FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: DNT-162OD-R-CPd

Product name(s): EVRITELL 162 OD

Chemical active substance(s):

Dicamba, 110 g/L
Nicosulfuron, 40 g/L
Thifensulfuron methyl, 12 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: QEMETICA Agricultural Solutions Poland S.A. (formerly: CIECH Sarzyna S.A.).

Submission date: 01/2024

MS Finalisation date: 08/2024 03/2025

Version history

When	What
01/2024	First submission to zRMS
08/2024	ZRMs evaluated initial dRR submitted by Applicant.
03/2025	Final assessment

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Dicamba

Stability of Residues

Dicamba and 5-OH Dicamba residues were stable in maize (forage, fodder and grain) when stored at -17°C for up to 36 months.

In animal matrices, dicamba and DCSA residues were stable at -12°C for at least 18 months, in beef tissues and milk.

These data are sufficient to demonstrate the stability of dicamba residues in high starch commodities. It is concluded that the residue data are valid with regard to storage stability.

Metabolism in plants

No new data submitted in the framework of this application.

Plant residue definition for monitoring Dicamba (Reg. (EU) 2015/845)

Plant residue definition for risk assessment Dicamba + 5-OH-dicamba, free and conjugated (EFSA Journal 2011;9(1):1965)

Magnitude of residues in plants

Proposed GAP:

Maize

BBCH 12-16; 1 application 0.110 kg as./ha; PHI: N/A

EU GAP (maize) (SANCO/829/08 – final rev. 2, 12 July 2016):

BBCH until 16; 1 application 360 g as./ha; PHI: N/A

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1 x 0.110 kg as/ha, BBCH 16, outdoor

Residues: 4 x <0.01 mg/kg

Sufficient trials on maize are available to support the proposed uses. The residues arising from the proposed use will not exceed the MRLs established for maize (Reg. (EU) No. 2015/845: 0.5 mg/kg).

Magnitude of residues in livestock

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

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

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

Magnitude of residues in representative succeeding crops

Conclusion drawn from EFSA, 2011 are reported below:

DT90 is <100 days, therefore no studies are needed according to guidelines. No residues > 0.01 mg/kg of dicamba, DCSA or 5-OH-dicamba were seen 32, 131 and 365 DAT, respectively in mustards tops, turnips

tops and roots, wheat forage, wheat straw, wheat grain and wheat chaff in a confined rotational crop study.

There is no need to introduce any restrictions.

Other / special studies

Maize has not melliferous capacity. Additionally, the product is applied early in the growing season when bee foraging activity is low. Studies are not required.

Estimation of exposure through diet and other means

The proposed uses of Dicamba in the formulation EVRITELL 162 OD do not represent unacceptable chronic and acute risks for the consumer (calculation was conducted using EFSA PRIMo rev.3.1).

Nicosulfuron

Storage stability

Storage stability of active substances was investigated in the framework of the EU pesticides peer review. No new data was submitted in the framework of this application. Information provided is sufficient. It is concluded that the residue data are valid with regard to storage stability.

No further data are required to support the proposed uses.

Nicosulfuron is stable for up to 9 months when stored at temperatures of -20ºC in whole plant and ears and for up to 12 months in sweet corn, dried kernels, stover and forage.

Metabolism in plants and animals

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion process. No additional studies are available in the framework of this application.

Plant residue definition for monitoring and risk assessment: nicosulfuron (Reg. (EU) No 617/2014, EFSA 2007)

Animal residue definition for monitoring and risk assessment: nicosulfuron (EFSA 2007, EFSA Journal 2012;10(12):3048)

Magnitude of residues in plants

Maize

Proposed GAP: 1 application; BBCH 12-16, 40 g as/ha; PHI: n.a.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1 x 0.04 kg as/ha, BBCH 16, outdoor

4 x <0.01 mg/kg

The data submitted show that exceedance of the MRL (0.01 mg/kg) is unlikely. The proposed use is considered acceptable.

Magnitude of residues in livestock

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

There is no risk for animal MRL to be exceeded. Additional studies are no required.

Processing studies

Additional studies are not required since residues are below 0.01 mg/kg.

Residues in Representative Succeeding Crops

Occurrence of nicosulfuron residues in rotational crops was already investigated during the peer review of this substance. It was concluded that significant residues in rotational crops are not expected. No additional studies on rotational crops are considered necessary. No restrictions are necessary.

Other / special studies

Maize has not melliferous capacity. Additionally, the product is applied early in the growing season when bee foraging activity is low. Studies are not required.

Consumer risk assessment

The proposed uses of nicosulfuron in the formulation EVRITELL 162 OD does not represent unacceptable chronic risks for the consumer. As ARfD was not deemed necessary, acute risk assessment is not relevant.

PRIMo rev. 3.1 calculations are accepted.

Thifensulfuron methyl

Stability of residues

The available storage stability data are considered sufficient.

Residue trials are valid in relation to storage stability data.

Storage stability of Thifensulfuron-methyl was demonstrated for a period of at least 24 months in Corn grain, and 42 months in wheat grain and 12 months in wheat straw.

Metabolism

The intended uses are covered by the available metabolism studies reported in the EU.

Plant residue definition for monitoring: Thifensulfuron-methyl (parent for oilseeds and cereals) (EFSA 2015, Reg. (EU) No 617/2014)

Plant residue definition for risk assessment: For oilseeds and cereals: thifensulfuron-methyl and provisionally IN A4098 a (EFSA, 2015)

Animal residue definition for monitoring: Thifensulfuron-methyl (parent) (EFSA 2015, Reg. (EU) No 617/2014)

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)

Metabolite IN-A4098 is provisionally included in the residue definition for risk assessment for plant commodities (pending the outcome of the confirmatory data requirement on genotoxic potential).

Evaluation of IN-A4098 is not finished yet. EFSA PPR panel is currently assessing it (EFSA Supporting publication 2020:EN-1627).

Magnitude of residues in plants

Maize

Proposed GAP: 1 application; BBCH 12-16, 12 g as/ha; PHI: n.a.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1 x 0.012 kg as/ha, BBCH 16, outdoor

4 x <0.01 mg/kg

The data submitted show that exceedance of the MRL (0.01 mg/kg) is unlikely. The proposed use is considered acceptable.

Magnitude of residues in livestock

Animals are not exposed to residues via feed above the trigger value: 0.004 mg/kg. Therefore livestock

feeding studies are not required.

Magnitude of residues in processed commodities

No data on the effect of processing on the magnitude of residues are required as residues in the raw agricultural commodities are below the limit of determination.

Magnitude of residues in representative succeeding crops

No data are required. Based on the rapid degradation of thifensulfuron-methyl in soil and the findings of the metabolism studies assessed in DAR, detectable residues are not expected in rotational crops.

Other / special studies

Maize has not melliferous capacity. Additionally, the product is applied early in the growing season when bee foraging activity is low. Studies are not required.

Estimation of exposure through diet and other means

The input values used for the chronic and acute risk assessments are the current EU MRLs contained in Regulation (EU) No. 617/2014. Calculation is accepted.

The proposed uses of thifensulfuron-methyl in the formulation EVRITELL 162 OD do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation DNT-162OD-R-CPd are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone/EU for maize. A list of all intended uses within the zone/EU 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 0.5 mg/kg for dicamba, 0.01 mg/kg for nicosulfuron and 0.01 mg/kg for Thifensulfuron methyl as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of dicamba, nicosulfuron and Thifensulfuron methyl residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

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

Data gaps

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

Noticed data gaps are: none

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Maize 0500030	N-EU	DNT-162OD-R-CPd	F	Annual dicotyledonous weeds TTTDD Annual monocotyledonous weeds TTTMM	OD	Dicamba – 110 g/L; Nicosulfuron – 40 g/L; Thifensulfuron-methyl – 12 g/L	Spraying	Post-emergence of weeds, crop BBCH 12-16	1	n.a.	dicamba: 33.33 -110 g as/ha nicosulfuron: 13.33 - 40 g as/ha thifensulfuron methyl: 4 - 12 g as/ha	100 / 300	dicamba: 110 g as/ha nicosulfuron: 40 g as/ha thifensulfuron methyl: 12 g as/ha	n.a.	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation DNT-162OD-R-CPd is composed of dicamba, nicosulfuron and thifensulfuron methyl.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of dicamba, nicosulfuron and thifensulfuron methyl

Reference value	Source	Year	Value	Study relied upon	Safety factor
Dicamba					
ADI	EFSA Conclusion	2010	0.3 mg/kg bw/d	Rat, 2-generation study	100
ARfD			0.3 mg/kg bw	Rabbit, teratology study	100
Nicosulfuron					
ADI	EFSA Scientific Report (2007) 120, 1-91, Conclusion on the peer review of nicosulfuron	2007	2 mg/kg bw/d	Chronic rat supported by subchronic dog	100
ARfD			Not necessary- not allocated		
Thifensulfuron-methyl					
ADI	EFSA Journal 2015;13(7):4201, Peer review of the pesticide risk assessment of the active substance thifensulfuron-methyl	2015	0.01 mg/kg bw per day	2-yr rat study	100
ARfD			2 mg/kg bw	Rat developmental toxicity study1	100

7.1.2.1 Summary for Dicamba

Table 7.1-3: Summary for dicamba

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)	Yes PHI covered by the time between the last application and harvest	Yes	Yes	No	No

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

As residues of dicamba 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.

7.1.2.2 Summary for Nicosulfuron

Table 7.1-4: Summary for nicosulfuron

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	Yes	Yes (4)	Yes PHI covered by the time between the last application and harvest	Yes	Yes	No	No

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

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

7.1.2.3 Summary for Thifensulfuron methyl

Table 7.1-5: 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)	Yes PHI covered by the time between the last application and harvest	Yes	Yes	No	No

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

As residues of 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.

7.1.2.4 Summary for DNT-162OD-R-CPd

Table 7.1-6: Information on DNT-162OD-R-CPd (KCA 6.8)

Crop	PHI for DNT-162OD-R-CPd proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for DNT-162OD-R-CPd proposed by zRMS	zRMS Comments (if different PHI proposed)
		Dicamba	Nicosulfuron	Thifensulfuron methyl		
Maize	F	Yes	Yes	Yes		

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

Table 7.1-7: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for DNT-162OD-R-CPd
Crop group	Led by dicamba	Led by nicosulfuron	Led by Thifensulfuron methyl	
All crops	NR	NR	NR	

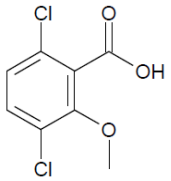
NR: not relevant

Assessment

7.2 Dicamba

General data on dicamba are summarized in the table below

Table 7.2-1: General information on dicamba

Active substance (ISO Common Name)	Dicamba
IUPAC	3,6-dichloro-2-methoxybenzoic acid
Chemical structure	
Molecular formula	$C_8H_6Cl_2O_3$
Molar mass	221.0 $g \cdot mol^{-1}$
Chemical group	Benzoic acid
Mode of action (if available)	Selective, systemic, absorbed through leaves and translocates throughout plant. Synthetic auxin
Systemic	Yes
Company (ies)	Syngenta Crop Protection AG*
Rapporteur Member State (RMS)	DK
Approval status	Approved Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC
Restriction	Only uses as a herbicide may be authorised
Review Report	SANCO/829/08 – final rev. 2 12 July 2016
Current MRL regulation	Reg. (EU) 2015/845
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	~~No*~~ *Conclusion on the peer review of the pesticide risk assessment of the active substance dicamba.* EFSA Journal 2011;9(1):1965
EFSA Journal: conclusion on article 12	No*
Current MRL applications on intended uses	None

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Maize	High starch content	36 months	DAR, 2007 Jimenez, N. C., DP-301949, 1995
Animal Products			
Ruminant	Fat, kidney, liver, muscle, milk	18 months	DAR, 2007 [redacted] 1996 DP-304489

Conclusion on stability of residues during storage

The storage stability study of dicamba and 5-OH dicamba in maize was evaluated in the DAR for dicamba. *The storage stability study showing dicamba and 5-OH-dicamba residues to be stable for up to 36 months in maize matrices (forage, fodder and grain), when stored frozen at c.a. -17°C.*
Also storage stability study of dicamba and metabolite DCSA in products of animal origin was evaluated in the DAR for dicamba. *The storage stability study showing dicamba and DCSA residues to be stable for up to 18 months in beef fat, kidney, liver, muscle and milk under freezer conditions.*
These data are sufficient to demonstrate the stability of dicamba residues in high protein/starch commodities.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

In new residue study, for Dicamba and 5-OH-dicamba, after extraction, extracts were stored refrigerated and analysed after maximum 2 days for grain and 2 days for straw.
For details please refer to Section B5.

Conclusion on stability of residues in sample extracts

The stability of the analytes in the final extracts was sufficiently proven according to the SANTE/2020/12830, Rev.1 guideline, as mean recoveries in the fortified samples were within the range 70-120%, measured against freshly prepared standards. Results of storage stability of extracts showed a good stability of Dicamba and 5-OH-dicamba residues in dry commodities for up to 17 days of refrigerated storage.

