries	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Blackberries	0.01	0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Loganberries	0.01	0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Raspberries	0.01	0.00000	L/C	0.00002	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Gooseberries	0.01	0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Blackcurrants	0.01	0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00000
Red currants	0.01	0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
White currants	0.01	L/C										
Avocados	0.01	0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	0.00001	L/C
Bananas	0.01	0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002	0.00002
Dates	0.01	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000	0.00000
Figs	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01	0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000
Lychees	0.01	0.00000	L/C									
Mangoes	0.01	0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	0.00000	L/C
Olives	0.01	0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	0.00000	L/C
Passion fruit	0.01	0.00000	L/C	0.00000	L/C	L/C						
Pineapples	0.01	0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001	0.00001
Beetroot	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.01	0.00001	0.00004	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Celeriac	0.01	0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C	L/C

Horseradish	0.01		0.00000	L/C	0.00000	L/C						
Jerusalem artichokes	0.01		0.00000	L/C								
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Salsify	0.01		L/C									
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C								
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.01		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001
Peppers	0.01		0.00000	L/C	0.00001	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Aubergines	0.01		0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Cauliflower	0.01		0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Chinese cabbage	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	L/C
Kohl Rabi	0.01		L/C									
Cress	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01		0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000

Spinach	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Watercress	0.01	0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	0.02	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Beans with pods	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01	0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01	0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01	0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01	0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01	0.00000	L/C								
Globe artichokes	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01	0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01	0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001
Lentils	0.01	0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01	0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.01	0.00003	0.00006	0.00007	0.00007	0.00006	0.00004	0.00004	0.00005	0.00003	0.00004
Potatoes	0.01	0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
dried (instant) Potatoes	0.01	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Crisps	0.01	0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Potato chips	0.01	0.00002	0.00003	0.00006	0.00004	0.00003	0.00003	0.00003	0.00002	0.00002	0.00001
Tea (dried leaves)	0.05	0.00001	0.00004	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Hops (dried 0.25% of beer)	0.05	0.00000	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	0.00000	0.00000

Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Millet	0.01		L/C	L/C	0.00000	L/C						
Buckwheat	0.01		L/C									
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.01		0.00002	0.00002	0.00003	0.00003	0.00002	0.00002	0.00002	0.00002	0.00002	0.00001
Meat fat	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.01		0.00002	0.00004	0.00004	0.00003	0.00003	0.00002	0.00002	0.00000	0.00002	0.00002
All types of kidney	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0.01		0.00000	0.00002	0.00002	0.00000	0.00000	0.00001	0.00000	L/C	0.00001	0.00000
Other types of offal	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001
Eggs	0.01		0.00001	0.00005	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Milk	0.01		0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012
Sugar beet	0.01		0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015
Refined sugar	0.01		0.00002	0.00005	0.00008	0.00005	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002

Isoxadifen-ethyl



Isoxadifen-ethyl			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.03	ARID (mg/kg bw):	0.5
Source of ADI:	German	Source of ARID:	German
Year of evaluation:	2002	Year of evaluation:	2002

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI : ---						Exposure resulting from			
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	0.5%	NL toddler	0.16	0.5%	Maize/corn	0.0%	Rice	0.0%	Sweet corn		0.5%
	0.2%	GEMS/Food G10	0.06	0.1%	Rice	0.1%	Sweet corn	0.0%	Maize/corn		0.0%
	0.2%	GEMS/Food G06	0.06	0.1%	Rice	0.1%	Maize/corn	0.0%	Sweet corn		0.1%
	0.1%	UK infant	0.04	0.1%	Maize/corn	0.0%	Rice	0.0%	Sweet corn		0.1%
	0.1%	GEMS/Food G15	0.03	0.0%	Sweet corn	0.0%	Maize/corn	0.0%	Rice		0.0%
	0.1%	GEMS/Food G07	0.03	0.1%	Sweet corn	0.0%	Rice	0.0%	Maize/corn		0.0%
	0.1%	FR child 3 15 yr	0.03	0.0%	Rice	0.0%	Maize/corn	0.0%	Sweet corn		0.0%
	0.1%	PT general	0.03	0.1%	Rice	0.0%	Maize/corn	0.0%			0.0%
	0.1%	RO general	0.02	0.1%	Maize/corn	0.0%	Rice	0.0%	Honey and other apiculture products		0.1%
	0.1%	IE adult	0.02	0.1%	Sweet corn	0.0%	Rice	0.0%	Maize/corn		0.0%
	0.1%	GEMS/Food G08	0.02	0.0%	Maize/corn	0.0%	Sweet corn	0.0%	Rice		0.0%
	0.1%	DE child	0.02	0.0%	Sweet corn	0.0%	Rice	0.0%	Maize/corn		0.0%
	0.1%	UK toddler	0.02	0.0%	Rice	0.0%	Sweet corn	0.0%	Honey and other apiculture products		0.0%
	0.1%	FI 3 yr	0.02	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.1%	FR toddler 2 3 yr	0.02	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.1%	SE general	0.02	0.0%	Sweet corn	0.0%	Rice	0.0%	Honey and other apiculture products		0.0%
	0.1%	ES child	0.02	0.0%	Rice	0.0%	Maize/corn	0.0%	Honey and other apiculture products		0.0%
	0.0%	UK vegetarian	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	GEMS/Food G11	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	DK child	0.01	0.0%	Sweet corn	0.0%	Rice	0.0%	Maize/corn		0.0%
	0.0%	FI 6 yr	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	UK adult	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Honey and other apiculture products		0.0%
	0.0%	NL child	0.01	0.0%	Maize/corn	0.0%	Rice	0.0%	Sweet corn		0.0%
	0.0%	IE child	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Honey and other apiculture products		0.0%
	0.0%	ES adult	0.01	0.0%	Rice	0.0%	Maize/corn	0.0%	Honey and other apiculture products		0.0%
	0.0%	IT toddler	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	NL general	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Sweet corn		0.0%
	0.0%	FR adult	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	IT adult	0.01	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	LT adult	0.00	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	DE women 14-50 yr	0.00	0.0%	Sweet corn	0.0%	Maize/corn	0.0%	Honey and other apiculture products		0.0%
	0.0%	FI adult	0.00	0.0%	Rice	0.0%	Sweet corn	0.0%	Maize/corn		0.0%
	0.0%	DE general	0.00	0.0%	Sweet corn	0.0%	Maize/corn	0.0%	Honey and other apiculture products		0.0%
	0.0%	FR infant	0.00	0.0%	Rice	0.0%	Maize/corn	0.0%	Sweet corn		0.0%
	0.0%	DK adult	0.00	0.0%	Rice	0.0%	Sweet corn	0.0%			0.0%
	0.0%	PL general	0.00	0.0%	Maize/corn	0.0%	Poppy seeds				0.0%