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)

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Pulses and oilseeds	soybeans	[phenyl-(U)-^{14}C]-dicamba	F	5.17 µg of ^{14}C dicamba	1	14	-	DAR, 2007 Butz, R. G.; Atallah, Y. H., 1982 SAN837/5260
	cotton	[phenyl-(U)-^{14}C]-dicamba	F	5.9 g/ha	1	0 7 14	-	DAR, 2007 Butz, R. G., 1982; SAN837/5140 Butz, R. G., 1984 SAN837/5255
		[phenyl-(U)-^{14}C]-dicamba	G	2.24 kg as/ha 4.48 kg as/ha	1	0 175 351	-	DAR, 2007 Butz, R. G., 1988 SAN837/5256
Cereals	wheat	[phenyl-(U)-^{14}C]-dicamba	F	144 g as/ha	1	18 85	-	DAR, 2007 Völlmin, S., 1999 SAN837/5879
	sugar cane	[phenyl-(U)-^{14}C]-dicamba	G	1.12 kg as/ha	1	0 1 2 5 12 21 28	-	DAR, 2007 Butz, R. G.; Atallah, Y. H., 1981a SAN837/5160 Butz, R. G.; Atallah, Y. H., 1981b SAN837/5534

Summary of plant metabolism studies reported in the EU

Metabolism in plants was investigated in cereals (wheat, sugarcane) and in the pulse/oilseed plant group (soya, cotton), using ^{14}C-dicamba labelled on the phenyl moiety applied by foliar spraying (wheat), or by droplet applications by means of a micro-syringe to a limited number of leaves (sugar cane, soya, cotton). In sugar cane, soya and cotton, where the characterization of the residues was investigated shortly after the application (6 to 28 days), dicamba remains the major component of the residues, accounting for 22 -

29 % of the TRR in sugar cane leaves, 44 - 94 % of the TRR in soya beans, and 72 % of the TRR in cotton seed. Other identified metabolites were observed in low proportions (< 2 % TRR), except 5-OH-dicamba, which represented 47 % and 20 % of the TRR in sugar cane leaves, 12 and 28 days after application, respectively. In wheat, dicamba seems to be more extensively metabolised, accounting for 10 % of the TRR in immature plant (forage), and 2 % and 16 % of the TRR respectively in straw and grain at harvest. 5-OH-dicamba is detected as the major metabolite in wheat forage (65 % TRR), but it represents less than 4 % TRR in grain and straw at harvest. Both the parent compound and 5-OH-dicamba were observed in free and conjugated form. Considering the different structures identified, the following metabolic pathway in plants was proposed. The metabolism of dicamba proceeds first by hydroxylation to form 5-OH-dicamba, or by demethylation to the DCSA metabolite, both compounds being further degraded to DCGA. Based on these studies, it was proposed to define the residue for monitoring as dicamba and its salts (free and conjugates). For risk assessment, the PRAPeR TC 50 discussed whether 5-OH-dicamba should be included additionally in the residue definition, since it was not observed at significant levels in the edible parts used for human consumption. Finally, and considering the conclusion of the PRAPeR meeting on mammalian toxicology (PRAPeR 83) stating that 5-OH-dicamba is not of higher toxicity than the parent compound, and having regard to the important levels at which this metabolite was observed in the residue trials conducted on pasture, it was agreed to include this metabolite in the residue definition for risk assessment.

Conclusion on metabolism in primary crops

The metabolism of dicamba has been investigated in cereals and legumes in the DAR for dicamba (2007). Following the evaluation of the metabolism studies on cereals and legumes, the residue definition in plants based on the these two crop groups for monitoring was agreed to be dicamba and its salts and conjugated dicamba expressed as dicamba and for risk assessment was agreed to be Dicamba + 5-OH-dicamba, free and conjugated. Given that the proposed use is on a crop which has already been considered in the DAR, no further consideration is necessary.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	mustard	[phenyl-(U)-^{14}C]-dicamba	F	0.56	32 131 369	74 189 423	-	DAR, 2007 Moore, P. A., 1989 SAN837/5108
	collards	[phenyl-(U)-^{14}C]-dicamba	F	0.84	30 120 365	At maturity	-	DAR, 2007 M. V. Pierotti, 1995 SAN837/5282
Root and tuber vegetables	turnip	[phenyl-(U)-^{14}C]-dicamba	F	0.56	32 131 369	74 189 423	-	DAR, 2007 Moore, P. A., 1989 SAN837/5108
	carrots	[phenyl-	F	0.84	30	At maturity	-	DAR, 2007

		(U)-^{14}C]-dicamba			120 365			M. V. Pierotti, 1995 SAN837/5282
Pulses and oilseeds	soybean	phenyl-(U)-^{14}C	Soil application, F	0.84	365	Immature (forage) Maturity (grain, straw, chaff)	-	M. V. Pierotti, 1995 SAN837/5282
Cereals	wheat	[phenyl-(U)-^{14}C]-dicamba	F	0.56	32 131 369	74 406 423	-	DAR, 2007 Moore, P. A., 1989 SAN837/5108
	barley	[phenyl-(U)-^{14}C]-dicamba	F	0.84	30 120 365	Intermediate stage (6-8 weeks)	-	DAR, 2007 M. V. Pierotti, 1995 SAN837/5282

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

Summary of plant metabolism studies reported in the EU

Wheat, turnips and mustard were grown in soil treated with ^{14}C dicamba, equivalent to 0.56 kg as/ha. No dicamba, DCSA or 5-OH-dicamba was found in amounts of > 0.01 mg/kg 32, 131 and 365 DAT, respectively.
Barley, carrots and collards greens were planted as rotational crops to maize treated with ^{14}C dicamba, equivalent to 0.840 kg as/ha. TRR was < 0.04 mg/kg 120 DAT. TRR 30 DAT was high (1.022 mg/kg in carrot roots and 0.272 mg/kg in barley grain). Since no residues of dicamba, DCSA and 5-OH-dicamba was found in the study, where wheat, turnips and mustard were used as rotational crops it is not expected either that the residues found in barley, carrots and collard greens 30 DAT will be due to dicamba, DCSA and 5-OH-dicamba. They could be due to incorporation of $^{14}CO_2$ or other breakdown products into plant constituents such as lignin or cellulose.

Conclusion on metabolism in rotational crops

All metabolism data are active substance data and were evaluated in the EU review of dicamba.
Based on the available data DAR for dicamba levels of dicamba in rotational crops were not exceeded 0.05 mg/kg, therefore no additional studies are required.
Taking above into consideration additional studies on metabolism in rotational crops are not regarded as necessary.
According to the *EFSA Journal 2011;9(1):1965* no parent compound but only metabolites 5-OH and DCSA were identified in the rotational crops. Dicamba forming only one major soil metabolite, DCSA. The metabolic pathway in rotational crops is sufficiently addressed and no additional metabolism studies are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	% radioactive recovery in control samples: 102.6 % radioactive recovery for hydrolysates: 101.9, 101.8	DAR, 2007 S. J. Grout, 2003 RJ3333B
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	% radioactive recovery in control samples: 105.5 % radioactive recovery for hydrolysates: 106.9, 105.3	
Sterilisation (20 minutes, 120°C, pH 6)	% radioactive recovery in control samples: 107.9 % radioactive recovery for hydrolysates: 111.2, 105.6	

Conclusion on nature of residues in processed commodities

All processing data are active substance data and were evaluated in the EU review of dicamba.
Based on the available data DAR for dicamba it can be concluded that dicamba is hydrolytically stable under condition representative of pasteurisation, baking, brewing, boiling and sterilisation.
Taking above into consideration additional studies on nature of the residues in processed commodities are not regarded as necessary.

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

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (wheat and sugar cane) Pulses/oilseeds (soybean and cotton)
Rotational crops covered	Leafy crops (mustard and collard ~~greans~~ greens), root vegetables (carrot and turnips) and cereals (wheat and barley)
Metabolism in rotational crops similar to metabolism in primary crops?	No, parent, 5-OH-dicamba and DCSA identified in the rotational crops. DCSA identified in soil.
Processed commodities	Not provided and not required.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Dicamba (Regulation n°2015/845)
Plant residue definition for risk assessment	Dicamba + 5-OH-dicamba, free and conjugated (EFSA 2011)*
Conversion factor from enforcement to RA	None

* If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.2-7: 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	Cow	[phenyl-(U)-^{14}C]-dicamba	1	2.2	5	Milk	twice daily	DAR, 2007 Oehler, D. D.; Ivie, G. W. 1980 SAN837/5145
						Urine	twice daily	
						Faeces	daily	
						Tissues	at sacrifice	
	Goats	[phenyl-(U)-^{14}C]-dicamba	3	Goat A – 10 mg [phenyl-(U)-^{14}C]-dicamba/kg feed Goat B – 1000 mg [phenyl-(U)-^{14}C]-dicamba/kg feed Goat C - control	4	Milk	twice daily	DAR, 2007 [redacted] 1994 SAN837/5286
						Urine and faeces	twice daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[phenyl-(U)-^{14}C]-dicamba	3x4	Group A – 1 mg/kg bw Group B – 100 mg/kg bw Group C – 1 mg/kg bw (ntravenous injection)	-	Excreta	daily	DAR, 2007 [redacted] 1983 SAN837/5254
						Tissues	at sacrifice	
	Hens	[phenyl-(U)-^{14}C]-dicamba	8	Group A – 0.6 mg/kg bw Group B – 30 mg/kg bw	4	Eggs	daily	DAR, 2007 Nietschmann, [redacted] 1994 SAN837/5285
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Metabolism in animals was considered in cow, goat and poultry, using $_{14}$C-dicamba. The transfer in fat, milk and eggs was limited, the highest TRRs being observed in kidney and liver. Dicamba (free and conjugated) was by far the major compound identified in all animal matrices, accounting for more than 50 % of the TRR. In addition, DCSA was also observed in ruminants, but only in kidney and liver, up to 21 % of the TRR. 5-OH-dicamba was not detected in animal matrices, except in urine and excreta, but at insignificant levels and proportions (< 0.01 % TRR). Having regard to the high levels of 5-OH-dicamba in grass, and consequently its significant intake by ruminants (*c.a.* 1.5 mg/kg bw/day), the PRAPeR TC 50 meeting of experts discussed whether a specific metabolism study using this metabolite needs to be re-

quired. The experts were of the opinion that a similar pathway to the parent is expected for 5-OH-dicamba, this metabolite being probably more extensively excreted than the parent compound since it is more polar. This assertion is supported by the results of the cow feeding study conducted with 5-OH-dicamba, where this metabolite was almost not detected in any matrices, except in kidney, at the 5N dose rate. It was therefore concluded that a specific ruminant metabolism study should not be required for 5-OH-dicamba. Finally, dicamba and its salts (free and conjugates) was proposed to define the residue for monitoring, and MRLs were derived for ruminant products from the feeding study conducted with the parent dicamba. For risk assessment, considering the lower ADI of 0.01 mg/kg bw/day proposed for the metabolite DCSA when compared to the parent compound (see section 2), the PRAPeR TC 50 meeting of experts proposed to define the residue as parent dicamba and DCSA (free and conjugates). However, after the meeting, the consumer risk assessment conducted for DCSA, taking into account the expected residue levels in kidney and liver, showed highest intakes below 0.2 % of the ADI. Having regard to the very low contribution of the DCSA metabolite to the consumer exposure and considering that the animal intake will not be increased if additional uses are envisaged, EFSA is of the opinion that the residue definition for risk assessment should be limited to the parent dicamba only.

Conclusion on metabolism in livestock

The detailed studies about metabolism in livestock are presented in Draft Assessment Report (DAR) for dicamba (February 2007 – Annex B7), and additional studies are not regarded as necessary.

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

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Cow, goat and hens
Time needed to reach a plateau concentration	Milk: *c.a.* 20 days
Animal residue definition for monitoring	Dicamba and its salts and conjugated dicamba expressed as dicamba (Regulation n°2015/845)
Animal residue definition for risk assessment	Dicamba (free and conjugated) (EFSA 2011)*
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of DNT-162OD-R-CPd 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	New trials	N-EU	Trials GAP: 1 x 0.110 kg as/ha, BBCH 16, outdoor 4 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	4 x <0.01	0.01	0.01	0.01	0.5	Yes
Maize straw	New trials	N-EU	Trials GAP: 1 x 0.110 kg as/ha, BBCH 16, outdoor 3 x <0.01, 0.03	N/A				
	Overall supporting data for cGAP	N-EU	3 x <0.01, 0.03	0.01	0.03	-	-	-

* Source of EU MRL: Reg. (EU) 2015/845

7.2.3.2 Conclusion on the magnitude of residues in plants

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

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

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation using Animal model 2017 (considering the intended uses)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of dicamba and 5-OH-dicamba, free and conjugated, expressed as dicamba				
Corn, field grain	0.01	STMR	-	
Corn, pop grain	0.01	STMR	-	
Corn, field milled by-pdts	0.01	STMR x PF*	-	
Corn, field hominy meal	0.01	STMR x PF*	-	
Corn, field gluten feed	0.01	STMR x PF*	-	
Corn, field gluten meal	0.01	STMR x PF*	-	
Distiller's grain	0.01	STMR x PF*	-	
Corn, field stover	0.01	STMR	0.03	HR
Corn, pop stover	0.01	STMR	0.03	HR

*STMR residue maize grain and stover (**Table 7.2-11**),), PF = 1 (default PF waived in case residues in RAC <LOQ) (Animal model 2017.xls)

Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Sum of dicamba and 5-OH-dicamba, free and conjugated, expressed as dicamba					
Beef cattle*	0.0004	0.001	Corn, field stover	0.02	N
Dairy cattle*	0.0005	0.001	Corn, field stover	0.02	N
Ram/ewe	0.0004	0.001	Corn, field gluten feed	0.00	N
Lamb	0.0005	0.001	Corn, field gluten feed	0.01	N
Breeding swine	0.000	0.000	Corn, field stover	0.02	N
Finishing swine*	0.000	0.000	Corn, field milled by pdts	0.01	N

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Broiler poultry	0.001	0.001	Corn, field milled bypdts	0.01	N
Layer poultry*	0.001	0.001	Corn, field milled bypdts	0.01	N
Turkey	0.001	0.001	Corn, field milled bypdts	0.01	N

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009, above 0.004 mg/kg. Therefore livestock feeding studies are not required.

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

No further studies has been performed. Dicamba residue levels in maize grain are below 0.01 mg/kg. Therefore magnitude of residues in processed commodities are not requires.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see **Błąd! Nie można odnaleźć źródła odwołania.**), no study dealing with magnitude of residues in succeeding crops is needed.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of EVRITELL 162 OD. Therefore, other special studies are not needed.

Maize is not melliferous plant according to SANTE/11956/2016 rev. 9 and is not foraged by bees, therefore residue in honey study is not 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 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of dicamba and 5-OH-dicamba, free and conjugated, expressed as dicamba				
Maize	~~0.05~~ 0.5	EU MRL (In force MRL according to Reg. (EU) 2015/845)	0.05	EU MRL (In force MRL according to Reg. (EU) 2015/845)
All other commodities	various		-	-

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

	Normal mode	Refined mode
TMDI (% ADI) according to EF-SA PRIMo rev. 3.1	19 % (based on GEMS/Food G11)	1 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	TMDI values do not exceed ADI therefore IEDI calculations are not required.	TMDI values do not exceed ADI therefore IEDI calculations are not required.
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Unprocessed commodities: Asparagus: 32 % (children) Soyabeans: 18 % (adults) Processed commodities: Soyabeans/soya drink: 14% (children) Barley/beer: 17% (adults)	Unprocessed commodities: Maize/corn: 1 % (children) Maize/corn: 0.4 % (adults) Processed commodities: Maize/oil: 4% (children) Maize/oil: 2% (adults)
NTMDI (% ADI) **	Not necessary	Not necessary
NEDI (% ADI)**	Not necessary	Not necessary
NESTI (% ARfD) **	Not required	Not required

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

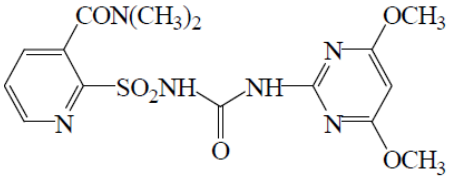
The proposed uses of dicamba in the formulation EVRITELL 162 OD do not represent unacceptable acute and chronic risks for the consumer.

7.3 Nicosulfuron

General data on nicosulfuron are summarized in the table below

Table 7.3-1: General information on nicosulfuron

Active substance (ISO Common Name)	Nicosulfuron

IUPAC	2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*N,N*-dimethylnicotinamide
Chemical structure	
Molecular formula	$C_{15}H_{18}N_6O_6S$
Molar mass	410.4 g/mol
Chemical group	Sulfonylurea
Mode of action (if available)	Selective, systemic absorbed by foliage and roots and trans-located. Inhibits plant amino acid synthesis - acetohydroxy-acid synthase AHAS
Systemic	Yes
Company (ies)	ISK Biosciences Europe S.A.*
Rapporteur Member State (RMS)	LV
Approval status	Approved Date of (01/01/2009) and reference to decision (COMMISSION DIRECTIVE 2008/40/EC) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0040&from=EN
Restriction	see COMMISSION DIRECTIVE 2008/40/EC
Review Report	SANCO/3780/07 – rev. 1 22/01/2008
Current MRL regulation	COMMISSION REGULATION (EU) No 617/2014 of 3 June 2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	Yes**
EFSA Journal: conclusion on article 12	No**
Current MRL applications on intended uses	Reasoned opinion available (EFSA Journal 2012;10(12):3048)

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, 2007 - see list of references

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			
Maize	High protein/high starch content (dry)	9 months	Schulz, M. Ullrich-Mitzel, A., 1995c, Report no. 304762

Summary of storage stability studies reported in the EU

The data supplied in the storage stability study demonstrated that residues of nicosulfuron are stable for at least 9 months which is sufficient to cover the storage period of the residue trials.

Conclusion on stability of residues during storage

All data on the stability of residues are active substance data, are presented in Draft Assessment Report (DAR) for nicosulfuron (November 2005) and were evaluated in the EU review of nicosulfuron. No further review is required.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

In new residue studies, for Nicosulfuron, after extraction, extracts were stored frozen and analysed after maximum 2 days for grain and 4 days for straw.
For details please refer to Section B5.

Conclusion on stability of residues in sample extracts

The stability of the analyte(s) in the final extracts was sufficiently proven according to the SANTE/2020/12830, Rev.1 guideline, as mean recoveries in the fortified samples were within the range 70-120%, measured against freshly prepared standards. Results of storage stability of extracts showed a good stability of Nicosulfuron residues in dry commodities (grain and straw) for up to 5 days of frozen storage.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Maize	[5, ^{14}C-pyrimidinyl] nicosulfuron	G	0.060 (N) and 5N	1	0 14 30 60 102	-	Schanné C., 1991a, report no. 274173
		[2, ^{14}C-pyridyl]						Mamouni A., 1995a, report no. 272158

Summary of plant metabolism studies reported in the EU

Metabolism of nicosulfuron was studied in maize. Two studies, one for pyridyl- and one for pyrimidinyl-labelled nicosulfuron are available for maize grown in soil. The field rate (N) and 5N application rates were used, with a 4% SC formulation and direct foliar application.
In the pyrimidinyl study, a few hours after application a considerable amount of metabolism had already occurred. Nicosulfuron was present at 24 % TRR (0.69 mg/kg) and metabolite HMUD 4 % TRR (0.11 mg/kg). At the 60 day time interval the TRR was low with only 0.06 mg/kg in the straw and only 0.003 mg/kg in the grain and the metabolite profile has changed considerably. The metabolites identified were not present initially. Nicosulfuron was still the most significant residue at 52 % TRR (0.029 mg/kg), and metabolites identified were DMPU 5.9 % TRR (0.003 mg/kg) and ADMP 5.5 % TRR (0.003 mg/kg). The other two metabolites were M1 and M5, with M1 being the most significant at 13% TRR (0.007 mg/kg). At the 102 day harvest point the residue profile was very similar to the 60 day harvest; however some slight increases in metabolite levels were noted which is deemed a result of a decrease in water content.
In the pyridyl labelled study, immediately after application nicosulfuron was the predominant residue at 51 % TRR (0.79 mg/kg). Six metabolite fractions were characterised and three identified as AUSN 20.4 % TRR (0.32 mg/kg), HMUD 3.6 % TRR (0.056 mg/kg) and ASDM 17.3 % TRR (0.27 mg/kg). AUSN and ASDM were not identified in the pyrimidinyl study since cleavage of the ring structures has occurred. The only other significant metabolite fraction present was M1 at 1.6 % TRR (0.025 mg/kg). At day 60 the TRR had decreased to 0.05 mg/kg in the straw and 0.001 mg/kg in the grain, and the same fractions and compounds were characterised as at the 0 day sampling interval. Nicosulfuron was still present at 41% TRR (0.024 mg/kg), AUSN 13.5 % TRR (0.008 mg/kg), ASDM 16.7 % TRR (0.01 mg/kg.) and HMUD 0.1 % TRR (0.001 mg/kg). No other metabolites were present at significant levels. At the 102 day interval it would appear that the M1 metabolite fraction had increased from 0.1 % TRR to 29 % TRR. Further work was undertaken to clarify how metabolite M1 was formed, the reason for the significant difference in levels of M1 found between the day 60 and day 102 interval is still unknown. However, M1 was shown to be a fraction of metabolites (partially conjugates of parent and ASDM) rather than one single metabolite and individual residues are generally low.
Based on the metabolism and residue data submitted for maize, residues in this crop should be defined as nicosulfuron.

Conclusion on metabolism in primary crops

All metabolism data are active substance data, are presented in Draft Assessment Report (DAR) for nicosulfuron (November 2005) and were evaluated in the EU review of metazachlor.

Additional studies are not regarded as necessary.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

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

Conclusion on metabolism in rotational crops

All metabolism data are active substance data, are presented in Draft Assessment Report (DAR) for nicosulfuron (November 2005) and were evaluated in the EU review of nicosulfuron.

Additional studies are not regarded as necessary.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

According to requirements of Reg (EU) No 283/2013 studies on the nature of residues in processing shall be provided where residues in products of plant or animal origin subject to processing may occur at a level of or higher than 0.01 mg/kg. Submitted residue studies indicated that residues of nicosulfuron in maize grain are below 0.01 mg/kg. Therefore studies on the nature of residues in processing are not required.

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

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

Endpoints	
Plant groups covered	Cereals (maize)
Rotational crops covered	Not required. Lysimeter studies indicated low uptake by cereal plants (TRR <0.01 mg/kg) and the phytotoxic effect of nicosulfuron and its soil metabolites on dicot plants leads to a self-limitation in the re-planting period
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No data supplied or required

Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Nicosulfuron (Regulation n°617/2014) *
Plant residue definition for risk assessment	Nicosulfuron (EFSA 2007)*
Conversion factor from enforcement to RA	None

* If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.3-5: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[^{14}C]nicosulfuron (Pyridine)	1	8.3	3	Milk	twice daily	[redacted] 1995a, 358323
						Urine and faeces	daily	
						Tissues	at sacrifice	[redacted] 1995b, RCC 358312
		[^{14}C]nicosulfuron (Pyrimidin)		8.64				

Summary of animal metabolism studies reported in the EU

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

Conclusion on metabolism in livestock

All metabolism data are active substance data, are presented in Draft Assessment Report (DAR) for nicosulfuron (November 2005) and were evaluated in the EU review of nicosulfuron.

Additional studies are not regarded as necessary.

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

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

	Endpoints
Animals covered	Ruminants
Time needed to reach a plateau concentration	Unable to assess due to low total radioactive residues.
Animal residue definition for monitoring	Unable to propose, however intakes are not significant (<0.1 mg/kg diet). (EFSA 2007)*
Animal residue definition for risk assessment	Unable to propose, however intakes are not significant (<0.1 mg/kg diet). (EFSA 2007)*
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue: (yes/no)	No

* If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

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

Table 7.3-7: Summary of EU reported and new data supporting the intended uses of DNT-162OD-R-CPd 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	New trials	N-EU	Trials GAP: 1 x 0.04 kg as/ha, BBCH 16, outdoor 4 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	4 x <0.01	0.01	0.01	0.01	0.01*	Yes/No
Maize straw	New trials	N-EU	Trials GAP: 1 x 0.04 kg as/ha, BBCH 16, outdoor 4 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	4 x <0.01	0.01	0.01	-	-	-

* Source of EU MRL: Reg. (EU) No 617/2014
Due to the lack of confirmatory analytical data for enforcement in dry commodities, only a tentative MRL was adopted

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.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3-8: Input values for the dietary burden calculation using Animal model 2017 (considering the intended uses)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Nicosulfuron				
Corn, field grain	0.01	STMR	-	
Corn, pop grain	0.01	STMR	-	
Corn, field milled by-pdts	0.01	STMR x PF	-	
Corn, field hominy meal	0.01	STMR x PF	-	
Corn, field gluten feed	0.01	STMR x PF	-	
Corn, field gluten meal	0.01	STMR x PF	-	
Distiller's grain	0.01	STMR x PF	-	
Corn, field stover	0.01	STMR	0.01	HR
Corn, pop stover	0.01	STMR	0.01	HR

*STMR residue maize grain and stover (**Table 7.3-9**),), PF = 1 (default PF waived in case residues in RAC <LOQ) (Animal model 2017.xls)

Table 7.3-9: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Nicosulfuron					
Beef cattle*	0.0004	0.000	Corn, field gluten feed	0.02	N
Dairy cattle*	0.0005	0.001	Corn, field gluten feed	0.01	N
Ram/ewe	0.0004	0.001	Corn, field gluten feed	0.02	N
Lamb	0.0005	0.001	Corn, field gluten feed	0.02	N
Breeding swine	0.000	0.000	Corn, field milled by-pdts	0.01	N

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Finishing swine*	0.001	0.001	Corn, field milled bypdts	0.01	N
Broiler poultry	0.001	0.001	Corn, field milled bypdts	0.01	N
Layer poultry*	0.001	0.001	Corn, field milled bypdts	0.01	N
Turkey	0.001	0.001	Corn, field milled bypdts	0.01	N

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

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009, above 0.004 mg/kg. Therefore livestock feeding studies are not required.

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

No further studies has been performed. Nicosulfuron residue levels in maize grain are below 0.01 mg/kg. Therefore magnitude of residues in processed commodities are not requires.

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 **Błąd! Nie można odnaleźć źródła odwołania.**), no study dealing with magnitude of residues in succeeding crops is needed.

7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of EVRITELL 162 OD. Therefore, other special studies are not needed.