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

Isoxadifen-ethyl – UK Model

Active substance:	Isoxadifen-ethyl	ADI:	0.03	mg/kg bw/day	Source:	German 2002 Austria 2006
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TOTAL INTAKE based on 97.5th percentile										
	Adult	Infant	Toddler	4-6 Years	7-10 Years	11-14 Years	15-18 Years	Vegetarian	Elderly (Own Home)	Elderly (Residential)
mg/kg bw/day	0.00010	0.00021	0.00032	0.00018	0.00022	0.00013	0.00012	0.00010	0.00011	0.00004
% of ADI	<1%	<1%	1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%

Commodity	STMR	P	COMMODITY INTAKES									
	(mg/kg)		(mg/kg bw/day)									
Sweet corn	0.1		0.00005	0.00010	0.00023	0.00011	0.00012	0.00005	0.00006	0.00006	0.00008	0.00003
Maize	0.02		0.00000	0.00009	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Rice	0.02		0.00005	0.00006	0.00009	0.00007	0.00010	0.00008	0.00005	0.00004	0.00002	0.00001

A 3.2 IEDI calculations
 Not applicable since TMDI < 100% of ADI for all actives

A 3.3 IESTI calculations - Raw commodities

Rimsulfuron – PRIMo 3.1

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

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

Show results for all crops

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.004%	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)								

Thifensulfuron methyl

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

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

Show results for all crops

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.0034%	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)								

Thifensulfuron methyl – UK Model

Acute Intakes (97.5th percentiles)

Commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Maize	0.01		0.00000	0.0	0.00007	0.0	0.00004	0.0	0.00002	0.0	0.00001	0.0
Maize	0.01		0.00000	0.0	0.00007	0.0	0.00004	0.0	0.00002	0.0	0.00001	0.0

Commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Maize	0.01		0.00001	0.000367	0.00001	0.0005431	0.00002	0.001049	0.00000	0.000226	0.00000	0.000123
Maize	0.01		0.00001	0.0	0.00001	0.0	0.00002	0.0	0.00000	0.0	0.00000	0.0

Isoxadifen-ethyl

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

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

Show results for all crops

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.03%	Maize/corn	0.02 / 0.02	0.13	0.01%	Maize/corn	0.02 / 0.02	0.04
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Isoxadifen-ethyl – UK Model

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Maize	0.02		0.00001	0.0	0.00013	0.0	0.00008	0.0	0.00003	0.0	0.00002	0.0
Maize	0.02		0.00001	0.0	0.00013	0.0	0.00008	0.0	0.00003	0.0	0.00002	0.0

Acute Intakes (97.5th percentiles)

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Maize	0.02		0.00001	0.002933	0.00002	0.0043448	0.00004	0.008396	0.00001	0.001808	0.00000	0.000987
Maize	0.02		0.00001	0.0	0.00002	0.0	0.00004	0.0	0.00001	0.0	0.00000	0.0

A 3.4 IESTI calculations - Processed commodities

Rimsulfuron

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		IESTI	
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
0.01%	Maize / oil	0.01 / 0.25	0.23	0.0%	Maize / oil	0.01 / 0.25	0.13	
0.0%	Maize / processed (not spec)	0.01 / 0.01	0.02	#NUM!	#NUM!	#NUM!	#NUM!	
Expand/collapse list								
<p>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.</p>								

Thifensulfuron methyl

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		IESTI	
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
0.012%	Maize / oil	0.01 / 0.25	0.23	0.0%	Maize / oil	0.01 / 0.25	0.13	
0.0%	Maize / processed (not speci	0.01 / 0.01	0.02	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
Expand/collapse list								
<p>Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Thifensulfuron-methyl is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.</p>								

Isoxadifen-ethyl

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
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IESTI		MRL / input for RA		IESTI		MRL / input for RA		
Highest % of ARfD/ADI	Processed commodities	(mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	(mg/kg)	Exposure (µg/kg bw)	
0.1%	Maize / oil	0.02 / 0.5	0.47	0.1%	Maize / oil	0.02 / 0.5	0.25	
0.0%	Maize / processed (not speci	0.02 / 0.02	0.04	#NUM!	#NUM!	#NUM!	#NUM!	
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Expand/collapse list								
<p>Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Isoxadifen-ethyl is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.</p>								