Maize is not melliferous plant according to SANTE/11956/2016 rev. 9 and is not foraged by bees, therefore residue in honey study is not 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 7.1.2).
As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Nicosulfuron				
Maize	0.01	EU MRL (In force MRL according to Reg. (EU) No 617/2014)	Not relevant	
All other commodities	various	All other commodities		

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-11: Consumer risk assessment

	Normal mode	Refined mode
TMDI (% ADI) according to EFSA PRIMo rev.3.1	0.1 % (based on NL toddler)	0.0 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	TMDI values do not exceed ADI therefore IEDI calculations are not required.	TMDI values do not exceed ADI therefore IEDI calculations are not required.
IESTI (% ARfD) according to EFSA PRIMo*	As ARfD was not deemed necessary, acute risk assessment is not relevant.	
NTMDI (% ADI) **	Not necessary	Not necessary
NEDI (% ADI)**	Not necessary	Not necessary
NESTI (% ARfD) **	Not necessary	Not required

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

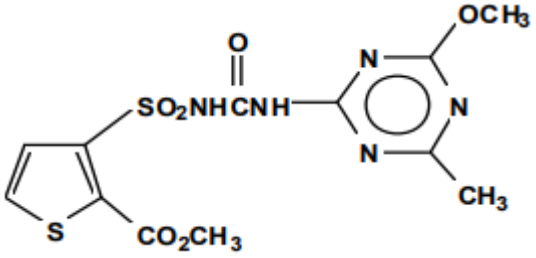
The proposed uses of nicosulfuron in the formulation EVRITELL 162 OD do not represent unacceptable acute and chronic risks for the consumer.

7.4 Thifensulfuron methyl

General data on Thifensulfuron methyl are summarized in the table below

Table 7.4-1: General information on Thifensulfuron methyl

Active substance (ISO Common Name)	Thifensulfuron-methyl
IUPAC	methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate

Chemical structure	
Molecular formula	$C_{12}H_{13}N_5O_6S_2$
Molar mass	387.39 g/mol
Chemical group	Sulfonylurea herbicide; Triazinylsulfonylurea herbicide
Mode of action (if available)	~~Selective, absorbed through folInhibits plant amino acid synthesis - acetohydroxyacid synthase AHAS~~ Selective, absorbed through foliage, stems and roots and translocated throughout the plant. Inhibits plant amino acid synthesis - acetohydroxyacid synthase AHAS.
Systemic	Yes
Company (ies)	Du Pont de Nemours and EU TSM AIR2 Task Force (Rotam Agrochemical Europe Ltd. and Cheminova AS) *
Rapporteur Member State (RMS)	FR
Approval status	Approved Date of (01/07/2002) and reference to decision (Commission Directive 2001/99/EC of 20 November 2001)
Restriction	-
Review Report	SANTE/10150/2016 rev. 2 12 July 2016
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 Journal: conclusion on article 12	Yes**
Current MRL applications on intended uses	-

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, 2015 - see list of references

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.4-2: Summary of stability data achieved at ≤ - 20°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	RMS, 2014
Corn	High starch content	24 months	
Wheat grain	High starch content	12 months*	RMS, 2014 Sadgrove, L., 2012, PII0018
Wheat straw	Dry		
Wheat plant	High water		

*Applies to Thifensulfuron-methyl and the metabolites IN-L9225 and IN-V7160. For IN-A4098, stability was only demonstrated for 3 months for grain and 6 months for sugar beet roots / tops.

Conclusion on stability of residues during storage

In the framework of the peer review, storage stability of Thifensufuron-methyl was demonstrated for a period of 42 months and 24 months at -20 °C in dry commodities - wheat grain and corn respectively (France, 1996). This study was not reported in detail and it appears that the storage stability of Thifensufuron-methyl in wheat straw was not investigated. However, on the basis of the storage data for wheat grain and corn, extrapolation to wheat straw is possible.
IN-A4098 is a triazine-amine metabolite that is common to several active ingredients. A recent public EFSA conclusion on the active tribenuron-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)).

7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

In new residue studies for thifensulfuron-methyl and triazine amine IN-A4098, after extraction, extracts were stored frozen and analysed after maximum 2 days for grain and 4 days for straw.
For details please refer to Section B5.

Conclusion on stability of residues in sample extracts

The stability of the analyte(s) in the final extracts was sufficiently proven according to the SANTE/2020/12830, Rev.1 guideline, as mean recoveries in the fortified samples were within the range 70-120%, measured against freshly prepared standards. Results of storage stability of extracts showed a good stability of thifensulfuron-methyl and triazine amine IN-A4098 residues in dry commodities (grain and straw) for up to 5 days of frozen storage.

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Pulses and oilseeds	soybean	[triazine-2-14C]Thifensulfuron-methyl	F	16 g a.s./ha and 8 g a.s./ha including a surfactant (0.25% X-77)	1	0 7 30	-	RMS 2014 Brattsten L.B.. (1987), AMR 547-86
	soybean	[thiophene-2-14C]Thifensulfuron-methyl	G	16 g a.s./ha and 8 g a.s./ha including a surfactant (0.25% X-77)	1	0 7 30	-	RMS 2014 Brown, H.M. (1987), AMR 572-86
Cereals	wheat	thiophene-2- ^{14}C] and [triazine-2- ^{14}C]	F	74.2 g a.s./ha and 80 g a.s/ha)	1	0 4 8 21 28 63	-	RMS 2014 Cotterman J.C.. (1987), AMR 794-87 Steveson I.E.. (1986), AMR 783-87 Friedman P.L. and Stevenson I.E. (1986), AMR 498-86 Friedman P.L. and Lichtner F.T. (1986), AMR 513-86
	corn	thiophene-2- ^{14}C] and [triazine-2- ^{14}C]	F	36.3 g a.s./ha and 39 g a.s/ha	1	0 3 10 30 72 113	-	RMS 2014 Wittenbach V.A. (1987), AMR 532-86

Summary of plant metabolism studies reported in the EU

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 and therefore not further identified (< 0.01 – 0.036 mg/kg). In the leafy crop parts, parent underwent deesterification to form thifensulfuron acid (IN-L9225), a major residue in the tested commodities at harvest (10-16% TRR in wheat straw; 28-31% TRR in soybean leaves). Moreover hydrolysis of the triazinylsulfonylurea structure led to the two groups of thiophene ring structured metabolites (e.g. 2-acid-3 sulfonamide (IN-L9223), 59% TRR in maize straw) and triazine ring structured 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 around 11-15% TRR in wheat straw, <10% TRR in soybean leaves with surfactant use and 44% TRR in soybean leaves without surfactant use, and was not identified in maize commodities at harvest, probably as for the PHI investigated in maize (113 days) being much longer than for wheat (63 days) and soybean (30 days). Residue trials with thifensulfuron-methyl were conducted in undersown crops, small grain cereals, maize and soybean. Some of the trials (grass, alfalfa) analysed for both thifensulfuron-methyl and thifensulfuron acid (IN L9225). Validation of the analytical methods used was sufficient as were the storage stability data for both compounds.

Conclusion on metabolism in primary crops

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.

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Root and tuber vegetables	Beet	[Thiophene-2- ^{14}C]	G	86-94 g a.s./ha	30	16 29 43 86	-	RMS 2014 Hardesty P.T (1984), AMR 256-84
					120	13 27 49 101		

Pulses and oilseeds	Peas	[Thiophene-2- ^{14}C]	G	86-94 g a.s./ha	30	16 29 43 65	-	
					120	13 27 49		
	Sunflowers	[Thiophene-2- ^{14}C]	G	86-94 g a.s./ha	30	16 29 43 100	-	
					120	13 27 101		
Cereals	Wheat	[triazine-2-^{14}C]Thifensulfuron-methyl	G	36 g a.s./ha	-	45 75	-	RMS 2014 Brown A.M (1987), AMR 582-86
		[thiophene 2- ^{14}C] or [triazine 2-^{14}C] Thifensulfuron-methyl	F	33.6 g a.s./ha	90 241	327	-	RMS 2014 Ferguson E.M. (1992), AMR 858-87

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

Summary of plant metabolism studies reported in the EU

In the rotational crops peas, beetroot, sunflower and wheat good comparability was demonstrated with the primary crop metabolism studies as metabolites 2-acid-3-sulfonamide (IN-L9223), IN-A4098, triazine urea (IN-V7160) and O-demethyl triazine amine (IN-B5528) were detected in plant tissues. The principal plant metabolite was IN-A4098. The mammalian toxicology evaluation has identified that the genotoxic potential of the metabolite IN-A4098 cannot be ruled out based on the available data (refer to Section 2). Significant residue levels of IN-A4098 were mainly found in cereal straw and in foliage of pulses/oilseeds in the rotational crop metabolism study, and in the rotational crop residue trials in the leafy crops. However, storage stability data on IN-A4098 showed a rapid decline of the compound in all tested matrices.

Conclusion on metabolism in rotational crops

Residues in rotational crops were studied in peas, beet root, sunflower and wheat. The primary plant metabolism study corresponds with the residues observed in rotational crops where the majority of the radioactivity could be attributed to incorporation into natural compounds or minor unidentified fractions. Residues exceeding the LOQ are therefore not expected in rotational crops.

7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

According to requirements of Reg (EU) No 283/2013 studies on the nature of residues in processing shall be provided where residues in products of plant or animal origin subject to processing may occur at a level of or higher than 0.01 mg/kg. Submitted residue studies indicated that residues of Thifensulfuron methyl in maize grain are below 0.01 mg/kg. Therefore studies on the nature of residues in processing

are not required.

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

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

Endpoints	
Plant groups covered	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
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-methy (Reg. (EU) No 617/2014) **
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

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.4-6: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								

Lactating ruminants	Goat	[thiophene- 2- ^{14}C] and [triazine-2- ^{14}C]Thifensulfuron-methyl	2	50 mg (gelatine capsule) that was equivalent to 28 ppm in the diet	7	Milk	twice daily	RMS, 2014; [redacted] 1986, AMR 326-85
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[thiophene- 2- ^{14}C] and [triazine-2- ^{14}C]Thifensulfuron-methyl	5	0.05 mg/kg and 50 mg/kg	14 and 5 days	Eggs	daily	RMS, 2014; [redacted] 1992, AMR-2022-91
						Excreta	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

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.

Conclusion on metabolism in livestock

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 is relatively low. Thifensulfuron-methyl was the major component found in milk, muscle and tissues. Hence it was concluded that the residue definition for risk assessment and enforcement in ruminants and swine products should be thifensulfuron-methyl. Detectable residues in ruminants and swine commodities are also not expected and validated analytical methods for enforcement of the residue definition are available with an LOQ of 0.01 mg/kg in milk, cream, meat, fat, liver, kidney and eggs.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	3 days in milk
	5 days in eggs
Animal residue definition for monitoring	Thifensulfuron-methyl (parent only) (Reg. (EU) No 617/2014) *
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

Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

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

Table 7.4-8: Summary of EU reported and new data supporting the intended uses of DNT-162OD-R-CPd 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	New trials	N-EU	Trials GAP: 1 x 0.012 kg as/ha, BBCH 16, outdoor 4 x <0.01 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	4 x <0.01 mg/kg	0.01	0.01	0.01	0.01*	Yes
Maize straw	New trials	N-EU	Trials GAP: 1 x 0.012 kg as/ha, BBCH 16, outdoor 4 x <0.01 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	4 x <0.01 mg/kg	0.01	0.01	-	-	-

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

7.4.3.2 Conclusion on the magnitude of residues in plants

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

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

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

Table 7.4-9: Input values for the dietary burden calculation using Animal model 2017 (considering the intended uses)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Thifensulfuron-methyl and provisionally triazine amine (IN-A4098)				
Corn, field grain	0.01	STMR	-	
Corn, pop grain	0.01	STMR	-	
Corn, field milled by-pdts	0.01	STMR x PF	-	
Corn, field hominy meal	0.01	STMR x PF	-	
Corn, field gluten feed	0.01	STMR x PF	-	
Corn, field gluten meal	0.01	STMR x PF	-	
Distiller's grain	0.01	STMR x PF	-	
Corn, field stover	0.01	STMR	0.01	HR
Corn, pop stover	0.01	STMR	0.01	HR

STMR residue maize grain and stover (**Table 7.3-10**),), PF = 1 (default PF waived in case residues in RAC <LOQ) (Animal model 2017.xls)

Table 7.4-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Thifensulfuron-methyl and provisionally triazine amine (IN-A4098)					
Beef cattle*	0.0004	0.000	Corn, field gluten feed	0.02	N
Dairy cattle*	0.0005	0.001	Corn, field gluten feed	0.01	N
Ram/ewe	0.0004	0.001	Corn, field gluten feed	0.02	N
Lamb	0.0005	0.001	Corn, field gluten feed	0.02	N
Breeding swine	0.000	0.000	Corn, field milled bypdts	0.01	N

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Finishing swine*	0.001	0.001	Corn, field milled bypdts	0.01	N
Broiler poultry	0.001	0.001	Corn, field milled bypdts	0.01	N
Layer poultry*	0.001	0.001	Corn, field milled bypdts	0.01	N
Turkey	0.001	0.001	Corn, field milled bypdts	0.01	N

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

7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009, above 0.004 mg/kg. Therefore livestock feeding studies are not required.

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

No further studies has been performed. Thifensulfuron-methyl residue levels in maize grain are below 0.01 mg/kg. Therefore magnitude of residues in processed commodities are not requires.

7.4.6 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 **Błąd! Nie można odnaleźć źródła odwołania.**), no study dealing with magnitude of residues in succeeding crops is needed.

7.4.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of DNT-162OD-R-CPd. Therefore, other special studies are not needed.

Maize is not melliferous plant according to SANTE/11956/2016 rev. 9 and is not foraged by bees, therefore residue in honey study is not required.

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

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

7.4.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Thifensulfuron-methyl and provisionally triazine amine (IN-A4098)				
Maize	0.01*	EU MRL (In force MRL according to Reg. (EU) No 617/2014)	0.01*	EU MRL (In force MRL according to Reg. (EU) No 617/2014)
All other crops	various		-	-

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.4-12: Consumer risk assessment

	Normal mode	Refined mode
TMDI (% ADI) according to EF-SA PRIMo rev. 3.1	12 % (based on NL toddler)	0.7% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	TMDI values do not exceed ADI therefore IEDI calculations are not required.	TMDI values do not exceed ADI therefore IEDI calculations are not required.
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Raw commodities: Potatoes: 0.08 % (based on children) Head cabbage: 0.02 % (adults) Processed commodities: Sugar beet root/sugar: 0.1 % (based on children) Sugar beet root/sugar: 0.02 % (adults)	Raw commodities: 0% Processed commodities: 0%
NTMDI (% ADI) **	Not necessary	Not necessary
NEDI (% ADI)**	Not necessary	Not necessary
NESTI (% ARfD) **	Not required	Not required

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

The proposed uses of thifensulfuron-methyl in the formulation EVRITELL 162 OD 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 mul-

tiple active substances; this approach is not mandatory at EU level.

The product is a mixture of three active substances and for at least two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.5.1 Acute consumer risk assessment from combined exposure

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.2) 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)	HQ (based on NESTI according to national model)*
Maize	Dicamba	0.011333	-
	Nicosulfuron	0	-
	Thifensulfuron methyl	0.000035	-
	Cumulative risk maize (HI)	**0.011368**	**-**

* if national model wanted, otherwise to be deleted

The Hazard Index is <1. Thus combined exposure to all active substances in DNT-162OD-R-CPd 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.

7.6 References

EFSA Journal 2011;9(1):1965, Conclusion on the peer review of the pesticide risk assessment of the active substance dicamba.

SANCO/829/08 – final rev. 2,12 July 2016, Review report for the active substance dicamba.

Commission Regulation (EU) 2015/845 of 27 May 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, chlorantraniliprole, cyantraniliprole, dicamba, difenoconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapic, imazapyr, indoxacarb, isoxaflutole, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spirotetramat and trinexapac in or on certain products.

Draft Assessment Report, Initial risk assessment provided by the Member State Denmark for the existing active substance Dicamba, Volume 3, Annex B, part 3, B.7, November 2007.

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

EFSA Scientific Report (2007) 120, 1-91, Conclusion on the peer review of nicosulfuron, Conclusion regarding the peer review of the pesticide risk assessment of the active substance nicosulfuron finalised: 29 November 2007.

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

Draft Assessment Report (DAR) Initial risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance Nicosulfuron of the third stage (part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC, Volume 3, Annex B, B.7, June 2006.

COMMISSION REGULATION (EU) No 617/2014 of 3 June 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ethoxysulfuron, metsulfuron-methyl, nicosulfuron, prosulfuron, rimsulfuron, sulfosulfuron and thifensulfuron-methyl in or on certain products.

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

Final Review report for the active substance thifensulfuron-methyl finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 12 July 2016 in view of the renewal of the approval of the active substance thifensulfuron-methyl in accordance with Regulation (EC) No 1107/2009, Thifensulfuron-methyl SANTE/10150/2016 rev. 2 12 July 2016.

DAR July 2014, Thifensulfuron-methyl - Volume 3, Annex B.7 : Residues.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCA 6.3/01	Thomas-Delille E.	2023	Determination of Dicamba, Nicosulfuron and Thifensulfuron-methyl Residues in Maize Following Foliar application with DNT-162OD-R-CPd under Field Conditions in Northern Europe in 2022 C2156 Anadiag GLP Unpublished	N	CIECH Sarzyna S.A.
KCA 6.3/02	Thomas-Delille E.	2023	Amendment no. R C2156_230908 to final report no. R C2156 Anadiag GLP Unpublished	N	CIECH Sarzyna S.A.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1/01	[redacted]	1996	Stability of Dicamba and 3,6-Dichlorosalicylic acid in stored frozen beef tissues and milk SAN837/5242 ! 5242 ! 480068 ! 151 ! DP-304489 ! 95/01/09A [redacted] fGLP: Yes Published: No	Y	SYD
KCA 6.1/02	Jimenez, N. C.	1995	Stability of Dicamba and 5-Hydroxy Dicamba in stored frozen field corn SAN837/5433 ! 5433 ! 480068 ! 127 ! DP-301949 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	SYD
KCA 6.1/03	Schulz, M.; Ullrich-Mitzel, A.	1995	Storage stability of SL-950 and its metabolites ASDM and ADMP in corn plants and ears RCC 304762 GLP: Yes Published: No	N	ISK Task Force Nicosulfuron
KCA 6.1/04	Schanné, C.	1991	^{14}C-SL-950 (P) Plant metabolism study with corn in the greenhouse RCC Umweltchemie AG, GLP: Yes Published: No	N	ISK Task Force Nicosulfuron
KCA 6.1/05	Sadgrove, L.	2012	THIFENSULFURON-METHYL AND METSULFURON METHYL: Storage Stability of Residues in Wheat Matrices When Stored at Approximately -20°C for Twelve Months HLS Ltd Report No.: PII0018 GLP, Unpublished	N	ROT
KCA 6.2.1/01	Mamouni, A.	1995	^{14}C-SL-950 (P) Plant metabolism study with corn in the greenhouse 272158 GLP: Open Published: Open	N	ISK Task Force Nicosulfuron
KCA 6.2.1/02	Butz, R. G.	1982	Foliar absorption, metabolism and translocation of Dicamba by cotton plants SAN837/5140 ! 5140 ! 44 ! DP 302643 ! 480068 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes	N	SYD

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**
			Published: No		
KCA 6.2.1/03	Butz, R. G.	1984	Characterization of radiocarbon from seeds of 14C-Dicamba treated cotton plants after acid hydrolysis SAN837/5255 ! 5255 ! 70 ! DP302642 ! 480068 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	SYD
KCA 6.2.1/04	Butz, R. G.; Atallah, Y. H.	1981	Metabolic fate of Dicamba in sugarcane plants SAN837/5160 ! DP302640 ! 480068 ! 24 Novartis Crop Protection AG, Basel, Switzerland GLP: No Published: No	N	SYD
KCA 6.2.1/05	Butz, R. G.; Atallah, Y. H.	1982	Foliar absorption, metabolism and translocation of Dicamba by soybeans at early podfill and late senescent stages SAN837/5260 ! 5260 ! 39 ! 480068 ! DP 302641 Novartis Crop Protection AG, Basel, Switzerland GLP: No Published: No	N	SYD
KCA 6.2.1/06	Völlmin, S.	1999	Metabolism and behavior of Dicamba in fieldgrown spring wheat after application of [Phenyl-(U)-14C] material SAN837/5879 ! 97SV01 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	SYD
KCA 6.2.1/07	Brattsten, L. B.	1987	Metabolism of [triazine-2- 14C]DPX-M6316 in greenhouse-grown soybean plants DuPont Experimental Station AMR 547-86, Revision No. 1 GLP: Yes Published: No	N	DuPont
KCA 6.2.1/08	Brown, H.M.	1987	Metabolism of [thiophene-2- 14C] DPX-M6316 in greenhouse-grown soybeans DuPont Experimental Station AMR 572-86 GLP: No	N	DuPont

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**
			Published: No		
KCA 6.2.1/09	Cotterman J.C.	1987	Metabolism of [Triazine-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in forage and straw DuPont Experimental Station, Wilmington, Delaware, USA AMR 794-87 GLP: No Published: No	N	DuPont
KCA 6.2.1/10	Steveson I.E..	1986	Metabolism of [Thiophene-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in forage and straw DuPont Experimental Station, Wilmington, Delaware, USA AMR 783-87 GLP: No Published: No	N	DuPont
KCA 6.2.1/11	Friedman P.L. and Stevenson I.E	1986	Metabolism of [Thiophene-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in mature grain DuPont Experimental Station, Wilmington, Delaware, USA AMR 498-86 GLP: No Published: No	N	DuPont
KCA 6.2.1/12	Friedman P.L. and Lichtner F.T.	1986	Metabolism of [Triazine-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in mature grain DuPont Experimental Station, Wilmington, Delaware, USA AMR 513-86 GLP: No Published: No	N	DuPont
KCA 6.2.1/13	Wittenbach V.A.	1987	Metabolism of [thiophene-2- 14C] DPX-M6316 and [triazine-2- 14C] DPX-M6316 in field –grown corn DuPont Experimental Station, Wilmington, Delaware, USA AMR 532-86 GLP: No Published: No	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.2-6.2.5/01	[redacted]	1994	Metabolism of Dicamba in lactating goats SAN837/5286 ! 5286 ! 28 ! 480065 ! DP-301499 [redacted] GLP: Yes Published: No	Y	SYD
KCA 6.2.2-6.2.5/02	[redacted]	1994	Dicamba: Metabolism in laying hens SAN837/5285 ! 5285 ! 25 ! 480065 ! DP301493 [redacted] GLP: Yes Published: No	Y	SYD
KCA 6.2.2-6.2.5/03	[redacted]	1980	Metabolic fate of the herbicide Dicamba in a lactating cow CBK 101'296/87 ! SAN837/5145 GLP: No Published: No	Y	SYD
KCA 6.2.2-6.2.5/04	[redacted]	1983	Pharmacokinetics and metabolism of 14C-Dicamba in hens SAN837/5254 ! CBK 12 144/88 ! 480068 ! 65 ! DP 302659 ! CBK 101 428/87 [redacted] GLP: No Published: No	Y	SYD
KCA 6.2.2-6.2.5/05	[redacted]	1986	Goat metabolism study of ^{14}C-DPX-M6316 AMR 326-85 GLP: No Published: No	Y	DuPont
KCA 6.2.2-6.2.5/06	[redacted]	1992	Metabolism of ^{14}C-DPX-M6316 in laying hens AMR-2022-91 GLP: No Published: No	Y	DuPont
KCA 6.5.1	Grout, S. J.	2003	Aqueous hydrolysis at 90, 100 & 120°C. SAN837/6087 ! 6087 ! RJ3333B Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	SYD
KCA	Moore, P. A.; Butz,	1989	Confined accumulation studies of Dicamba on rotational crops after spring application SAN837/5108 !	N	SYD

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**
6.6.1/01	R. G.		CBK 13'004/89 ! 16 ! 480065 ! DP 302788 Novartis Crop Protection AG, Basel, Switzerland GLP: No Published: No		
KCA 6.6.1/02	Pierotti, M. V.	1995	Confined accumulation studies of Dicamba on rotational crops SAN837/5282 ! 5282 ! 22 ! DP 301712 ! 480065 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	SYD
KCA 6.6.1/03	Hardesty P.T	1984	Crop rotation studies with DPX-M6316 [Thiophene-2- 14C] in the greenhouse DuPont Experimental Station, Wilmington, Delaware, USA AMR 256-84 GLP: No Published: No	N	DuPont
KCA 6.6.1/04	Brown A.M	1987	Greenhouse accumulation study of [triazine-2- 14C]DPX-M6316 on rotational crops DuPont Experimental Station, Wilmington, Delaware, USA AMR 582-86 GLP: No Published: No	N	DuPont
KCA 6.6.1/05	Ferguson E.M.	1992	Confined Accumulation Study of 14C-DPX-M6316 on Wheat as a Rotational Crop DuPont Experimental Station, Wilmington, Delaware, USA AMR 858-87 GLP: No Published: No	N	DuPont

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Dicamba

A 2.1.1 Stability of residues

No new or additional studies have been submitted.

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

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	1	0.360 kg as/ha	-	Post-emergence until BBCH 16	-
Intended cGAP (1*)	1	0.110 kg/ha	-	Post-emergence of weeds, crop BBCH 12-16	-

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted. Trials are independent and valid in terms of storage stability data. They were performed in accordance with the proposed application. The field phase was performed and reported in accordance with current requirements. The analytical method used was properly validated. Detailed method validation is presented and accepted in section B5.

Reference:	KCA 6.3
Report	Determination of Dicamba, Nicosulfuron and Thifensulfuron-methyl Residues in Maize Following Foliar application with DNT-162OD-R-CPd under Field Conditions in Northern Europe in 2022, Thomas-Delille E.,2023, R C2156
Guideline(s):	Yes (OECD 509, Sante/2019/12752))
Deviations:	No

GLP: Yes

Acceptability: Yes

Four new residue trials in maize were conducted in the growing season 2021/2022. The test item was maize grains and straw samples treated with product DNT-162OD-R-CPd and control samples. The product was applied once at rate of 1.0 L/ha (corresponding to 110 g/ha of dicamba). Specimens were collected at normal commercial harvest. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Maize samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 263 days. Results on residue trials in maize are detailed summarised in Table A2. The residues of dicamba in grain samples treated with DNT-162OD-R-CPd were below the limit of quantification, i.e. 0.01 mg/kg. Hence, they were below the maximum residue limits, i.e 0.5 mg/kg in maize. Detailed method validation is presented in section B5.

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Dicamba	5-OH-dicamba		
	(a)	(b)				(c)					(d)	(e)
C2156 ND1 Steenbecquw 59189 Northern France	Maize/Metropolixx	1. 28/04/2022 2. 10/07/2022 to 20/08/2022 3. 26/10/2022	113.7	207	55.0	28/06/2022	16	Grain Straw	NDR NDR	NDR 0.03	111 111	LOQ = 0.01 mg/kg
C2156 BW1 Schweighofen 76889 Germany	Maize/A75	1. 21/04/2022 2. 30/06/2022 to 15/07/2022 3. 26/09/2022	100.2	273	36.7	22/05/2022	16	Grain Straw	NDR NDR	NDR <LOQ	123 123	LOQ = 0.01 mg/kg
C2156 PL1 Swinice Warckie 99140 Poland	Maize/AGRO POLIS	1. 30/04/2022 2. 05/07/2022 to 24/07/2022 3. 13/10/2022	114.9	313	36.7	08/06/2022	16	Grain Straw	NDR NDR	NDR <LOQ	126 126	LOQ = 0.01 mg/kg
C2156 HU1 Mocsa 2911 Hungary	Maize/DKC4391	1. 26/04/2022 2. 13/06/2022 to 17/06/2022 3. 15/10/2022	111.2	303	36.7	26/05/2022	16	Grain Straw	NDR NDR	NDR NDR	133 133	LOQ = 0.01 mg/kg

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (below the LOD ; LOD = 0.002 mg/kg for Dicamba and 5-OH-dicamba (corresponding to 0.003 mg/kg for Dicamba glycoside and 5-OH-dicamba glycoside))

A 2.1.4 Magnitude of residues in livestock

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 2.1.6 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 Nicosulfuron

A 2.2.1 Stability of residues

No new or additional studies have been submitted.

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

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 3: 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	1	60 g sa/ha	-	BBCH 12-18	-
Intended cGAP (1*)	1	40 g sa/ha	-	Post-emergence of weeds, crop BBCH 12-16	-

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

A 2.2.3.1.1 Study 1

Comments of zRMS:	Study is accepted Trials are independent and valid in terms of storage stability data. They were performed in accordance with the proposed application. The field phase was performed and reported in accordance with current requirements. The analytical method used was properly validated. Detailed method validation is presented and accepted in section B5.

Reference:	KCA 6.3/01
Report	Determination of Dicamba, Nicosulfuron and Thifensulfuron-methyl Residues in Maize Following Foliar application with DNT-162OD-R-CPd under Field Conditions in Northern Europe in 2022, Thomas-Delille E.,2023, R C2156
Guideline(s):	Yes (OECD 509, Sante/2019/12752))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Comments of zRMS:	Study is accepted

Reference:	KCA 6.3/02
Report	Amendment no. RC2156_230908 to final report no. R C2156, Thomas-Delille E.,2023, R C2156
Guideline(s):	Yes (OECD 509, Sante/2019/12752))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four new residue trials in maize were conducted in the growing season 2021/2022. The test item was maize grains and straw samples treated with product DNT-162OD-R-CPd and control samples. The product was applied once at rate of 1.0 L/ha (corresponding to 40 g/ha of nicosulfuron). Specimens were collected at normal commercial harvest. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Maize samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 134 days. Results on residue trials in maize are detailed summarised in Table A4. The residues of nicosulfuron in grain samples treated with DNT-162OD-R-CPd were below the limit of quantification, i.e. 0.01 mg/kg. Hence, they were below the maximum residue limits, i.e 0.01 mg/kg in maize. Detailed method validation is presented in section B5.

Table A 4: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Nicosulfuron		
	(a)	(b)				(c)				(d)	(e)
C2156 ND1 Steenbecquw 59189 Northern France	Maize/Metropolixx	1. 28/04/2022 2. 10/07/2022 to 20/08/2022 3. 26/10/2022	41.3	207	20.0	28/06/2022	16	Grain Straw	NDR NDR	111 111	LOQ = 0.01 mg/kg
C2156 BW1 Schweighofen 76889 Germany	Maize/A75	1. 21/04/2022 2. 30/06/2022 to 15/07/2022 3. 26/09/2022	36.4	273	13.3	22/05/2022	16	Grain Straw	NDR NDR	123 123	LOQ = 0.01 mg/kg
C2156 PL1 Swinice Warckie 99140 Poland	Maize/AGRO POLIS	1. 30/04/2022 2. 05/07/2022 to 24/07/2022 3. 13/10/2022	41.8	313	13.3	08/06/2022	16	Grain Straw	NDR NDR	126 126	LOQ = 0.01 mg/kg
C2156 HU1 Mocsa 2911 Hungary	Maize/DKC4391	1. 26/04/2022 2. 13/06/2022 to 17/06/2022 3. 15/10/2022	40.4	303	13.3	26/05/2022	16	Grain Straw	NDR NDR	133 133	LOQ = 0.01 mg/kg

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (below the LOD ; LOD = 0.003 mg/kg)

A 2.2.4 Magnitude of residues in livestock

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 2.2.6 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 2.1 Thifensulfuron methyl

A 2.1.1 Stability of residues

No new or additional studies have been submitted.

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

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 5: 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	1-2	1 × 5.6-11.25 g as/ha or 5.6235+ 3.75 = 9.375 g as/ha(total) or 2 × 3.75 = 7.5 g as/ha (total)	7/10	BBCH 12-18	n/a, except 60 (DK, SE, LI silage or feed of whole plant, cob, kernels)
cGAP EU (Art. 12,	1	15 g as/ha	-	BBCH 12-18	-

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
EFSA, 2012)					
Intended cGAP (1*)	1	12 g as/ha	1	Post-emergence of weeds, crop BBCH 12-16	-

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted Trials are independent and valid in terms of storage stability data. They were performed in accordance with the proposed application. The field phase was performed and reported in accordance with current requirements. The analytical method used was properly validated. Detailed method validation is presented and accepted in section B5.

Reference:	KCA 6.3
Report	Determination of Dicamba, Nicosulfuron and Thifensulfuron-methyl Residues in Maize Following Foliar application with DNT-162OD-R-CPd under Field Conditions in Northern Europe in 2022, Thomas-Delille E.,2023, R C2156
Guideline(s):	Yes (OECD 509, Sante/2019/12752))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four new residue trials in maize were conducted in the growing season 2021/2022. The test item was maize grains and straw samples treated with product DNT-162OD-R-CPd and control samples. The product was applied once at rate of 1.0 L/ha (corresponding to 12 g/ha of Thifensulfuron methyl). Specimens were collected at normal commercial harvest. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Maize samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 134 days. Results on residue trials in maize are detailed summarised in Table A6. The residues of Thifensulfuron methyl in grain samples treated with DNT-162OD-R-CPd were below the limit of quantification, i.e. 0.01 mg/kg. Hence, they were below the maximum residue limits, i.e 0.01 mg/kg in maize. Detailed method validation is presented in section B5.

Table A 6: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				IN-A4098	Thifensulfuron methyl		
C2156 ND1 Steenbecquw 59189 Northern France	Maize/Metropolixx	1. 28/04/2022 2. 10/07/2022 to 20/08/2022 3. 26/10/2022	12.4	207	6.0	28/06/2022	16	Grain Straw	NDR NDR	NDR NDR	111 111	LOQ = 0.01 mg/kg
C2156 BW1 Schweighofen 76889 Germany	Maize/A75	1. 21/04/2022 2. 30/06/2022 to 15/07/2022 3. 26/09/2022	10.9	273	4.0	22/05/2022	16	Grain Straw	NDR NDR	NDR NDR	123 123	LOQ = 0.01 mg/kg
C2156 PL1 Swinice Warckie 99140 Poland	Maize/AGRO POLIS	1. 30/04/2022 2. 05/07/2022 to 24/07/2022 3. 13/10/2022	12.5	313	4.0	08/06/2022	16	Grain Straw	NDR NDR	NDR NDR	126 126	LOQ = 0.01 mg/kg
C2156 HU1 Mocsa 2911 Hungary	Maize/DKC4391	1. 26/04/2022 2. 13/06/2022 to 17/06/2022 3. 15/10/2022	12.1	303	4.0	26/05/2022	16	Grain Straw	NDR NDR	NDR NDR	133 133	LOQ = 0.01 mg/kg

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (below the LOD ; LOD = 0.003 mg/kg)

A 2.1.4 Magnitude of residues in livestock

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 2.1.6 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.

Appendix 3 Pesticide Residue Intake Model (PRIMo rev.3.1)

Dicamba

A 3.1 TMDI calculations (normal mode)

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : –

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	19%	GEMS/Food G11	57,54	12%	Soyabeans	2%	Wheat	2%	Barley	0,3%	0,0%
	17%	GEMS/Food G10	51,27	11%	Soyabeans	3%	Wheat	1%	Barley	0,3%	0,1%
	16%	NL toddler	48,50	10%	Milk: Cattle	3%	Wheat	1%	Maize/corn	0,6%	1%
	14%	GEMS/Food G08	40,80	7%	Soyabeans	3%	Wheat	2%	Barley	0,3%	0,1%
	13%	GEMS/Food G15	38,94	6%	Soyabeans	3%	Wheat	2%	Barley	0,3%	0,1%
	13%	GEMS/Food G07	37,67	6%	Soyabeans	3%	Wheat	1%	Barley	0,3%	0,1%
	11%	GEMS/Food G06	32,96	5%	Wheat	4%	Soyabeans	0,6%	Sugar canes	0,3%	0,2%
	9%	UK infant	27,10	6%	Milk: Cattle	2%	Wheat	0,2%	Bovine: Muscle/meat	0,2%	0,2%
	9%	NL child	25,55	4%	Milk: Cattle	3%	Wheat	0,7%	Soyabeans	0,5%	0,0%
	8%	FR child 3 15 yr	23,60	4%	Milk: Cattle	3%	Wheat	0,2%	Bovine: Muscle/meat	0,3%	0,1%
	8%	FR toddler 2 3 yr	23,48	5%	Milk: Cattle	2%	Wheat	0,2%	Bovine: Muscle/meat	0,3%	0,0%
	8%	DE child	23,31	3%	Milk: Cattle	3%	Wheat	0,4%	Apples	0,4%	0,0%
	7%	UK toddler	20,13	3%	Milk: Cattle	3%	Wheat	0,2%	Bovine: Muscle/meat	0,3%	0,0%
	7%	DK child	19,84	3%	Wheat	2%	Milk: Cattle	0,9%	Rye	0,2%	0,0%
	6%	RO general	17,67	3%	Wheat	2%	Milk: Cattle	0,2%	Maize/corn	0,3%	0,2%
	6%	ES child	17,20	3%	Wheat	2%	Milk: Cattle	0,2%	Bovine: Muscle/meat	0,2%	0,0%
	5%	DE general	16,28	2%	Milk: Cattle	1%	Wheat	1%	Barley	0,2%	0,0%
	5%	SE general	16,26	2%	Wheat	2%	Milk: Cattle	0,7%	Bovine: Muscle/meat	0,3%	
	5%	DE women 14-50 yr	14,74	2%	Milk: Cattle	1%	Wheat	0,4%	Barley	0,3%	0,0%
	5%	IT toddler	14,52	4%	Wheat	0,2%	Other cereals	0,0%	Apples	0,1%	0,0%
	4%	NL general	12,92	1%	Milk: Cattle	1%	Wheat	0,7%	Barley	0,2%	0,0%
	4%	PT general	12,48	3%	Wheat	1%	Soyabeans	0,1%	Potatoes	0,2%	0,1%
	4%	ES adult	11,92	2%	Wheat	1%	Barley	0,8%	Milk: Cattle	0,2%	0,0%
	4%	FR infant	10,98	3%	Milk: Cattle	0,5%	Wheat	0,1%	Bovine: Muscle/meat	0,2%	0,0%
	3%	IE adult	9,72	2%	Wheat	0,7%	Milk: Cattle	0,2%	Asparagus	0,4%	0,0%
	3%	IT adult	9,18	3%	Wheat	0,1%	Other cereals	0,0%	Apples	0,1%	0,0%
	3%	FR adult	8,09	1%	Wheat	0,7%	Milk: Cattle	0,1%	Bovine: Muscle/meat	0,2%	0,0%
	2%	UK vegetarian	6,55	1%	Wheat	0,5%	Milk: Cattle	0,0%	Barley	0,1%	0,0%
	2%	DK adult	6,05	0,9%	Milk: Cattle	0,7%	Wheat	0,1%	Bovine: Muscle/meat	0,1%	
	2%	UK adult	5,93	1%	Wheat	0,5%	Milk: Cattle	0,1%	Bovine: Muscle/meat	0,1%	0,0%
	2%	LT adult	5,92	0,7%	Wheat	0,7%	Milk: Cattle	0,2%	Rye	0,1%	0,0%
	1%	FI 3 yr	4,44	0,8%	Wheat	0,2%	Barley	0,1%	Rye	0,2%	0,0%
	1%	IE child	4,43	0,8%	Wheat	0,6%	Milk: Cattle	0,0%	Rice	0,0%	0,0%
	1%	FI 6 yr	3,57	0,6%	Wheat	0,1%	Barley	0,1%	Rye	0,2%	0,0%
	0,7%	FI adult	2,07	0,2%	Wheat	0,1%	Rye	0,1%	Coffee beans	0,2%	0,0%
	0,2%	PL general	0,64	0,1%	Apples	0,1%	Potatoes	0,0%	Tomatoes	0,1%	0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

TMDI do not exceed ADI therefore IEDI calculation is not required.

A 3.3 IESTI calculations - Raw commodities (normal mode)

Unprocessed commodities

Show results for all crops

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
32%	Asparagus	5 / 5	96
21%	Milk: Cattle	0,5 / 0,5	62
13%	Barley	7 / 7	39
10%	Wheat	2 / 2	29
8%	Soyabeans	10 / 10	23
4%	Sorghum	4 / 4	13
4%	Apples	0,1 / 0,1	11
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Soyabeans	10 / 10	55
13%	Asparagus	5 / 5	38
11%	Barley	7 / 7	34
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
6%	Milk: Cattle	0,5 / 0,5	19
6%	Wheat	2 / 2	17
5%	Rooibos	40 / 40	16
5%	Rooibos	40 / 40	16
4%	Hybiscus/roselle	40 / 40	12
2%	Parsley	4 / 4	4,8
1%	Milk: Goat	0,2 / 0,2	3,7

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
33%	Asparagus	5 / 5	98
21%	Milk: Cattle	0,5 / 0,5	62
13%	Barley	7 / 7	39
10%	Wheat	2 / 2	29
8%	Soyabeans	10 / 10	23
4%	Sorghum	4 / 4	13
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
3%	Chamomille	40 / 40	8,0
2%	Apples	0,1 / 0,1	6,2

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Asparagus	5 / 5	89
18%	Soyabeans	10 / 10	55
11%	Barley	7 / 7	34
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
8%	Chamomille	40 / 40	24
6%	Milk: Cattle	0,5 / 0,5	19
6%	Wheat	2 / 2	17
5%	Rooibos	40 / 40	16
5%	Rooibos	40 / 40	16
4%	Hybiscus/roselle	40 / 40	12
2%	Parsley	4 / 4	4,8
1%	Milk: Goat	0,2 / 0,2	3,7

A 3.4 IESTI calculations - Processed commodities (normal mode)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Soyabeans / soya drink	10 / 10	42	17%	Barley / beer	7 / 1,4	50	14%	Soyabeans / soya drink	10 / 10	42	17%	Barley / beer	7 / 1,4	50
8%	Barley / cooked	7 / 7	25	3%	Wheat / bread/pizza	2 / 2	8,8	8%	Barley / cooked	7 / 7	25	3%	Wheat / bread/pizza	2 / 2	8,8
8%	Wheat / milling (flour)	2 / 2	24	3%	Wheat / pasta	2 / 2	7,6	8%	Wheat / milling (flour)	2 / 2	24	3%	Wheat / pasta	2 / 2	7,6
5%	Soyabeans / boiled	10 / 4	15	2%	Wheat / bread (wholemeal)	2 / 2	7,0	5%	Soyabeans / boiled	10 / 4	15	2%	Wheat / bread (wholemeal)	2 / 2	7,0
4%	Barley / milling (flour)	7 / 7	13	2%	Maize / oil	0,5 / 12,5	6,3	4%	Barley / milling (flour)	7 / 7	13	2%	Maize / oil	0,5 / 12,5	6,3
4%	Maize / oil	0,5 / 12,5	12	2%	Sugar canes / sugar	1 / 1	5,7	4%	Maize / oil	0,5 / 12,5	12	2%	Sugar canes / sugar	1 / 1	5,7
4%	Wheat / milling (wholemeal)	2 / 2	11	1%	Apples / juice	0,1 / 0,1	3,3	4%	Wheat / milling	2 / 2	11	1%	Apples / juice	0,1 / 0,1	3,3
3%	Sugar canes / sugar	1 / 1	9,2	0,9%	Pumpkins / boiled	0,05 / 0,05	2,8	3%	Sugar canes / sugar	1 / 1	9,2	0,7%	Sugar beets (root) / sugar	0,05 / 0,6	2,2
2%	Sugar beets (root) / sugar	0,05 / 0,6	5,5	0,7%	Sugar beets (root) / sugar	0,05 / 0,6	2,2	2%	Sugar beets (root) / sugar	0,05 / 0,6	5,5	0,7%	Pumpkins / boiled	0,05 / 0,05	2,0
2%	Apples / juice	0,1 / 0,1	5,4	0,7%	Cauliflowers / boiled	0,05 / 0,05	2,1	2%	Apples / juice	0,1 / 0,1	5,4	0,4%	Cauliflowers / boiled	0,05 / 0,05	1,2
2%	Potatoes / fried	0,05 / 0,05	4,7	0,6%	Beetroots / boiled	0,05 / 0,05	1,9	1,0%	Potatoes / dried (flakes)	0,05 / 0,23	3,0	0,4%	Rooibos leaves / infusion	40 / 0,4	1,2
1%	Pumpkins / boiled	0,05 / 0,05	4,4	0,6%	Celeries / boiled	0,05 / 0,05	1,7	0,9%	Camomille flowers /	40 / 0,4	2,8	0,4%	Camomille flowers / infusion	40 / 0,4	1,2
1%	Witloofs / boiled	0,05 / 0,05	4,4	0,4%	Broccoli / boiled	0,05 / 0,05	1,2	0,9%	Camomille flowers /	40 / 0,4	2,8	0,4%	Rice / milling (polishing)	0,3 / 0,12	1,2
1%	Broccoli / boiled	0,05 / 0,05	3,9	0,4%	Rooibos leaves / infusion	40 / 0,4	1,2	0,9%	Pumpkins / boiled	0,05 / 0,05	2,7	0,4%	Witloofs / boiled	0,05 / 0,05	1,1
1%	Cauliflowers / boiled	0,05 / 0,05	3,5	0,4%	Camomille flowers /	40 / 0,4	1,2	0,9%	Oranges / juice	0,05 / 0,05	2,6	0,3%	Wine grapes / juice	0,05 / 0,05	1,0
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.5 TMDI calculations (refined mode)

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : –

	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1%	NL toddler	3,52	1%	Maize/corn						1%
	0,2%	GEMS/Food G06	0,63	0,2%	Maize/corn		FRUIT AND TREE NUTS				0,2%
	0,2%	UK infant	0,51	0,2%	Maize/corn		FRUIT AND TREE NUTS				0,2%
	0,2%	RO general	0,48	0,2%	Maize/corn		FRUIT AND TREE NUTS				0,2%
	0,1%	GEMS/Food G10	0,33	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	GEMS/Food G15	0,32	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	PT general	0,24	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	GEMS/Food G08	0,22	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	FR child 3 15 yr	0,21	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	GEMS/Food G07	0,15	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,0%	ES child	0,14	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	NL child	0,14	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IE adult	0,11	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DE child	0,08	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	GEMS/Food G11	0,06	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	NL general	0,05	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FR toddler 2 3 yr	0,04	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	ES adult	0,04	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DE women 14-50 yr	0,03	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FR adult	0,03	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DE general	0,03	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IT toddler	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FI 6 yr	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FR infant	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IT adult	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FI 3 yr	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	UK toddler	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	UK vegetarian	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	LT adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FI adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	UK adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	PL general	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IE child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DK child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
		DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
		DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.6 IEDI calculations

TMDI do not exceed ADI therefore IEDI calculation is not required.

A 3.7 IESTI calculations - Raw commodities (refined mode)

Unprocessed commodities

Show results for all crops

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

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

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

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

IESTI				**IESTI**				IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Maize/corn	0,5 / 0,5	3,4	0,4%	Maize/corn	0,5 / 0,5	1,1	1%	Maize/corn	0,5 / 0,5	3,4	0,4%	Maize/corn	0,5 / 0,5	1,1

Expand/collapse list

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

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

A 3.8 IESTI calculations - Processed commodities (refined mode)

Processed commodities

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

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

IESTI

Highest % of ARfD/ADI (children)	Processed commodities (children)	MRL / input for RA (mg/kg) (children)	Exposure (µg/kg bw) (children)	Highest % of ARfD/ADI (adults)	Processed commodities (adults)	MRL / input for RA (mg/kg) (adults)	Exposure (µg/kg bw) (adults)
4%	Maize / oil	0,5 / 12,5	12	2%	Maize / oil	0,5 / 12,5	6,3
0,4%	Maize / processed (not spec	0,5 / 0,5	1,1	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list

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

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

IESTI new

Highest % of ARfD/ADI (children)	Processed commodities (children)	MRL / input for RA (mg/kg) (children)	Exposure (µg/kg bw) (children)	Highest % of ARfD/ADI (adults)	Processed commodities (adults)	MRL / input for RA (mg/kg) (adults)	Exposure (µg/kg bw) (adults)
4%	Maize / oil	0,5 / 12,5	12	2%	Maize / oil	0,5 / 12,5	6,3
0,4%	Maize / processed (not	0,5 / 0,5	1,1	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.1 Nicosulfuron

A 3.2 TMDI calculations (normal mode)

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : –

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	0,1%	NL toddler	1,91	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Maize/corn	0,1%	0,0%
	0,1%	UK infant	1,04	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Eggs: Chicken	0,1%	0,0%
	0,0%	NL child	0,97	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,0%	0,0%
	0,0%	FR toddler 2 3 yr	0,90	0,0%	Milk: Cattle	0,0%	Apples	0,0%	Wheat	0,0%	0,0%
	0,0%	DE child	0,87	0,0%	Milk: Cattle	0,0%	Apples	0,0%	Wheat	0,0%	0,0%
	0,0%	FR child 3 15 yr	0,85	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Sugar beet roots	0,0%	0,0%
	0,0%	UK toddler	0,69	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
	0,0%	DK child	0,59	0,0%	Milk: Cattle	0,0%	Rye	0,0%	Swine: Muscle/meat	0,0%	0,0%
	0,0%	GEMS/Food G11	0,58	0,0%	Milk: Cattle	0,0%	Soyabeans	0,0%	Potatoes	0,0%	0,0%
	0,0%	ES child	0,56	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat	0,0%	0,0%
	0,0%	SE general	0,55	0,0%	Milk: Cattle	0,0%	Bovine: Muscle/meat	0,0%	Potatoes	0,0%	
	0,0%	GEMS/Food G07	0,53	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
	0,0%	RO general	0,53	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
	0,0%	GEMS/Food G15	0,52	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
	0,0%	DE women 14-50 yr	0,52	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,0%	0,0%
	0,0%	GEMS/Food G08	0,51	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Soyabeans	0,0%	0,0%
	0,0%	DE general	0,51	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,0%	0,0%
	0,0%	GEMS/Food G10	0,51	0,0%	Milk: Cattle	0,0%	Soyabeans	0,0%	Wheat	0,0%	0,0%
	0,0%	FR infant	0,47	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples	0,0%	0,0%
	0,0%	GEMS/Food G06	0,45	0,0%	Wheat	0,0%	Milk: Cattle	0,0%	Tomatoes	0,0%	0,0%
	0,0%	NL general	0,43	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Potatoes	0,0%	0,0%
	0,0%	IE adult	0,42	0,0%	Milk: Cattle	0,0%	Sweet potatoes	0,0%	Wheat	0,0%	0,0%
	0,0%	FI adult	0,35	0,0%	Coffee beans	0,0%	Potatoes	0,0%	Rye	0,0%	0,0%
	0,0%	FR adult	0,30	0,0%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat	0,0%	0,0%
	0,0%	ES adult	0,29	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat	0,0%	0,0%
	0,0%	DK adult	0,24	0,0%	Milk: Cattle	0,0%	Swine: Muscle/meat	0,0%	Potatoes	0,0%	
	0,0%	LT adult	0,22	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Swine: Muscle/meat	0,0%	0,0%
	0,0%	PT general	0,22	0,0%	Potatoes	0,0%	Wheat	0,0%	Wine grapes	0,0%	0,0%
	0,0%	UK vegetarian	0,18	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
	0,0%	UK adult	0,18	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
	0,0%	FI 3 yr	0,18	0,0%	Potatoes	0,0%	Bananas	0,0%	Wheat	0,0%	0,0%
	0,0%	IT toddler	0,17	0,0%	Wheat	0,0%	Other cereals	0,0%	Tomatoes	0,0%	0,0%
	0,0%	FI 6 yr	0,14	0,0%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat	0,0%	0,0%
	0,0%	IE child	0,12	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,0%	0,0%
	0,0%	IT adult	0,12	0,0%	Wheat	0,0%	Tomatoes	0,0%	Apples	0,0%	0,0%
	0,0%	PL general	0,10	0,0%	Potatoes	0,0%	Apples	0,0%	Tomatoes	0,0%	0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.3 IEDI calculations

TMDI do not exceed ADI therefore IEDI calculation is not required.

A 3.4 IESTI calculations - Raw commodities (normal mode)

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

A 3.5 IESTI calculations - Processed commodities (normal mode)

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

A 3.6 TMDI calculations (refined mode)

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : –

	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1%	NL toddler	3,52	1%	Maize/corn						1%
	0,2%	GEMS/Food G06	0,63	0,2%	Maize/corn		FRUIT AND TREE NUTS				0,2%
	0,2%	UK infant	0,51	0,2%	Maize/corn		FRUIT AND TREE NUTS				0,2%
	0,2%	RO general	0,48	0,2%	Maize/corn		FRUIT AND TREE NUTS				0,2%
	0,1%	GEMS/Food G10	0,33	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	GEMS/Food G15	0,32	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	PT general	0,24	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	GEMS/Food G08	0,22	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	FR child 3 15 yr	0,21	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,1%	GEMS/Food G07	0,15	0,1%	Maize/corn		FRUIT AND TREE NUTS				0,1%
	0,0%	ES child	0,14	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	NL child	0,14	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IE adult	0,11	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DE child	0,08	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	GEMS/Food G11	0,06	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	NL general	0,05	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FR toddler 2 3 yr	0,04	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	ES adult	0,04	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DE women 14-50 yr	0,03	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FR adult	0,03	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DE general	0,03	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IT toddler	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FI 6 yr	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FR infant	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IT adult	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FI 3 yr	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	UK toddler	0,01	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	UK vegetarian	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	LT adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	FI adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	UK adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	PL general	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	IE child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
	0,0%	DK child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				0,0%
		DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
		DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.7 IEDI calculations

TMDI do not exceed ADI therefore IEDI calculation is not required.

A 3.8 IESTI calculations - Raw commodities (refined mode)

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

A 3.9 IESTI calculations - Processed commodities (refined mode)

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

Thifensulfuron methyl

A 3.10 TMDI calculations (normal mode)

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : –

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

Calculated exposure (% of ADI)	MS Diet	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
12%	NL toddler	1,24	6%	Milk: Cattle	1%	Apples	0,7%	Maize/corn	12%	0,7%
7%	NL child	0,66	2%	Milk: Cattle	0,8%	Sugar beet roots	0,6%	Apples	7%	0,0%
6%	DE child	0,63	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%	
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%	
2%	LT adult	0,16	0,4%	Milk: Cattle	0,3%	Potatoes	0,2%	Apples	2%	0,0%
1%	UK vegetarian	0,15	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	1%	0,0%
1%	FI 6 yr	0,14	0,4%	Potatoes	0,1%	Cocoa beans	0,1%	Wheat	1%	0,0%
1%	UK adult	0,14	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	1%	0,0%
1%	IT adult	0,12	0,4%	Wheat	0,1%	Tomatoes	0,1%	Apples	1%	0,0%
1,0%	PL general	0,10	0,3%	Potatoes	0,2%	Apples	0,1%	Tomatoes	1,0%	0,0%
0,8%	IE child	0,08	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,8%	0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.11 IEDI calculations

TMDI do not exceed ADI therefore IEDI calculation is not required.

A 3.12 IESTI calculations - Raw commodities (normal mode)

Unprocessed commodities

Show results for all crops

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

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

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,08%	Potatoes	0,01 / 0,01	1,5
0,08%	Melons	0,01 / 0,01	1,5
0,07%	Pears	0,01 / 0,01	1,4
0,07%	Oranges	0,01 / 0,01	1,3
0,06%	Milk: Cattle	0,01 / 0,01	1,2
0,06%	Watermelons	0,01 / 0,01	1,2
0,05%	Apples	0,01 / 0,01	1,1
0,05%	Pineapples	0,01 / 0,01	1,0
0,05%	Bananas	0,01 / 0,01	0,97
0,05%	Peaches	0,01 / 0,01	0,95
0,04%	Mangoes	0,01 / 0,01	0,79
0,04%	Grapefruits	0,01 / 0,01	0,79
0,04%	Table grapes	0,01 / 0,01	0,73
0,03%	Cucumbers	0,01 / 0,01	0,66
0,03%	Carrots	0,01 / 0,01	0,63

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,02%	Head cabbages	0,01 / 0,01	0,42
0,02%	Watermelons	0,01 / 0,01	0,41
0,02%	Melons	0,01 / 0,01	0,39
0,02%	Milk: Cattle	0,01 / 0,01	0,39
0,02%	Swedes/rutabagas	0,01 / 0,01	0,34
0,02%	Table grapes	0,01 / 0,01	0,34
0,02%	Oranges	0,01 / 0,01	0,31
0,02%	Pears	0,01 / 0,01	0,31
0,01%	Potatoes	0,01 / 0,01	0,30
0,01%	Pineapples	0,01 / 0,01	0,30
0,01%	Yams	0,01 / 0,01	0,28
0,01%	Apples	0,01 / 0,01	0,28
0,01%	Cucumbers	0,01 / 0,01	0,28
0,01%	Aubergines/egg plants	0,01 / 0,01	0,27
0,01%	Mangoes	0,01 / 0,01	0,26

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,06%	Milk: Cattle	0,01 / 0,01	1,2
0,05%	Melons	0,01 / 0,01	0,91
0,04%	Watermelons	0,01 / 0,01	0,73
0,03%	Oranges	0,01 / 0,01	0,67
0,03%	Potatoes	0,01 / 0,01	0,66
0,03%	Apples	0,01 / 0,01	0,62
0,03%	Bananas	0,01 / 0,01	0,61
0,03%	Pineapples	0,01 / 0,01	0,61
0,03%	Pears	0,01 / 0,01	0,59
0,03%	Peaches	0,01 / 0,01	0,54
0,02%	Apricots	0,01 / 0,01	0,49
0,02%	Mangoes	0,01 / 0,01	0,47
0,02%	Grapefruits	0,01 / 0,01	0,47
0,02%	Table grapes	0,01 / 0,01	0,44
0,02%	Kiwi fruits (green, red,	0,01 / 0,01	0,40

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,02%	Oranges	0,01 / 0,01	0,47
0,02%	Plums	0,01 / 0,01	0,39
0,02%	Milk: Cattle	0,01 / 0,01	0,39
0,02%	Pears	0,01 / 0,01	0,36
0,02%	Mandarins	0,01 / 0,01	0,33
0,02%	Potatoes	0,01 / 0,01	0,31
0,02%	Apples	0,01 / 0,01	0,30
0,01%	Bananas	0,01 / 0,01	0,28
0,01%	Yams	0,01 / 0,01	0,27
0,01%	Kaki/Japanese persimmons	0,01 / 0,01	0,27
0,01%	Head cabbages	0,01 / 0,01	0,25
0,01%	Watermelons	0,01 / 0,01	0,24
0,01%	Wine grapes	0,01 / 0,01	0,24
0,01%	Melons	0,01 / 0,01	0,24
0,01%	Mangoes	0,01 / 0,01	0,23

A 3.13 IESTI calculations - Processed commodities (normal mode)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,1%	Sugar beets (root) / sugar	0,01 / 0,12	1,1	0,0%	Pumpkins / boiled	0,01 / 0,01	0,55	0,06%	Sugar beets (root) / sugar	0,01 / 0,12	1,1	0,02%	Sugar beets (root) / sugar	0,01 / 0,12	0,44
0,0%	Potatoes / fried	0,01 / 0,01	0,93	0,02%	Sugar beets (root) / sugar	0,01 / 0,12	0,44	0,03%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,02%	Pumpkins / boiled	0,01 / 0,01	0,40
0,0%	Pumpkins / boiled	0,01 / 0,01	0,89	0,02%	Cauliflowers / boiled	0,01 / 0,01	0,42	0,03%	Apples / juice	0,01 / 0,01	0,54	0,02%	Apples / juice	0,01 / 0,01	0,33
0,0%	Witloofs / boiled	0,01 / 0,01	0,89	0,02%	Beetroots / boiled	0,01 / 0,01	0,39	0,03%	Pumpkins / boiled	0,01 / 0,01	0,53	0,01%	Cauliflowers / boiled	0,01 / 0,01	0,25
0,0%	Broccoli / boiled	0,01 / 0,01	0,79	0,02%	Celeries / boiled	0,01 / 0,01	0,34	0,03%	Oranges / juice	0,01 / 0,01	0,53	0,01%	Coffee beans / extraction	0,05 / 0,01	0,24
0,0%	Cauliflowers / boiled	0,01 / 0,01	0,70	0,02%	Apples / juice	0,01 / 0,01	0,33	0,02%	Broccoli / boiled	0,01 / 0,01	0,47	0,01%	Witloofs / boiled	0,01 / 0,01	0,22
0,0%	Escaroles/broad-leaved endiv	0,01 / 0,01	0,66	0,01%	Broccoli / boiled	0,01 / 0,01	0,24	0,02%	Witloofs / boiled	0,01 / 0,01	0,47	0,01%	Wine grapes / juice	0,01 / 0,01	0,21
0,0%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,01%	Coffee beans / extraction	0,05 / 0,01	0,24	0,02%	Potatoes / fried	0,01 / 0,01	0,44	0,01%	Celeries / boiled	0,01 / 0,01	0,20
0,0%	Leeks / boiled	0,01 / 0,01	0,57	0,01%	Courgettes / boiled	0,01 / 0,01	0,23	0,02%	Wine grapes / juice	0,01 / 0,01	0,44	0,01%	Broccoli / boiled	0,01 / 0,01	0,20
0,0%	Apples / juice	0,01 / 0,01	0,54	0,01%	Parsnips / boiled	0,01 / 0,01	0,21	0,02%	Cauliflowers / boiled	0,01 / 0,01	0,42	0,01%	Rhubarbs / sauce/puree	0,01 / 0,01	0,19
0,0%	Oranges / juice	0,01 / 0,01	0,53	0,01%	Kohlrabies / boiled	0,01 / 0,01	0,21	0,02%	Escaroles/broad-leaved	0,01 / 0,01	0,40	0,01%	Beetroots / boiled	0,01 / 0,01	0,17
0,0%	Turnips / boiled	0,01 / 0,01	0,51	0,01%	Wine grapes / juice	0,01 / 0,01	0,21	0,02%	Carrots / juice	0,01 / 0,01	0,36	0,01%	Courgettes / boiled	0,01 / 0,01	0,16
0,0%	Parsnips / boiled	0,01 / 0,01	0,51	0,01%	Escaroles/broad-leaved endives /	0,01 / 0,01	0,20	0,02%	Leeks / boiled	0,01 / 0,01	0,33	0,01%	Escaroles/broad-leaved endives /	0,01 / 0,01	0,16
0,0%	Sweet potatoes / boiled	0,01 / 0,01	0,50	0,01%	Florence fennels / boiled	0,01 / 0,01	0,19	0,02%	Pears / juice	0,01 / 0,01	0,33	0,01%	Oranges / juice	0,01 / 0,01	0,15
0,0%	Florence fennels / boiled	0,01 / 0,01	0,45	0,01%	Turnips / boiled	0,01 / 0,01	0,19	0,01%	Currants (red, black and	0,01 / 0,01	0,29	0,01%	Leeks / boiled	0,01 / 0,01	0,14
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.14 TMDI calculations (refined mode)

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	0,7%	NL toddler	0,07	0,7%	Maize/corn					0,7%	0,7%
	0,1%	GEMS/Food G06	0,01	0,1%	Maize/corn		FRUIT AND TREE NUTS			0,1%	0,1%
	0,1%	UK infant	0,01	0,1%	Maize/corn		FRUIT AND TREE NUTS			0,1%	0,1%
	0,1%	RO general	0,01	0,1%	Maize/corn		FRUIT AND TREE NUTS			0,1%	0,1%
	0,1%	GEMS/Food G10	0,01	0,1%	Maize/corn		FRUIT AND TREE NUTS			0,1%	0,1%
	0,1%	GEMS/Food G15	0,01	0,1%	Maize/corn		FRUIT AND TREE NUTS			0,1%	0,1%
	0,0%	PT general	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	GEMS/Food G08	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	FR child 3 15 yr	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	GEMS/Food G07	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	ES child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	NL child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	IE adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	DE child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	GEMS/Food G11	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	NL general	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	FR toddler 2 3 yr	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	ES adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	DE women 14-50 yr	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	FR adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	DE general	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	IT toddler	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	FI 6 yr	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	FR infant	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	IT adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	FI 3 yr	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	UK toddler	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	UK vegetarian	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	LT adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	FI adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	UK adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	PL general	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	IE child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
	0,0%	DK child	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS			0,0%	0,0%
		DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
		DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Please insert here the MRLs of COM database (use "paste values" function) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.15 IEDI calculations

TMDI do not exceed ADI therefore IEDI calculation is not required.

A 3.16 IESTI calculations - Raw commodities (refined mode)

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,00%	Maize/corn	0,01 / 0,01	0,07	0,00%	Maize/corn	0,01 / 0,01	0,02	0,00%	Maize/corn	0,01 / 0,01	0,07	0,00%	Maize/corn	0,01 / 0,01	0,02
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)							

A 3.17 IESTI calculations - Processed commodities (refined mode)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,0%	Maize / oil	0,01 / 0,25	0,23	0,0%	Maize / oil	0,01 / 0,25	0,13
0,0%	Maize / processed (not spe	0,01 / 0,01	0,02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,01%	Maize / oil	0,01 / 0,25	0,23	0,01%	Maize / oil	0,01 / 0,25	0,13
0,00%	Maize / processed (not	0,01 / 0,01	0,02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Please insert here the MRLs of COM database (use 'paste values' function) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant