FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SAE053H/01

Product name(s): KAGURA/GENKI

Chemical active substances:

Mesotrione 80 g/L

Nicosulfuron 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Document number - SAEDoc-00018 CEU

(authorization)

Applicant: Sumi Agro Europe Limited

Submission date: November 2019

MS Finalisation date: 12/02/2022

Version history

When	What
November 2019	dRR submitted by applicant
August 2020	Dossier sent for evaluation to Merit Mark (PL)
October 2021	zRMS finalised evaluation
January 2022	Final version prepared by zRMS after Commenting period
February 2022	Final version prepared by zRMS after Commenting period

Table of Contents

zRMS comments:
The text highlighted in grey was provided by the evaluator.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

This documentation has been prepared by the Applicant. All comments and changes introduced by zRMS are marked in gray.

The SAE 053H contains nicosulfuron (30 g/L) and mesotrione (80 g/L). The proposed use according to the GAP is on maize.

Nicosulfuron

EU GAP (EFSA Journal 2012;10(12):3048):

Maize: 1 appl., BBCH 12-20, max appl. rate 0.06 kg a.s./ha

GAP proposed for SAE 053H:

Maize: 1 appl., BBCH 12-19, max appl. rate 0.036 kg a.s./ha (36 g nicosulfuron + 96 g mesotrione)

Critical GAP for SAE053H/01 presented in the Part B, Section 7

Maize: 1 appl., BBCH 12-19, max appl. rate 0.045 kg a.s./ha (45 g nicosulfuron + 120 g mesotrione)

GAP proposed for SAE 053H is covered by EU GAP for nicosulfuron.

According to the EFSA Journal 2012;10(12):3048: *In the framework of the peer review, storage stability of nicosulfuron was demonstrated for a period of 9 months at -20°C in dry commodities (maize grain) and in high water content commodities (maize whole plant) (United Kingdom, 2005). All residues trial samples were stored in compliance with the storage conditions reported above. Degradation of residues during storage of the trial samples is therefore not expected.*

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

The Applicant has not submitted any new studies on the magnitude of residues in plants for the purpose of this application. The use of nicosulfuron proposed in the GAP for SAE053H is covered by GAP already evaluated at EU level. In all studies considered in the evaluation at EU level residues of nicosulfuron in maize grains (n=18) and whole plants (n=18) were below LOQ (0.01 mg/kg). Sufficient residue trials are available to support the use of nicosulfuron on maize at the GAP proposed for SAE053H. Additional studies are not required.

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

Magnitude of residues in representative succeeding crops was evaluated at EU level. The available studies were considered sufficient by EFSA to demonstrate the absence of residues in rotational crops, provided that nicosulfuron is applied in compliance with the GAPs reported in EFSA Journal 2012;10(12):3048. GAP proposed for nicosulfuron in SAE 053H is less critical than GAP evaluated at EU level. Additional studies are not required.

It was not possible to propose residue definitions in animal products however, residues in animal products are not expected to be significant (animal dietary intakes are <0.1 mg/kg diet) (EFSA Scientific Report (2007) 120, 1-91; EFSA Journal 2012;10(12):3048). Studies on the magnitude of residues in livestock are not required.

Studies on the effect on the level of residues in pollen and bee products are not required. According to the Appendix II of *Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey*, SANTE/11956/2016 rev. 9, maize was considered a crop from which it is not possible to produce honey.

TMDI calculation performed using EFSA PRIMo Rev. 3.1 covered all MRLs in force (Reg. (EU) 617/2014). The highest chronic exposure was calculated for NL toddler, representing 0.1 % of the ADI.

Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

The use of nicosulfuron on maize according to the GAP proposed for SAE053H did not indicate a risk to consumers.

Mesotrione

EU GAP (EFSA Journal 2016;14(3):4419):

Maize: 1 appl., BBCH 12-18, max appl. rate 150 g a.s./ha

GAP proposed for SAE 053H:

Maize: 1 appl., BBCH 12-19, max appl. rate 96 g a.s./ha (36 g nicosulfuron + 96 g mesotrione)

Critical GAP for SAE053H/01 presented in the Part B, Section 7

Maize: 1 appl., BBCH 12-19, max appl. rate 120 g a.s./ha (36 g nicosulfuron + 120 g mesotrione)

GAP proposed for SAE 053H is covered by EU GAP for mesotrione

The stability of residues for the active substance mesotrione was evaluated at EU level (EFSA Journal 2016;14(3):4419). Sufficient storage stability data are available for mesotrione on maize grain and forage. Mesotrione was considered to be stable at -18°C ± 5°C for 42 months in high starch content products (maize grain) and 31 months in products of high water content (maize forage). MNBA which is a metabolite of mesotrione is stable at the above mentioned temperature for 42 months in high water content product and high starch content products (maize grain and forage).

According to the EFSA Journal 2016;14(3):4419 conclusions: "*Since the absolute concentration of all metabolites was below 0.01 mg/kg in the seeds***, the residue definition for enforcement and risk assessment was set as mesotrione only for food commodities. For feed commodities, the potential inclusion of the predominant metabolites MNBA and AMBA (free and conjugated) besides mesotrione in the residue definition for risk assessment was envisaged.**"

"*MNBA was characterized as non genotoxic and of lower toxicity compared to the parent compound and was never detected in the GAP-compliant residue trials on maize (<0.01 mg/kg). In contrast, a genotoxic potential in vivo could not be excluded for AMBA and repeated dose toxicity profile needs to be addressed (see data gap in section 2). For risk assessment in feed commodities and pending on the toxic logical profile of AMBA conjugates, the residue definition is provisionally proposed as mesotrione and AMBA (including its conjugates). If it can be demonstrated that the conjugates of AMBA are not genotoxic and of no toxicological relevance, additional residue trials on maize where AMBA is analysed for are not needed and only mesotrione has to be included in the residue definition. These residue definitions are valid for conventional crops (cereals, pulses and oilseeds) only. For future uses on genetically modified crops and considering the significant proportions of 4/5-hydroxy mesotrione recovered in soya bean forage and hay, this compound may have to be included in the residue definition for risk assessment pending on its toxicological relevance*".

The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain <0.01 mg/kg). In all studies evaluated at EU level and new studies submitted by the Applicant residues of mesotrione and were below LOQ (0.01 mg/kg).

Livestock metabolism studies are not triggered considering the estimated dietary burden calculation.

Residue trials evaluated on DAR can support the use proposed for SAE053H. BBCH proposed in the GAP for SAE053H – 19 is in principal growth stage 1: leaf development as in the case of the growth phase accepted in the EU GAP (BBCH 18). The residue results can be assumed to be comparable.

In addition the Applicant submitted four new trials conducted on maize during 2015 in Austria, Denmark and the United Kingdom. One application was performed at BBCH 15-18 at a nominal rate of 1.5 L/ha (120 g mesotrione plus 45 g nicosulfurone/ha). The GAP proposed for SAE 063H (Part B, section 0) is less critical: 1 appl., BBCH 12-19, max appl. rate 1.2 L/ha (96 g mesotrione/ha plus 36 g nicosulfurone/ha). Specimen extraction and determination of residues were performed according to multi-residue method QuEChERS. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for mesotrione in maize matrices with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The mean recoveries at each fortification level in all specimens (maize grain, rest of plant and whole plant) were in the range of 70 - 110 % with RSD ≤ 20 % - see Part B, Section 5.

Max. storage time for samples (< -18 °C) was 211 days (sampling to extraction) - it is covered by stability of mesotione (42 months for grain and 31 days for forage).

No residues of mesotrione above the LOD were detected in any of the untreated specimens. Metabolite AMBA has not been considered.

According to the EFSA Journal 2016;14(3):4419 data gap is set for clarification of the genotoxic potential of AMBA and of its toxicological profile. Pending the outcome of the requested data on the toxicological relevance of this compound, maize residue trials for the determination of the residues of AMBA conjugates in feed items may be needed.

The dossier for SAE053H may need to be re-evaluated after the toxicological data for AMBA has been assessed at Community level. At this stage, the available data are sufficient to confirm that the use proposed for SAE053H on maize is acceptable and an exceedance of current MRL of 0.01 mg/kg (Reg. (EU) 2017/626) is not expected.

At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and **residue definitions for animal commodities are provisionally not required** for the representative use (maize). This assessment has however to be reconsidered pending the outcome of AMBA toxicity. At this stage, the available data are sufficient to confirm that the use proposed for SAE053H on maize is acceptable and an exceedance of current MRLs for animal products (Reg. (EU) 2017/626) is not expected.

As quantifiable residues of mesotrione are not expected in maize and the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the magnitude of residues in processed commodities.

Magnitude of residues in representative succeeding crops was evaluated at EU level. According to the EFSA Journal 2016;14(3):4419: *Bare soil application of mesotrione labelled respectively on cyclohexane-2-^{14}C and phenyl-U^{14}C at a dose rate of 164 g a.s./ha (1N). At 120 day plant back interval (PBI), TRRs are very low in all crop parts: <0.01 mg/kg in wheat grain and radish root, 0.012 mg/kg in broad-leaves endive and up to 0.033 mg/kg in wheat forage and straw. Metabolites' identification at 300 d PBI not further investigated.*

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

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

Studies on the effect on the level of residues in pollen and bee products are not required. According to the Appendix II of Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, SANTE/11956/2016 rev. 9, maize was considered a crop from which it is not possible to produce honey.

TMDI calculation performed using EFSA PRIMo Rev. 3.0 covered all MRLs in force (Reg. (EU) 2017/626).

The highest chronic exposure was calculated for NL toddler, representing 12 % of the ADI. The highest acute exposure corresponded to 0.3 % ARfD.

The use of mesotrione on maize according to the GAP proposed for SAE053H did not indicate a risk to consumers. Taking into account that clarification on the genotoxic potential of AMBA and of its toxicological profile is requestes, the dossier for SAE053H may need to be re-evaluated after the toxicological data for AMBA has been assessed at Community level.

Authorization can be granted.

7.1.1 Critical GAP(s) and overall conclusion

The intended maximal application rate to be registered is 1.2 L product/ha, which is equivalent to 96 g mesotrione/ha and 36 g nicosulfuron/ha. Nevertheless, the dossier has been prepared for a maximal application rate of 1.5 L product/ha, and thus all risk and exposure assessments presented have been performed with that exaggerated application rate, unless otherwise stated. An application rate of 1.5 L product/ha is regarded as worst case and is therefore covering the intended rate of 1.2 L product/ha.

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation SAE053H/01 are presented in **Table 7.1-1**. They have been selected from the individual GAPs in the central zone for maize. A list of all intended uses within the central zone is given in Part B, Section 0.

The critical GAP of 120 g a.s./ha mesotrione and 45 g a.s./ha nicosulfuron represents the highest field application rate in maize. A single application per year at BBCH 12-19 is supported.

Overall conclusion

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

The chronic and the short-term intakes of mesotrione and nicosulfuron 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

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(GAP in PART B, Section 0)	Maize 0500030	CEU	SAE053 H	F	*Broadleaved weeds (TTTDD) and grasses (TTTMM)*	OD	mesotrione 80 g/kg nicosulfuron 30 g/kg	Foliar spray	BBCH 12-19	1	n.a.	-	200 / 400	mesotrione: 96 g/ha nicosulfuron: 36 g/ha	n.a.	A
~~1~~ cGAP	Maize 0500030	C	SAE053 H/01	F	*Broad-leaved weeds and grasses*	OD	mesotrione 80 g/kg nicosulfuron 30 g/kg	Foliar spray	BBCH 12-19	1	n.a.	mesotrione 0.030 / 0.060 nicosulfuron 0.011 / 0.023	200 / 400	mesotrione: 0.120 + nicosulfuron: 0.045	n.a.	A **not correspond to the critical use reported in the Part B0**

* 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 SAE053H/01 is composed of mesotrione and nicosulfuron.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesotrione - Parent compound (if applicable)					
ADI	Reg. (EU) 2017/725	2017	0.01 mg/kg bw/d	Mouse multi-generation	200
ARfD	Reg. (EU) 2017/725	2017	0.02 mg/kg bw	Mouse multi-generation	100
Nicosulfuron - Parent compound (if applicable)					
ADI	Dir 08/40	2008	2 mg/kg bw/d	Chronic rat Supported by subchronic dog	100 (rat)
ARfD	Dir 08/40	2008	Not applicable	-	-

7.1.2.1 Summary for Mesotrione

Table 7.1-3: Summary for Mesotrione

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	Yes	Yes	~~n.a.~~ Yes	Yes	Yes	No	No

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

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

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in edible succeeding crops. Based on the results, residues from rotational crops are also not expected to increase the dietary burden intake of livestock or to have an impact on the residue level in products of animal origin.

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

No unacceptable risk for consumers has been identified for maize.

The intended use on conventionally grown maize is considered acceptable. Future uses on genetically modified crops need to be assessed separately and are not included in this evaluation.

In 2015 EFSA proposed (reasoned opinion on existing MRLs) that the residue definition for risk assessment of maize forage and grass should be the sum of mesotrione and its metabolite AMBA (free and conjugated), expressed as mesotrione. A data gap was set by EFSA (2016) for clarification of the genotoxic potential of AMBA and of its toxicological profile, however, it was agreed that the metabolite AMBA is unlikely to be genotoxic (EFSA, 2018, Technical report in light of confirmatory data). As of now, no field residue trial data according to the 2015 proposed plant residue definition for risk assessment (mesotrione+AMBA (including its conjugates)) are available.

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	~~n.a.~~ Yes	Yes	Yes	No	No

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

As residues of 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.

Residues in succeeding crops have been previously investigated and no evaluation is required taking into account the specific circumstances of the cGAP uses being considered here. Based on the results of the confined rotational crop study, no residues of nicosulfuron are to be expected in rotational crops.

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

No unacceptable risk for consumers has been identified for maize.

7.1.2.3 Summary for SAE053H/01

Table 7.1-5: Information on SAE053H/01 (KCA 6.8)

Crop	PHI for SAE053H/01 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SAE053H/01 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mesotrione	Nicosulfuron		
Maize	~~n.a.~~ F**	~~NR~~ Yes	~~NR~~ Yes	~~NR~~ 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 7.1-6: wszystkie uprawy

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for SAE053H/01
Crop group	**Led by Mesotrione**	**Led by Nicosulfuron**	**Led by active substance 3**	
			Not applicable	Do not grow XXX in the treated field less than XXX days after application of SAE053H/01
All crops that can be grown as succeeding crops	NR	NR		NR

NR: not relevant

Assessment

For mesotrione referral is made to the Draft Assessment Report (DAR) by the United Kingdom (1999) and the Renewal Assessment Report (RAR) also by the United Kingdom (2015), the EFSA Conclusion Reports (2016) and EFSA reasoned opinion on existing MRLs (2015) and for mesotrione throughout this dossier submission. Most of the underpinning studies submitted to support the EU evaluation of mesotrione have been evaluated by RMS, United Kingdom.

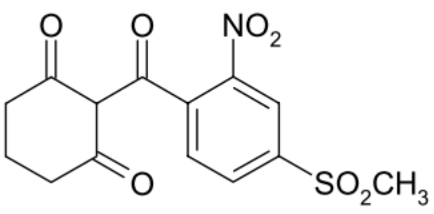
For nicosulfuron referral is made to the Draft Assessment Report (DAR) by the United Kingdom (2006) and its addendum (2007), the EFSA Conclusion Reports (2007) and EFSA Reasoned Opinions on MRLs (2012). Nicosulfuron is currently under evaluation for Annex I Renewal, referral is therefore also made to the AIR dossier (2016) which is currently under review. Most of the underpinning studies submitted to support the EU evaluation of nicosulfuron have been evaluated by RMS, United Kingdom.

This application is for the first authorisation of SAE053H/01 and therefore this product has not previously been assessed according to the Uniform Principles. The notifier either owns or has access to all of the underlying studies.

7.2 Active substance 1 – Mesotrione

General data on mesotrione are summarized in the table below

Table 7.2-1: General information on mesotrione

Active substance (ISO Common Name)	Mesotrione
IUPAC	2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione
Chemical structure	
Molecular formula	$C_{14}H_{13}NO_7S$
Molar mass	339.3 g/mol

Chemical group	Herbicide Triketone
Mode of action (if available)	Member of the class of HPPD inhibitors; inhibiting the plant enzyme 4-hydroxyphenylpyruvate dioxygenase which is required for carotenoid biosynthesis, which in turn protects chlorophyll from being degraded by sunlight.
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	RMS: UK Co-RMS: Belgium
Approval status	Approved on 01/06/2017 in Commission Implementing Regulation (EU) 2017/725 and reference to decision Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 Implementing Regulation (EC) No 1107/2009 Commission implementing Regulation (EU) 2003/68/EC of 11 July 2003 and – Regulation (EU) 2016/950 for the extension of the approval period http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1552 Expiration of approval 31/05/2032
Restriction (e.g. is restricted to use as "...")	To use as herbicide see Approval Directive 2003/68/EC and Commission Implementing Regulation (EU) 2017/725
Review Report	~~SANCO/1416/2014~~ ~~14/04/2003~~ SANTE/11654/2016 21/03/2017
Current MRL regulation	Regulation (EU) No 2017/626
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 2016**
EFSA Journal: conclusion on article 12	Yes EFSA 2015**
Current MRL applications on intended uses	None Commodities: Maize, current MRL - 0.01 mg/kg (Regulation (EU) No 2017/626)

* Notifier in the EU process to whom the a.s. originally belonged.
** see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

The storage stability of mesotrione was investigated in the framework of the peer review under Regulation (EC) No. 1107/2009. 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			

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Maize grain	High starch content	At least 42 months (mesotrione) At least 42 months (MNBA)	UK, 2015; Wiebe L.A., Peyton C.S., 1999 Report No. RR 97-042B EFSA, 2016
Maize forage	High water content	At least 31 months (mesotrione) At least 42 months (MNBA)	
Maize fodder	No group	At least 42 months (mesotrione) At least 42 months (MNBA) Considered acceptable in the RAR but not included in EFSA conclusion List of Endpoints (EFSA, 2016)	
Processed Commodities			
Not required, no residues in products of plant/animal origin subject to processing at or higher than 0.01 mg/kg			
Animal Products			
Not required, intake not expected to exceed 0.004 mg/kg bw/day			

Conclusion on stability of residues during storage

The stability of residues for the active substance mesotrione was already addressed during the EU Review process. Regarding uses intended with this submission, the active substance mesotrione and its metabolite MNBA (4-methylsulfonyl-2-nitro benzoic acid) was shown to be stable in maize grain, maize fodder and maize forage. Residues of mesotrione were found to be stable at -18°C±5°C for at least 42 months in maize grain (high starch content) and maize fodder and for at least 31 months in maize forage (high water content). Residues of its metabolite MNBA were found to be stable at -18°C±5°C for at least 42 months in maize grain, forage and fodder commodities. This data was considered acceptable and no further data is required.

Storage stability of mesotrione and MNBA was not investigated in and is not required for processed commodities, animal tissues, milk and eggs as metabolism studies in those commodities are not triggered.

zRMS comments:
Stability of mesotrione residues during storage of samples was evaluated at EU level (EFSA Journal 2016;14(3):4419). Sufficient data are available for mezotrione on maize grain and forage. Additional studies are not required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No study on the stability of residues in sample extracts was conducted. Storage of extracts is not explicitly mentioned in the studies evaluated in the RAR (RMS United Kingdom, 2015) and by EFSA (2016). Despite that, study results were considered acceptable. It can be assumed that samples were generally analysed within 24 hours of preparation. If not, the procedural recoveries performed in fortified samples which run concurrently with each set of samples in the residue field trials showed that mesotrione was sufficiently stable in the sample extract.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Studies on metabolism of mesotrione in plants were already addressed during the EU Review process and were considered acceptable. No new data on maize have been submitted in the framework of this application.

Plant metabolism was studied in maize (pre-and post-emergence) with mesotrione labelled on cyclohexane-2-^{14}C and phenyl-U-^{14}C. It was concluded that the data submitted were sufficient to propose a metabolic pathway of mesotrione in maize.

Information on crops tested, application and sampling details are given in **Table 7.2-3** below.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Maize	^{14}C-cyclohexane labelled mesotrione	foliar treatment, F	Nominal: 0.140 kg a.s./ha Actual: 0.161 kg a.s./ha	1	28 (forage) 125 (grain, fodder)	Application 28 days after planting (post-emergence)	UK, 1999, UK, 2015, Wei, Y, Dohn D.R. 1997 Report No. RR 96-026B EFSA, 2016
				Nominal: 0.280 kg a.s./ha Actual: 0.307 kg a.s./ha	1	27 (forage) 153 (grain, fodder)	Application 1 days after planting (Pre-emergence)	
	Maize	^{14}C-phenyl labelled mesotrione	foliar treatment, F	Nominal: 0.140 kg a.s./ha Actual: 0.164 kg a.s./ha	1	28 (forage) 125 (grain, fodder)	Application 28 days after planting (post-emergence)	UK, 1999, UK, 2015, Tarr, J.B., van Neste, 1997 Report No. RR 96-007B EFSA, 2016
				Nominal: 0.280 kg a.s./ha Actual: 0.280 kg a.s./ha	1	27 (forage) 154 (grain, fodder)	Application 1 days after planting (Pre-emergence)	

Summary of plant metabolism studies reported in the EU

From the data evaluated during the EU Review, it was concluded that metabolism of mesotrione proceeds by oxidation of the parent molecule to 4/5-hydroxy mesotrione and to MNBA with subsequent reduction to AMBA and its many conjugates (RMS United Kingdom 2015, EFSA, 2016).

Conclusion on metabolism in primary crops

The intended GAPs for SAE053H/01 include foliar application to maize (cereals) with one application per season/crop at a maximum rate of 120 g/ha mesotrione. The available metabolism studies cover the intended uses.

Based on the available information, the residue definition for enforcement was proposed as mesotrione only and the residue definition for risk assessment was proposed as mesotrione only for food commodities and provisionally mesotrione and AMBA (including its conjugates) in feed commodities in the EU review (EFSA, 2016). The provisional inclusion of metabolite AMBA in the residue definition for risk assessment (feed commodities) was based on its potential genotoxicity, however, it was recently agreed that the metabolite AMBA is unlikely to be genotoxic (EFSA, 2018, Technical report in light of confirmatory data).

zRMS comments:
According to the EFSA Journal 2016;14(3):4419 conclusions: "*Since the absolute concentration of all metabolites was below 0.01 mg/kg in the seeds,* ***the residue definition for enforcement and risk assessment was set as mesotrione only for food commodities****. For feed commodities, the potential inclusion of the predominant metabolites MNBA and AMBA (free and conjugated) besides mesotrione in the residue definition for risk assessment was envisaged."*
"MNBA was characterized as non genotoxic and of lower toxicity compared to the parent compound and was never detected in the GAP-compliant residue trials on maize (<0.01 mg/kg). In contrast, a genotoxic potential in vivo could not be excluded for AMBA and repeated dose toxicity profile needs to be addressed (see data gap in section 2). ***For risk assessment in feed commodities and pending on the toxic logical profile of AMBA conjugates, the residue definition is provisionally proposed as mesotrione and AMBA (including its conjugates).*** *If it can be demonstrated that the conjugates of AMBA are not genotoxic and of no toxicological relevance, additional residue trials on maize where AMBA is analysed for are not needed and only mesotrione has to be included in the residue definition.* ***These residue definitions are valid for conventional crops (cereals, pulses and oilseeds) only.*** *For future uses on genetically modified crops and considering the significant proportions of 4/5-hydroxy mesotrione recovered in soya bean forage and hay, this compound may have to be included in the residue definition for risk assessment pending on its toxicological relevance"*.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data was submitted in the framework of this application. Studies on residues in succeeding crops were evaluated during the EU Review process of mesotrione and were considered to be acceptable. Studies are summarised in **Table 7.2-4** below.

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								
Cereals	wheat	[phenyl-U-^{14}C]-mesotrione	foliar treatment, G	1 x 0.164 kg a.s./ha	120 300	22 (forage) 57 (hay) 134 (straw, grain)	Application to bare soil	UK, 2015, Gorder G.W. et al., 1997 Report No. DP 59817 EFSA, 2016
Leafy vegetables	endive					78 At maturity of crop		
Root and tuber vegetables	radish					56 roots and top At maturity of crop		
Cereals	wheat	[cyclohexane-2-^{14}C]-mesotrione	foliar treatment, G	1 x 0.164 kg a.s./ha	120	22 (forage) 57 (hay) 134 (straw, grain)	Application to bare soil	UK, 2015, Spillner, C. et al., 1997 Report No.
Leafy vegetables	endive					78 At maturity of crop		

Root and tuber vegetables	radish					56 roots and top At maturity of crop		DP 59818 EFSA, 2016

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

Summary of plant metabolism studies reported in the EU

The nature of mesotrione residues in rotational crops was investigated on two rotational crop studies using [phenyl-U-14C]-mesotrione and [cyclohexane-2-^{14}C]-mesotrione and evaluated in the RAR (RMS United Kingdom, 2015; EFSA 2016). It was concluded that the metabolism of mesotrione was sufficiently addressed. The residue definitions for enforcement and risk assessment agreed in the peer review (EFSA, 2016) are applicable. A sowing interval at 30 DAT (crop failure scenario) was not investigated since replanting after this interval would not be anticipated for this crop.

All of the plant metabolites have also been determined in mammalian metabolism studies. The metabolism of mesotrione is similar in rotational crops to that observed in primary crops.

Conclusion on metabolism in rotational crops

The intended GAP for SAE053H/01 includes foliar application to maize (cereals) with one application per season/crop at a maximum rate of 120 g/ha mesotrione which is not more critical than the dose rates used in the previously evaluated metabolism studies in rotational crops (0.164 kg a.s./ha). The available metabolism studies in rotational crops therefore cover the intended uses. The residue definitions for monitoring and risk assessment for plant products are applicable.

zRMS comments:
According to the EFSA Journal 2016;14(3):4419: *The metabolism of mesotrione in rotational crops was found to be similar to the primary crops*. Additional studies are not required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

All samples evaluated in the RAR contained at harvest no residues of mesotrione or MNBA, with a limit of quantification of 0.01 mg/kg. As a result, hydrolysis studies addressing the nature of the residues in processed commodities were not triggered. In addition, consumer intakes of processed commodities accounted for less than 10% of the ADI. Therefore it was considered that processing studies are not required.

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

Hydrolysis studies addressing the nature of the residues in processed commodities were not triggered. In addition, consumer intakes of processed commodities accounts for less than 10% of the ADI. Therefore processing studies are not required.

zRMS comments:
According to the EFSA Journal 2016;14(3):4419: *Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain <0.01 mg/kg).* In all studies evaluated at EU level and new studies submitted by the Applicant residues of mesotrione and MNBA were below LOQ (0.01 mg/kg). Additional studies are not required.

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

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

Endpoints	
Plant groups covered	Cereals: maize (forage, fodder, grain) Studies conducted with mesotrione labelled on cyclohexane-2-^{14}C and phenyl-U-^{14}C
Rotational crops covered	Root/tuber crops (radish): PBI 120, 300 Leafy crops (broad leaves endive): PBI 120, 300 Cereal (small grain): PBI 120, 300 Mesotrione labelled on cyclohexane-2- ^{14}C and phenyl-U- ^{14}C was applied separately at a rate of 164 g a.s./ha to bare soil. The 300 DAT crops were not harvested.
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain < 0.01 mg/kg)
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Mesotrione (cereals and pulses/oilseeds only) (Regulation (EU) No 2017/626)
Plant residue definition for risk assessment	Food commodities: Mesotrione (cereals and pulses/oilseeds only) Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional. (EFSA 2016) According to EFSA (2016) “If it can be demonstrated that the conjugates of AMBA are not genotoxic and of no toxicological relevance, additional residue trials on maize where AMBA is analysed for are not needed and only mesotrione has to be included in the residue definition”.
Conversion factor from enforcement to RA	Not applicable (EFSA 2016)

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

Available data

Residues in animal feed are expected to be < 0.004 mg/kg bw/day in ruminants, poultry or pigs (see Point 7.2.4.1 below). Data on the metabolism of mesotrione in livestock are therefore not required.

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

However, studies on metabolism of in livestock were available during the EU Review process (DAR, RMS United Kingdom, 1999 and the RAR, RMS United Kingdom, 2015). Studies are summarised in **Table 7.2-6** below.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	cow	[phenyl-U-14C]-labelled AMBA	1	12 mg/kg diet approximately 0.4 mg/kg bw/day	7 consecutive days	Milk	At least daily	UK, 1999, UK, 2015, EFSA, 2016 1997 Report No. RJ2309B (R44276/0008)
						Urine and faeces	regularly*	
						Tissues (Liver, kidney, fat and muscle)	at sacrifice (23 hours after last dose)	

* sampled throughout the study duration

Summary of animal metabolism studies reported in the EU

The nature of mesotrione residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC and reported in the DAR (RMS United Kingdom, 1999) and the RAR (RMS United Kingdom, 2015). Reported metabolism studies include 1 study in ruminants using [phenyl-U-14C]-labelled AMBA mixed with unlabelled AMBA fed to cows at 12.2 mg/kg diet (approximatel 0.4 mg/kg bw/day) for seven consecutive days by gelatine capsule. The total recovery was 88.7% of the administered dose, it was mainly excreted via faeces (56.7%) and urine (32%). The radioactive residue AMBA equivalent in the edible tissues and milk were highest in kidney (0.053 mg/kg), followed by perirenal fat (0.018 mg/kg), liver (0.005 mg/kg) and subcutaneous fat (0.003 mg/kg). Residues in muscle and omental fat were < 0.001 mg/kg. The plateau level in milk was reached on day 5 (0.009 mg/kg). Most of the % TRR recovered in Tissues and urine was AMBA (perirenal fat: 61.6 %; kidney: 79%; urine: 95%) the remainder was not identified with the exception of perirenal fat, where an unknown was detected at 0.001 mg/kg (3.2%). In faeces only 17.4 % of the TRR was AMBA, 58.1 % of the radioactivity was unextracted and the largest other extracted fraction was at 3% TRR.

It can be concluded that AMBA is readily absorbed by ruminants, it is not extensively metabolised and is readily excreted. In addition, it is found in kidney and liver but it does not significantly accumulate in fats or milk.

Conclusion on metabolism in livestock

The intended GAPs for SAE053H/01 include foliar application to maize (cereals) which may serve as animal feed. However, residues in animal feed are expected to be < 0.004 mg/kg bw/day in ruminants, poultry or pigs (see Point 7.2.4.1 below). Data on the metabolism of mesotrione in livestock are therefore not required.

Despite that, a ruminant metabolism study was conducted with phenyl-U-^{14}C AMBA. EFSA (2016) concluded that at the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use.

Given the low residues in maize it is considered unlikely by EFSA (2016) that any significant intakes by fish will occur. In addition, since there is currently no EU agreed guidance for fish metabolism studies, this point cannot be addressed at present.

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

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Cow (beef cattle/dairy cattle) Livestock metabolism studies are not triggered considering the estimated dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data. A fish metabolism study is also not requested.
Time needed to reach a plateau concentration	in milk and eggs: Day 5
Animal residue definition for monitoring	Not required for the representative use (provisional) (EFSA 2016)*
Animal residue definition for risk assessment	Not required for the representative use (provisional) (EFSA 2016)*
Conversion factor	Not applicable (EFSA 2016)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	AMBA residues in muscle (< 0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat soluble.

* provisional, pending the outcome on the toxicological relevance of this compound.

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

The magnitude of residues of mesotrione in maize was evaluated in the DAR (RMS United Kingdom, 1999) in the RAR (RMS United Kingdom, 2015) and peer reviewed by EFSA (2015 and 2016). The studies evaluated in the DAR are no longer data protected.

One trial, which was included in the evaluation in the DAR and the RAR is not included in the table below. Its samples arrived thawed after 9 days of transit.
For some trials, which were evaluated in the DAR and the RAR, reported residues were determined as sum of mesotrione and MNBA expressed as mesotrione. Since the sum of both results in residues < 0.01 mg/kg it was assumed that residues of mesotrione on its own are also < 0.01 mg/kg and therefore it was concluded that it was acceptable to include these trials. Trials conducted with GMO maize were excluded from the evaluation in the RAR and are also excluded in the table below. Commodities of all trials were stored a maximum of 17 months and are therefore covered by the available storage stability data.

In addition, four new trials on the magnitude of residue on maize have been submitted by the applicant in the framework of this application. These studies are summarized in **Table 7.2-8** below. The detailed assessment of these studies is presented in Appendix 2.

A data gap was set by EFSA (2016) for clarification of the genotoxic potential of AMBA and of its toxicological profile, however, it was agreed that the metabolite AMBA is unlikely to be genotoxic (EFSA, 2018, Technical report in light of confirmatory data). As of now, no field residue trial data according to the proposed plant residue definition for risk assessment (mesotrione+AMBA (including its conjugates)) is available.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of SAE053H/01 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	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.150 kg mesotrione/ha, BBCH 16-18, PHI=NCH (normal commercial harvest), outdoor E = RA (food), E (feed): 5x < 0.01	N/A				

			RA (feed)*: currently no data					
	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.200 kg mesotrione/ha, BBCH 16-18, PHI=NCH (normal commercial harvest), outdoor E = RA (food), E (feed): 3x < 0.01 (sum of mesotrione+MNBA, expressed as mesotrione) RA (feed)*: currently no data					
	New trials	N-EU	Trials GAP: 1 x 0.120 kg mesotrione/ha, BBCH 15-18, PHI=NCH (normal commercial harvest), outdoor E = RA (food), E (feed): 4x < 0.01 RA (feed)*: currently no data					
	Overall supporting data for cGAP	N-EU	E = RA (food), E (feed): 12 x < 0.01 RA (feed)*: currently no data	0.01	0.01	0.01	0.01* (LOQ)	Yes
Maize Forage	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.150 kg mesotrione/ha, BBCH 16-18, PHI=30-63 (immature), outdoor E = RA (food), E (feed): 5x < 0.01 RA (feed)*: currently no data	N/A				
	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.200 kg mesotrione/ha, BBCH 16-18, PHI=44-56 (immature), outdoor E = RA (food), E (feed): 3x < 0.01 (sum of mesotrione+MNBA, expressed as mesotrione) RA (feed)*: currently no data					
	New trials	N-EU	Trials GAP: 1 x 0.120 kg mesotrione/ha, BBCH 16-18, PHI=41-42 (immature), outdoor E = RA (food), E (feed): 2x < 0.01 RA (feed)*: currently no data					
	Overall supporting data for cGAP	N-EU	E = RA (food), E (feed): 10 x < 0.01 RA (feed): currently no data	0.01	0.01	-	-	-
Maize Silage	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.150 kg mesotrione/ha, BBCH 16-18, PHI=68-80 (immature), outdoor E = RA (food), E (feed): 5x < 0.01 RA (feed)*: currently no data	N/A				
	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.200 kg mesotrione/ha, BBCH 16-18, PHI=86-110 (immature), outdoor					

			E = RA (food), E (feed): 3x < 0.01 (sum of mesotrione+MNBA, expressed as mesotrione) RA (feed)*: currently no data					
	New trials	N-EU	Trials GAP: 1 x 0.120 kg mesotrione/ha, BBCH 16-18, PHI=83-87 (immature), outdoor E = RA (food), E (feed): 2x < 0.01 RA (feed)*: currently no data					
	Overall supporting data for cGAP	N-EU	E = RA (food), E (feed): 10 x < 0.01 RA (feed)*: currently no data	0.01	0.01	-	-	-
Maize Grain + cob	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.150 kg mesotrione/ha, BBCH 16-18, PHI=NCH (normal commercial harvest), outdoor E = RA (food), E (feed): 5x < 0.01 RA (feed)*: currently no data	N/A				
	DAR (UK, 1999)	N-EU	Trials GAP: 1 x 0.200 kg mesotrione/ha, BBCH 16-18, PHI=NCH (normal commercial harvest), outdoor E = RA (food), E (feed): 3x < 0.01 (sum of mesotrione+MNBA, expressed as mesotrione) RA (feed)*: currently no data					
	Overall supporting data for cGAP	N-EU	E = RA (food), E (feed): 8 x < 0.01 RA (feed)*: currently no data	0.01	0.01	-	-	-
Maize Stover	New trials	N-EU	Trials GAP: 1 x 0.120 kg mesotrione/ha, BBCH 15-18, PHI=NCH (normal commercial harvest), outdoor E = RA (food), E (feed): 4x < 0.01 RA (feed)*: currently no data	N/A				
	Overall supporting data for cGAP	N-EU	E = RA (food), E (feed): 4 x < 0.01 RA (feed)*: currently no data	0.01	0.01	-	-	-

* Provisional plant residue definition for risk assessment - Feed commodities: Mesotrione and AMBA (including its conjugates)

7.2.3.2 Conclusion on the magnitude of residues in plants

The magnitude of residues of mesotrione in maize was evaluated in the DAR (RMS United Kingdom, 1999) and reviewed by EFSA (2015 and 2016). The trials evaluated on EU level and by the EFSA were performed with exaggerated application rates of 1x 0.150 kg/ha, and 1x 0.200 kg/ha than the critical GAP of SAE053H/01 (1 x 0.120 kg/ha mesotrione). Those trials can be regarded as a worst case situation which covers the intended use of SAE053H/01.

Residue trials with mesotrione in maize were conducted with different formulations (OD, SC and WG). The results indicate, that there is no significant influence of these formulation types on the level of residues. Therefore, the trials evaluated on EU level which are summarised above can be used to support the registration of SAE053H/01 containing mesotrione 120 g/L as OD formulation.

Four new trials have been submitted by the applicant in the framework of this application. Application rate and timing are according to the critical GAP (1 x 0.120 kg/ha mesotrione) and are therefore acceptable for support of the intended use of SAE053H/01.

According to the available data, the intended use on conventionally grown maize is considered acceptable and it is not expected to have residues above the EU MRL of 0.01 mg/kg mesotrione when SAE053H/01 is applied according to the GAP.

zRMS comments:
GAP proposed for SAE053H is covered by GAP evaluated at EU level for mesotrione. Residue trials evaluated on DAR can support the use proposed for SAE053H. BBCH proposed in the GAP for SAE053H – 19 is in principal growth stage 1: leaf development as in the case of the growth phase accepted in the EU GAP (BBCH 18). The residue results can be assumed to be comparable.
In addition the Applicant submitted four new trials conducted on maize during 2015 in Austria, Denmark and the United Kingdom. One application was performed at BBCH 15-18 at a nominal rate of 1.5 L/ha (120 g mesotrione plus 45 g nicosulfurone/ha). The GAP proposed for SAE 063H (Part B, section 0) is less critical: 1 appl., BBCH 12-19, max appl. rate 1.2 L/ha (96 g mesotrione/ha plus 36 g nicosulfurone/ha).
Specimen extraction and determination of residues were performed according to multi-residue method QuEChERS. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for mesotrione in maize matrices with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The mean recoveries at each fortification level in all specimens (maize grain, rest of plant and whole plant) were in the range of 70 - 110 % with RSD ≤ 20 % - see Part B, Section 5.
Max. storage time for samples (< -18 °C) was 211 days (sampling to extraction) - it is covered by stability of mesotione (42 months for grain and 31 days for forage).
No residues of mesotrione above the LOD were detected in any of the untreated specimens. Metabolite AMBA has not been considered.
According to the EFSA Journal 2016;14(3):4419 data gap is set for clarification of the genotoxic potential of AMBA and of its toxicological profile. Pending the outcome of the requested data on the toxicological relevance of this compound, maize residue trials for the determination of the residues of AMBA conjugates in feed items may be needed.
The dossier for SAE053H may need to be re-evaluated after the toxicological data for AMBA has been assessed at Community level.
At this stage, the available data are sufficient to confirm that the use proposed for SAE053H on maize is acceptable and an exceedance of current MRL of 0.01 mg/kg (Reg. (EU) 2017/626) is not expected.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Animal dietary burden calculation was performed in accordance to the Guidance Document on residues in livestock (Series on Pesticides No. 73, 2013) and OECD Test Guideline 505: Residues in livestock (2007). The excel calculator (Animal model 2017.xls) developed by EFSA was used to perform the animal dietary burden. The default value of processing factor was used for the relevant commodities.

The proposed residue definition for risk assessment for feed commodities is mesotrione and AMBA (including its conjugates) and is applicable for cereals, pulses and oilseeds only and only for conventional crops (EFSA, 2016). Currently no field residue trials are available which also contain analysis of AMBA (free and conjugated). EFSA, 2015 noted that, in order to better estimate dietary burden of livestock, additional trials are required analyzing mesotrione and its metabolite AMBA (free and conjugated). A data gap was set by (EFSA, 2016) for clarification of the genotoxic potential of AMBA and of its toxicological profile, however, it was agreed that the metabolite AMBA is unlikely to be genotoxic (EFSA, 2018, Technical report in light of confirmatory data).

For calculation of dietary burden calculation, the input parameters listed in EFSA (2016) were used. Since no field data according to the residue definition for risk assessment is currently available, input parameters for mesotrione are based on available field data while input parameters for AMBA were tentatively estimated by EFSA (2016) using the highest magnitude of AMBA conjugates residues in maize forage, fodder from the metabolism study and the total residues in maize grain.

The dietary burden calculation is therefore provisional pending the outcome of the toxicological evaluation of AMBA and it is only applicable to conventional maize.

The following tables summarise the residue level used in the calculations of the feeding intake and the dietary burden calculation for the active substance mesotrione and its metabolite AMBA. Input parameters for by-products of processing were calculated based on input values for maize grain using default processing factors.

Table 7.2-9: Input values for the dietary burden calculation (considering the intended uses) – Mesotrione

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Mesotrione				
Maize grain (field and pop)	0.01	Median residue (EFSA, 2016)	0.01	Highest residue (EFSA, 2016)
Maize fodder (field and pop)	0.01	Median residue (EFSA, 2016)	0.01	Highest residue (EFSA, 2016)
Maize forage	0.01	Median residue (EFSA, 2016)	0.01	Highest residue (EFSA, 2016)
Maize milled by-products	0.01	Median residue (EFSA, 2016) x default PF of 1	0.01	Highest residue (EFSA, 2016) x default PF of 1

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize hominy meal	0.06	Median residue (EFSA, 2016) x default PF of 6	0.06	Highest residue (EFSA, 2016) x default PF of 6
Maize gluten feed	0.025	Median residue (EFSA, 2016) x default PF of 2.5	0.025	Highest residue (EFSA, 2016) x default PF of 2.5
Maize gluten meal	0.01	Median residue (EFSA, 2016) x default PF of 1	0.01	Highest residue (EFSA, 2016) x default PF of 1
Maize distiller's grain	0.033	Median residue (EFSA, 2016) x default PF of 3.3	0.033	Highest residue (EFSA, 2016) x default PF of 3.3

Table 7.2-10: Input values for the dietary burden calculation (considering the intended uses) - AMBA

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
AMBA (including its conjugates)				
Maize grain (field and pop)	0.014	Total residues from the metabolism data (EFSA, 2016)	0.014	Total residues from the metabolism data (EFSA, 2016)
Maize fodder (field and pop)	0.301 (provisional)	Maximum residue levels of total AMBA (including its conjugates) recovered from the metabolism data. Pending clarification of the genotoxic potential of AMBA and of its toxicological profile GAP-compliant residue trials for the determination of AMBA conjugates residues in maize fodder, forage may be needed and the livestock dietary burden to be revised accordingly. (EFSA, 2016)	0.301 (provisional)	Maximum residue levels of total AMBA (including its conjugates) recovered from the metabolism data. Pending clarification of the genotoxic potential of AMBA and of its toxicological profile GAP-compliant residue trials for the determination of AMBA conjugates residues in maize fodder, forage may be needed and the livestock dietary burden to be revised accordingly. (EFSA, 2016)
Maize forage	0.043 (provisional)		0.043 (provisional)	
Maize milled by-products	0.014	Total residues from the metabolism data (EFSA, 2016) x default PF of 1	0.014	Total residues from the metabolism data (EFSA, 2016) x default PF of 1
Maize hominy meal	0.084	Total residues from the metabolism data (EFSA, 2016) x default PF of 6	0.084	Total residues from the metabolism data (EFSA, 2016) x default PF of 6
Maize gluten feed	0.035	Total residues from the metabolism data (EFSA, 2016) x default PF of 2.5	0.035	Total residues from the metabolism data (EFSA, 2016) x default PF of 2.5
Maize gluten meal	0.014	Total residues from the metabolism data (EFSA, 2016) x default PF of 1	0.014	Total residues from the metabolism data (EFSA, 2016) x default PF of 1

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize distiller's grain	0.046	Total residues from the metabolism data (EFSA, 2016) x default PF of 3.3	0.046	Total residues from the metabolism data (EFSA, 2016) x default PF of 3.3

Table 7.2-11: Results of the dietary burden calculation - Mesotrione

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Maximum dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Mesotrione					
Beef cattle*	0.001	0.001	Maize, gluten feed	0.04	No
Dairy cattle*	0.001	0.001	Maize, gluten feed	0.03	No
Ram/ewe	0.001	0.001	Maize, gluten feed	0.02	No
Lamb	0.001	0.001	Maize, gluten feed	0.02	No
Breeding swine	0.001	0.001	Maize, gluten feed	0.02	No
Finishing swine*	0.001	0.001	Maize, gluten feed	0.02	No
Broiler poultry	0.001	0.001	Maize, milled by-products	0.01	No
Layer poultry*	0.002	0.002	Maize, hominy meal	0.02	No
Turkey	0.001	0.001	Maize, hominy meal	0.02	No

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

Table 7.2-12: Results of the dietary burden calculation - AMBA

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)
AMBA (including its conjugates)					
Beef cattle*	0.003	0.003	Maize, stover	0.12	No
Dairy cattle*	0.004	0.004	Maize, stover	0.10	No
Ram/ewe	0.001	0.001	Maize, gluten feed	0.03	No
Lamb	0.001	0.001	Maize, gluten feed	0.03	No
Breeding swine	0.002	0.002	Maize, stover	0.10	No
Finishing swine*	0.001	0.001	Maize, gluten feed	0.03	No
Broiler poultry	0.001	0.001	Maize, milled by-products	0.02	No
Layer poultry*	0.003	0.003	Maize, forage/silage	0.04	No
Turkey	0.002	0.002	Maize, hominy meal	0.03	No

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application and no data was evaluated on EU level in the RAR (RMS United Kingdom 2015)

Results from the dietary burden calculation show that in all groups of livestock the dietary burden of both mesotrione as well as AMBA are below the trigger of 0.004 mg/kg bw/day.

In addition, results from plant metabolism studies showed that residues of mesotrione are low and the results of the available ruminant metabolism study with AMBA showed that total residues in animal matrices were also low. EFSA (2016) concluded that at the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use. However, they highlighted, that this assessment has to be reconsidered pending the outcome of AMBA toxicity. Furthermore, the setting of residue definitions for products of animal origin will also have to be assessed with regard to the authorized European uses for mesotrione (maize forage, grass) (EFSA, 2015), and in the case animals are fed with genetically modified soybean seed (meal) where mesotrione can be found at significant proportions.

Conclusion on feeding studies

The intended GAPs for SAE053H/01 include foliar application to maize (cereals) which may serve as animal feed. However, estimated animal intakes of mesotrione are low and no feeding studies are currently triggered. Therefore, no new studies are submitted in the Annex I Renewal of mesotrione and are not required and no studies were evaluated in the RAR and are currently considered. In addition, no residue definition was set for animal matrices for the representative uses (EFSA, 2016). This evaluation is provisional pending the outcome of the data gap which was set for clarification of the genotoxic potential of AMBA and of its toxicological profile and pending the evaluation of any future uses on genetically modified crops.

There is no risk for animal MRL to be exceeded.

zRMS comments:
zRMS agrees with informations provided by the Applicant. At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use (maize). This assessment has however to be reconsidered pending the outcome of AMBA toxicity. At this stage, the available data are sufficient to confirm that the use proposed for SAE053H on maize is acceptable and an exceedance of current MRLs for animal products (Reg. (EU) 2017/626) is not expected.

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

No studies are available for maize.

According to Commission Regulation (EU) No. 283/2013 studies concerning the magnitude of residues in the various processed commodities are not required if the level of residues is less than 0.1 mg/kg and the commodity under consideration contributes less than 10% of ADI to the estimated theoretical maximum daily intake (TMDI) or less than 10% of ARfD to the estimated daily intake for any European consumer group diet.

The only maize commodity which is processed is maize grain. At harvest, residues in maize grain are less than 0.1 mg/kg. In addition, maize contributes to the TMDI less than 10% of ADI and less than 10% of ARfD. Therefore, no processing study is required.

Default processing factors are available for calculation of dietary burden.

zRMS comments:
Not required. As quantifiable residues of mesotrione are not expected in maize and the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the magnitude of residues in processed commodities.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, $DT\ 90_{field}$ values of mesotrione are expected to range between 36 - 78 days which is far below the trigger value of 100 days. Furthermore, the major soil metabolites MNBA and AMBA were also demonstrated to be of low persistence ($DT\ 50_{lab}$ values of 7.5 and 3.2 days, respectively). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is not required.

It was concluded in the RAR (RMS United Kingdom, 2015) that magnitude of residues trials for rotational crops are not required as the available rotational metabolism data demonstrates that significant residues of mesotrione (greater than 0.01 mg/kg) are not expected in following crops as a result of the proposed use on maize. Similarly, EFSA (2016) concluded that field rotational crop studies are not triggered considering the very low TRRs in the evaluated confined rotational crops and considering also the low to moderate persistence of mesotrione, MNBA and AMBA.

Although not required, rotational crop field trials were evaluated in the framework of the peer review under Regulation (EC) No. 1107/2009. The studies evaluated in support of the Annex I listing of mesotrione are no longer data protected.

zRMS comments:
Magnitude of residues in representative succeeding crops was evaluated at EU level. According to the EFSA Journal 2016;14(3):4419: *Bare soil application of mesotrione labelled respectively on cyclohexane-2-^{14}C and phenyl-U^{14}C at a dose rate of 164 g a.s./ha (1N). At 120 day plant back interval (PBI), TRRs are very low in all crop parts: <0.01 mg/kg in wheat grain and radish root, 0.012 mg/kg in broad-leaves endive and up to 0.033 mg/kg in wheat forage and straw.*
Metabolites' identification at 300 d PBI not further investigated.
Additional studies are not required

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Rotational crop studies were already evaluated in the EU Review of mesotrione. They are summarised in **Table 7.2-13** below. No new data submitted in the framework of this application.

The magnitude of mesotrione residues in field rotational crop studies was investigated and summarized in the RAR (RMS United Kingdom, 2015) and reviewed by EFSA (2015 and 2016). These studies were conducted in the US but considered acceptable by the RMS.

Table 7.2-13: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)*	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Maize	0.34 (pre-planting)	Leaves (Leafy vegetables)	Soybean (forage, hay, seed)	30	UK, 2015 EFSA, 2016 Barnes, J.P. et al. 1997 Report No. RR 97-044B
		Roots (Root and tuber vegetables)	Radish (tops, roots)	56	
		Small grain (cereals)	Millet (forage, hay, straw, grain) Sorghum (forage)	30	
	0.34 + 0.22 (pre-planting + post-emergence at 60-90 cm crop height)	Leaves (Leafy vegetables)	Endive leaves	74	
		Roots (Root and tuber vegetables)	Radish (tops, roots)	85	
		Small grain (cereals)	Wheat (forage, hay, straw, grain)	100	
Maize	0.34 (pre-planting)	Leaves (Leafy vegetables)	Soybean (forage, hay, seed)	29	
		Roots (Root and tuber vegetables)	Radish (tops, roots)	29	
		Small grain (cereals)	Millet (forage, hay, straw, grain) Sorghum (forage)	29	
	0.34 + 0.22 (pre-planting + post-emergence at 60-90 cm crop height)	Leaves (Leafy vegetables)	Endive leaves	98	
		Roots (Root and tuber vegetables)	Radish (tops, roots)	98	
		Small grain (cereals)	Wheat (forage, hay, straw, grain)	98	

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

Two field rotational crops studies were conducted in the US in 1995-96 (two studies), in which mesotrione was applied either a) to soil and incorporated prior to planting of the maize crop, or b) to both the soil as above and post emergence to the maize crop at 24-36 inches tall (60 – 90 cm). After removal of the maize crop, succession crops were grown (soybean, endive, radish, millet, sorghum and wheat) and sampled at normal commercial harvest. Mesotrione was applied in admixture with a spray additive of crop oil concentrate (1% v/v) at rates of 0.34 kg mesotrione/ha (pre-planting) and 0.56 kg mesotrione/ha (0.34 kg/ha pre-planting and 0.22 kg/ha post-emergence). The first application was used to simulate early season crop failure and the second to simulate normal application post emergence. Succeeding crops were sown within 29/30 days (simulating crop failure) to 98/100 days after last application. The chosen crops and climatic conditions were considered comparable to growing conditions in Europe.

Crop samples of soybean (forage, hay and seed), endive (leaves), radish (tops and roots), millet (forage, hay, straw and grain), sorghum (forage) and wheat (forage, hay, straw and grain) were analysed for residues of mesotrione and MNBA. Residues in all crop commodities and all plant back intervals were below LOQ (< 0.01 mg/kg) for both mesotrione and MNBA. AMBA, which is contained in the provisional residue definition for risk assessment for feed commodities, was not analysed in the rotational crop study.

Magnitude of residues trials for rotational crops are not required as the available rotational metabolism data demonstrates that significant residues of mesotrione (greater than 0.01 mg/kg) are not expected in following crops as a result of the proposed use on maize. Results from the conducted residue field trials for rotational crops confirm that levels of mesotrione in rotational crops are likely to be < 0.01 mg/kg.

According to the RMS the field rotational crop studies submitted in the RAR provide sufficient evidence to demonstrate that relevant residues are not present and none of the established MRLs will be exceeded as a result of the cultivation of rotational crops. EFSA (2016) also considered these studies to be sufficient to demonstrate the absence of residues in rotational crops, provided that mesotrione is applied in compliance with the GAPs.

The proposed residue definition for risk assessment for feed commodities is mesotrione and AMBA (including its conjugates) and is applicable for cereals, pulses and oilseeds only and only for conventional crops (EFSA, 2016). Residues of AMBA were not determined in the available field rotational crop studies. However, it was postulated in the RAR (RMS United Kingdom, 2015), that if MNBA is taken as a representative marker for mesotrione metabolites, then no AMBA residues would be expected at the proposed use rate.

No MRLs are currently set for forage crops to account for residues arising from cultivation of rotated crops. Based on the results residues from rotational crops are not expected to increase the dietary burden intake of livestock or to have an impact on the residue level in products of animal origin.

Conclusion on rotational crops studies

The intended GAP for SAE053H/01 includes foliar application to maize (cereals) at 120 g mesotrione/ha. Therefore, the two available field rotational crops studies were all conducted at exaggerated application rates thus covering the intended uses.

At the supported GAP no residues of mesotrione above LOQ (0.01 mg/kg) are to be expected in succeeding edible crops (leafy and root vegetables and cereal grain) and thus, there is no risk for exceedance of EU MRL in edible rotational crops. At the supported GAP, residues of mesotrione above LOQ (0.01 mg/kg) are also not to be expected in succeeding for feeding stuff. Therefore, there is no risk of the animal MRL being exceeded.

zRMS comments:
Field rotational crop studies ware evaluated at EU level. According to the EFSA Journal 2016;14(3):4419: *Not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate and considering also the low to moderate persistence of mesotrione, MNBA and AMBA.*
US rotational crop field trials were conducted on pulses/oilseeds (soya bean), leafy vegetables (endive), root vegetables (radish) and cereals (small grains (wheat)) after bare soil application at 0.34 kg a.s./ha

or after bare soil application (0.34 kg a.s./ha) followed by a post-emergence application (0.22 kg a.s./ha). Residues of mesotrione and of MNBA were < 0.01 mg/kg in all crop parts.
Additional studies are not required.

7.2.7 Other / special studies (KCA 6.10, 6.10.1)

Two new studies investigating the residue decline of mesotrione in immature maize leaves are available. Results from these studies may be used to evaluate the potential exposure of wildlife (e.g. birds and mammals) to residues of mesotrione in maize seedlings as food items.

In the first of the studies (Bakker, F., Report number JS001LRM), three trials in Northern Europe and three trials in Southern Europe are available to determine residues of mesotrione in immature maize leaves in the four days following one field application of a 10% SC product containing nominally 100 g/L mesotrione at a rate of 1.5 L/ha, equivalent to 0.150 kg a.s./ha at BBCH 16-18. In the second study (van de Sandt, H.J., Report No. S17-05218), a further four residue field trials were performed on maize in Northern Europe investigating the residue decline over the four days following application at crop stage BBCH 14-15, where a single application of mesotrione 100 g/L SC was applied at a rate of 1.5 L/ha, equivalent to 0.150 kg a.s./ha.

The application rate in both studies was performed within the 25% difference of the critical GAP (120 g/ha mesotrione). Residues of mesotrione were determined in samples of maize leaves collected directly from the maize plants after last application at 0 day and at different time interval until up to 4 days after application. Mesotrione residues have been analysed according to an analytical procedure based on the multi-residue method QuEChERS followed by determination with LC-MS/MS.

A more detailed description is provided in Appendix A 2.1.7.

zRMS comments:
The studies described above ware not used in this evaluation (Part B, Section 7), hovewer provides additional information that can be used for the evaluation the potential exposure of wildlife (e.g. birds and mammals) to residues of mesotrione in maize seedlings as food items. The analytical methods used in these studies were fully validated.

7.2.7.1 Effect on the residue level in pollen and bee products (KCA 6.10.1)

During the peer review process EFSA (2016) identified a data gap with respect to determination of residues of mesotrione in pollen and bee products for human consumption which result from residues taken up by honeybees from crops at blossom. They suggest that this data is submitted for all representative uses evaluated. However, EFSA (2016) also noted that the RMS (United Kingdom, 2015) disagreed with the setting of this data gap.

In the RAR (RMS United Kingdom, 2015) it was concluded that Mesotrione is not a systemic herbicide and is not known to have any toxic effects to bees. In addition, it was argued that for the supported representative use of mesotrione on maize, applied at early growth stages (typically BBCH 02 to 18), there is no likelihood of mesotrione exposure to honey bees and residues of mesotrione in pure blossom honey or other bee products will not occur from this use. Lastly, there is currently no implemented EU guidance for residue levels in pollen and bee products. Therefore these data are not currently required.

zRMS comments:
Studies on the effect on the level of residues in pollen and bee products are not required. According to the Appendix II of *Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey,* SANTE/11956/2016 rev. 9, maize was considered a crop from which it is not possible to produce honey.

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).

Consumer risk assessment is limited to the representative uses and is considered to be not finalized (EFSA 2016) as clarification on the genotoxic potential of AMBA and of its toxicological profile is requested.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-14: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition : mesotrione				
Maize	0.01	EU MRL	0.01	EU MRL
Other commodities of plant and animal origin	MRL	EU MRL	-	-

The existing EU MRL for each commodity set in Regulation (EC) No 2017/626 amending Regulation (EC) No 396/2005 is used for exposure calculations.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-15: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	12 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	--
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: Maize/corn: 0.3% (Children) Maize/corn: 0.1% (Adults) Processed commodities: Maize/oil: 1% (Children) Maize/oil: 0.6% (Adults)

* include raw and processed commodities if both values are required for PRIMo

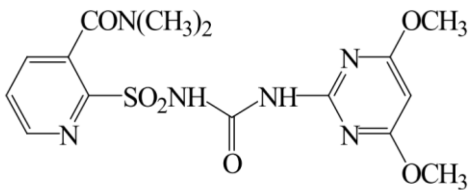
The proposed use of mesotrione in the formulation SAE053H/01 does not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
TMDI calculation performed using EFSA PRIMo Rev. 3.1 covered all MRLs in force (Reg. (EU) 2017/626).
The highest chronic exposure was calculated for NL toddler, representing 12 % of the ADI. The highest acute exposure corresponded to 0.3 % ARfD.
The use of mesotrione on maize according to the GAP proposed for SAE053H did not indicate a risk to consumers. Taking into account that clarification on the genotoxic potential of AMBA and of its toxicological profile is requestes, the dossier for SAE053H may need to be re-evaluated after the toxicological data for AMBA has been assessed at Community level.

7.3 Active substance 2 - 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 or 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-dimethylcarbamoyl-2-pyridylsulfonyl)urea
Chemical structure	
Molecular formula	$C_{15}H_{18}N_6O_6S$
Molar mass	410.4 g/mol
Chemical group	Sulfonyl urea herbicide
Mode of action (if available)	Selective, systemic herbicide, Inhibits acetolactate synthase (ALS), a key enzyme for branched-chain aminoacids synthesis, which results in cessation of cell division and plant growth. The selectivity is due to the capacity that the crop has to metabolize the herbicide and transform it into inactive metabolites.
Systemic	Yes
Company (ies)	DuPont/ISK*
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved on 01/01/2009 and reference to decision Commission implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1617

	Expiration of approval – 31/12/2020, Reg. (EU) 2019/1589
Restriction (e.g. is restricted to use as "...")	To use as Herbicide see Approval Directive 2008/40/EC
Review Report	SANCO/3780/07 – rev. 1 22/01/2008
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; EFSA 2012**
Current MRL applications on intended uses	Commodities: Maize 0.01 mg/kg (Regulation (EU) No 617/2014)

* Notifier in the EU process to whom the a.s. belong(s)
** 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 is submitted in the framework of this application. Data on the stability of nicosulfuron and its metabolites ASDM and ADMP in maize, was submitted for the first inclusion of nicosulfuron into Annex I of Council Directive 91/414/EEC and was reviewed under uniform principles.

Storage stability studies are available for nicosulfuron tested under GLP. The storage stability of nicosulfuron has been investigated in several commodities and was reported in the DAR (RMS United Kingdom, 2006) and the Addendum to the DAR (RMS United Kingdom, 2007). Residues of nicosulfuron were found to be stable at approximately -20°C for 9 months in maize which is sufficient to cover the storage period of the residue trials. Results are summarized in **Table 7.3-2** below.

No livestock feeding studies have been conducted. It is therefore not required to conduct a storage stability study on products of animal origin.

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 plant	High water content	Up to 9 months Nicosulfuron ASDM ADMP	UK, 2006 & 2007 EFSA, 2007 Schulz M., Ullrich-Mitzel A., 1995,
Maize ear	High starch content		

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
			Report No. 304762
Processed Commodities			
Not required, no residues in products of plant/animal origin subject to processing at or higher than 0.01 mg/kg			
Animal Products			
Not required, intake not expected to exceed 0.004 mg/kg bw/day			

Conclusion on stability of residues during storage

Residues of nicosulfuron were found to be stable at approximately -20°C for 9 months in maize which is sufficient to cover the storage period of the residue trials. No stability data is required for products of animal origin as no livestock feeding studies have been conducted.

The intended GAPs for SAE053H/01 include application to maize. The available storage stability studies cover the intended uses.

zRMS comments:
According to the EFSA Journal 2012;10(12):3048: *In the framework of the peer review, storage stability of nicosulfuron was demonstrated for a period of 9 months at -20°C in dry commodities (maize grain) and in high water content commodities (maize whole plant) (United Kingdom, 2005). All residues trial samples were stored in compliance with the storage conditions reported above. Degradation of residues during storage of the trial samples is therefore not expected.*
Additional studies are not required.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Extracted nicosulfuron residues were normally analysed within a 1-2-week period. In general, the stability of the residues in samples extracts are proven by the determination of the recovery in fortified samples which were extracted, stored and analysis in parallel with the residue samples.

7.3.2 Nature of residues in plants, livestock and processed commodities

zRMS comments:
Nature of residues in plants, livestock and processed commodities was evaluated at EU level.
The residue for enforcement and risk assessment in cereals is defined as nicosulfuron only. It was not possible to propose residue definitions in animal products however, residues in animal products are not expected to be significant (animal dietary intakes are <0.1 mg/kg diet) (EFSA Scientific Report (2007) 120, 1-91; EFSA Journal 2012;10(12):3048). The available metabolism studies on maize (cereals) cover the intended uses.

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data have been submitted in the framework of this application. The metabolism of nicosulfuron in corn was submitted for the first inclusion of nicosulfuron into Annex I of Council Directive 91/414/EEC and was reviewed under uniform principles. The data described in the DAR (RMS United Kingdom,

2006) and the addendum to the DAR (RMS United Kingdom, 2007) is still considered adequate to address this endpoint.

Plant metabolism was studied in maize with radiolabelled nicosulfuron.

Information on crops tested, application and sampling details are given in **Table 7.3-3** below.

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	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Corn	[pyridine-2-14C]-nicosulfuron	foliar treatment, G	60 g a.s./ha 300 g a.s./ha	1	0, 14, 30, 60 (silage) and 102 days (maturity)	GLP	UK, 2006 & 2007, Mamouni A., 1995, Report No. 272158 (and Amendment)
	Corn	[pyrimidine-5-14C]-nicosulfuron	foliar treatment, G	60 g a.s./ha 300 g a.s./ha	1	0, 14, 30, 60 (silage) and 102 days (maturity)	GLP	UK, 2006 & 2007, Schanné C., 1991, Report No. 274173

Summary of plant metabolism studies reported in the EU

Metabolism in plants has been investigated using foliar applications on maize, using radio-labelled nicosulfuron either in the ^{14}C-pyridine or the ^{14}C-pyrimidine ring (RMS United Kingdom, 2006 & 2007, EFSA, 2007).

The primary metabolic pathway is hydrolytic cleavage of the sulfonylurea bridge resulting in formation of ASDM, ADMP and DMPU. In early plant samples (Day 0) pathways involving O-demethylation of dimethoxy group on the pyrimidine ring (HMUD) followed by metabolism of the ring (AUSN) were observed, although HMUD was not present in corn RACs treated at the evaluated dose rate.

In both studies, minimal translocation of nicosulfuron residues from treated foliage to the grain was observed.

Conclusion on metabolism in primary crops

The intended GAP for SAE053H/01include foliar application to maize (cereals) with one application per season/crop at a maximum rate of 0.045 kg/ha nicosulfuron. The available metabolism studies on maize (cereals) cover the intended uses.

Based on the available information, the plant residue definition for enforcement and risk assessment was defined as nicosulfuron (EFSA, 2007).

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 and no studies on residues in rotational crops were submitted for Annex I inclusion of nicosulfuron.

Based on the soil DT_{50} of nicosulfuron and the phytotoxic effects of nicosulfuron which limits the re-planting period, it was concluded that no significant residues would be expected in rotational crops and no further data would be necessary (EFSA conclusion, 2007). Furthermore, with respect to the available phytotoxicity studies, lysimeter studies and studies indicating the non-toxicological relevance of potentially available metabolites, it was concluded that these studies are considered sufficient by EFSA to demonstrate the absence of residues in rotational crops (EFSA MRL review of nicosulfuron, 2012).

Conclusion on metabolism in rotational crops

The intended critical dose rate (1 x 0.045 kg a.s./ha) is not more critical than the dose rate of the representative use supported during Annex I inclusion and subsequent EFSA MRL review. It was concluded that significant residues in rotational crops are not expected (EFSA conclusion, 2007 and EFSA MRL review of nicosulfuron, 2012).

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Residue levels of 0.01 mg/kg or higher are not expected in raw commodities of the intended crops. In addition, consumer intakes of processed commodities accounted for less than 10% of the ADI. Therefore a study on the nature of the residue in processed commodities is not required

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

Hydrolysis studies addressing the nature of the residues in processed commodities were not triggered. In addition, consumer intakes of processed commodities accounts for less than 10% of the ADI. Therefore processing studies are not required.

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

Table 7.3-4: 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 (EU) No 617/2014; EFSA 2007)
Plant residue definition for risk assessment	Nicosulfuron (Regulation (EU) No 617/2014; EFSA 2007)
Conversion factor from enforcement to RA	None (EFSA 2007)

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

Available data

Residues in animal feed are expected to be < 0.004 mg/kg bw/day in ruminants, poultry or pigs (see Point 7.3.4.1 below). Data on the metabolism of nicosulfuron in livestock are therefore not required.

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

However, studies on metabolism of nicosulfuron in livestock were already evaluated during the EU Review process and were considered acceptable (DAR and the addendum to the DAR, RMS United Kingdom, 2006 & 2007). Studies are summarised in **Table 7.3-5** below.

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	[pyridine-2-14C]-nicosulfuron	1	2 x 4.14 mg/kg bw/d (total of 8.3 mg/kg bw/d)	3 consecutive days, Twice daily	Blood	0.5, 1, 2, 3, 4, 6, 8 hours after first administration and 16 hours after last administration (at sacrifice)	UK, 2006 xxx, 1995a, Report No. 358323
						Milk	twice daily 0.5 hours before administration	
		[pyrimidine-5-14C]-nicosulfuron	1	2 x 4.32 mg/kg bw/d (total of 8.64 mg/kg bw/d)	3 consecutive days, twice daily	Urine and faeces	24 hour intervals during dosing and after the last administration until sacrifice	UK, 2006 xxx, 1995b, Report No. 358312
						Organs (liver and kidney)	after sacrifice (16 hours after last dose)	
		[pyrimidine-5-14C]-nicosulfuron	1	0.0069 mg/kg bw/d	3 consecutive days, Twice daily	Tissues (fat and muscle)		UK, 2006 xxx, 1995c, Report No. 367356

* Denmark, 2007; EFSA, 2014
** samples were taken but TRR was not determined

Summary of animal metabolism studies reported in the EU

The nature of nicosulfuron residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC and reported in the DAR and the addendum to the DAR (RMS United Kingdom, 2006 & 2007). The reported metabolism studies include 3 studies in lactating goats using pyridine- and pyrimidine-labelled nicosulfuron.

The three metabolism studies gave very similar results. 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).

The metabolism of nicosulfuron in goats proceeds primarily by three pathways: (1) hydrolysis of the sulphonylurea bridge; (2) N-demethylation and loss of sulphur dioxide to form DDTP and (3) oxidation and conjugation at the 5-position of the pyrimidine ring.

Conclusion on metabolism in livestock

The intended GAP for SAE053H/01 includes foliar application to maize (cereals) which may serve as animal feed. However, residues in animal feed are expected to be < 0.004 mg/kg bw/day in ruminants, poultry or pigs (see Point 7.3.4.1 below). Data on the metabolism of nicosulfuron in livestock are therefore not required.

However, metabolism studies are available. The intended critical dose rate (1 x 0.045 kg a.s./ha) results in dietary intake which is much lower than the dose rates used in the metabolism studies. Therefore, the available metabolism studies can be used to support the intended uses of nicosulfuron.

It was concluded in the Addendum to the DAR (RMS United Kingdom, 2007), that the toxicity of some of the metabolites found in significant levels is not known and that therefore, it is not possible to propose residue definitions in animal products at this time. However, it was noted that based on the proposed uses, residues in animal products were not expected to be significant.

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).
Animal residue definition for risk assessment	Unable to propose, however intakes are not significant (<0.1 mg/kg diet).
Conversion factor	None (EFSA 2007)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

The magnitude of residues of nicosulfuron in maize was evaluated in the DAR (RMS United Kingdom, 2006), in the AIR dossier (2016) which is currently under review, and by EFSA (2007 and 2012). All documents used the same data set. Data of one trial which is listed in the AIR dossier (2016) was not used, as this trial data was not found in the DAR (RMS United Kingdom, 2006). Three trials which were used in the DAR (RMS United Kingdom, 2006) but not in the AIR dossier (2016) were also not included in the evaluation below as no information on the growth stage (BBCH) at application was provided. Similar to the AIR dossier (2016) trial data on maize ear (3 trials, residues all below LOQ) were included in the evaluation of maize grain, since residues in maize grain are below LOQ if residues of the complete maize ear are below LOQ. Unlike in the AIR dossier (2016), only one whole plant result (one sampling timing) per trial was used in the evaluation below.

No new studies on the magnitude of residue on maize have been submitted by the applicant in the framework of this application.

Table 7.3-7: Summary of EU reported and new data supporting the intended uses

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	DAR, 2006, AIR, 2016 EFSA 2012	N-EU	Trials GAP: 1 x 0.060 kg nicosulfuron/ha, BBCH 14-18, PHI=NCH (normal commercial harvest), outdoor E = RA: 16x<0.01	N/A				
	DAR, 2006, AIR, 2016 EFSA 2012	N-EU	Trials GAP: 1 x 0.080 kg nicosulfuron/ha, BBCH 13-18, PHI=NCH (normal commercial harvest), outdoor E = RA: 2x<0.01					
	Overall supporting data for cGAP	N-EU	E = RA: 18x <0.01	0.01	0.01	0.01	0.01	Yes
Maize Whole plant (silage/forage ***)	DAR, 2006, AIR, 2016 EFSA 2012	N-EU	Trials GAP: 1 x 0.060 kg nicosulfuron/ha, BBCH 15-19, PHI=46-100 (immature), outdoor E = RA: 15x<0.01, 1x0.015**	N/A				
	DAR, 2006, AIR, 2016 EFSA 2012	N-EU	Trials GAP: 1 x 0.080 kg nicosulfuron/ha, BBCH 13-18, PHI=95-96 (immature), outdoor E = RA: 2x<0.01					
	Overall supporting data for cGAP	N-EU	E = RA: 18x<0.01	0.01	0.01**	-	-	-

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

**The one positive residue in forage was probably due to contamination as samples taken two months earlier showed no quantifiable residues; this result was therefore not taken into consideration in the risk assessment by EFSA (2007).

***referred to as silage in the summary of the DAR (RMS United Kingdom, 2006) and in the AIR dossier (2016), referred to as forage in the EFSA conclusion (2007) and the EFSA reasoned opinion on MRLS (2012).

7.3.3.2 Conclusion on the magnitude of residues in plants

Field residue trials conducted in maize were evaluated in the DAR (RMS United Kingdom, 2006), in the AIR dossier (2016) or by EFSA review of MRL (2012). No new trials have been submitted by the applicant in the framework of this application. The trials evaluated on EU level and by the EFSA were performed with exaggerated application rates of 1x 0.060 kg/ha, and 1x 0.080 kg/ha than the critical GAP of SAE053H/01 (1 x 0.045 kg/ha nicosulfuron). Those trials can be regarded as a worst case situation which covers the intended use of SAE053H/01. In addition, a few trials have a slightly later application date and can be considered worst case. All trials are therefore acceptable for support of the intended use of SAE053H/01.

Residue trials with nicosulfuron in maize were conducted with OD formulation, therefore, the trials evaluated on EU level which are summarised above can be used to support the registration of SAE053H/01 containing nicosulfuron as OD formulation.

In summary, residues of nicosulfuron found in maize grains at harvest were always below the limit of determination (<0.01 mg/kg) even when applied at an exaggerated rate. The residues in plant parts potentially used as animal feed (including plants before maturity) were also below 0.01 mg/kg. However, in one trial in Northern France a residue of 0.015 mg/kg was found in the plants without ears 88 days after treatment. This result is considered to have been caused by contamination as samples taken two months earlier showed no quantifiable residues. It was not considered in the risk assessment by EFSA (2007) and it is not taken into account in risk assessment in the table above.

According to the available data, the intended use on maize is considered acceptable and it is not expected to have residues above the EU MRL of 0.01 mg/kg nicosulfuron when SAE053H/01 is applied according to the GAP.

Trials were also reanalysed for the metabolites ASDM and AUSN but both metabolites were never detected above the LOQ. The minimum LOQ was 0.02 mg/kg.

zRMS comments:
The Applicant has not submitted any new studies on the magnitude of residues in plants for the purpose of this application. The use of nicosulfuron proposed in the GAP for SAE053H is covered by GAP already evaluated at EU level. In all studies considered in the evaluation at EU level residues of nicosulfuron in maize grains (n=18) and whole plants (n=18) were below LOQ (0.01 mg/kg). Sufficient residue trials are available to support the use of nicosulfuron on maize at the GAP proposed for SAE053H.
Additional studies are not required.

7.3.4 Magnitude of residues in livestock

zRMS comments:
Not required. The residues of nicosulfuron in animal products are not expected to be significant (animal dietary intakes are < 0.1 mg/kg diet) (EFSA Journal, 2012;10(12):3048).

7.3.4.1 Dietary burden calculation

Nicosulfuron is authorised for use on maize grain and maize forage that might be fed to livestock.

Animal dietary burden calculation was performed in accordance to the Guidance Document on residues in livestock (Series on Pesticides No. 73, 2013) and OECD Test Guideline 505: Residues in livestock (2007). In addition, results of the field residue trials submitted in this dossier which are summarized in **Table 7.3-8** and which are not already listed by EFSA (2012) are also used in the animal intake calculation: maize milled byproducts, maize hominy meal, maize gluten feed, maize gluten meal and maize distiller's grain.

The excel calculator (Animal model 2017.xls) developed by EFSA was used to perform the animal dietary burden. The default value of processing factor was used for the relevant commodities.

The following table summarises the residue level used in the calculations of the feeding intake and the dietary burden calculation for the active substance nicosulfuron.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: nicosulfuron				
Maize grain (field and pop)	0.01	Median residue (EFSA, 2012)	0.01	Highest residue (EFSA, 2012)
Maize forage	0.01	Median residue (EFSA, 2012)	0.015	Highest residue (EFSA, 2012)
Maize milled by-products	0.01	Median residue (EFSA, 2012) x default PF of 1	0.01	Median residue (EFSA, 2012) x default PF of 1
Maize hominy meal	0.06	Median residue (EFSA, 2012) x default PF of 6	0.06	Median residue (EFSA, 2012) x default PF of 6
Maize gluten feed	0.025	Median residue (EFSA, 2012) x default PF of 2.5	0.025	Median residue (EFSA, 2012) x default PF of 2.5
Maize guten, meal	0.01	Median residue (EFSA, 2012) x default PF of 1	0.01	Median residue (EFSA, 2012) x default PF of 1
Maize distiller's grain	0.033	Median residue (EFSA, 2012) x default PF of 3.3	0.033	Highest residue (EFSA, 2012) x default PF of 3.3

Table 7.3-9: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition; nicosulfuron					
Beef cattle*	0.001	0.001	Maize, gluten feed	0.05	No

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)
Dairy cattle*	0.001	0.002	Maize, gluten feed	0.04	No
Ram/ewe	0.001	0.001	Maize, gluten feed	0.02	No
Lamb	0.001	0.001	Maize, gluten feed	0.02	No
Breeding swine	0.001	0.001	Maize, gluten feed	0.03	No
Finishing swine*	0.001	0.001	Maize, gluten feed	0.02	No
Broiler poultry	0.001	0.001	Maize, milled by-products	0.01	No
Layer poultry*	0.002	0.002	Maize, hominy meal	0.03	No
Turkey	0.001	0.001	Maize, hominy meal	0.02	No

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

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No data was submitted for evaluation in the DAR (RMS United Kingdom, 2006), its Addendum (RMS United Kingdom, 2007) or in the AIR dossier (2016) and no new data was submitted in the framework of this application. Intakes of nicosulfuron by domestic animals is considered to not be significant and livestock studies were therefore considered as not necessary (EFSA, 2007 and 2012).

Conclusion on feeding studies

No new studies are submitted in the Annex I Renewal of nicosulfuron and are not required. The calculated dietary burdens for all types of livestock were found to be below the trigger value of 0.004 mg/kg bw/d, therefore livestock feeding studies are not required. In addition, EFSA (2012) concluded that the setting of MRLs in commodities of animal origin is also not necessary.

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

No new data was required or submitted by the applicant in the framework of this application.

An evaluation of the distribution of residues between peel/pulp is not applicable to nicosulfuron as it is only intended for use in maize (cereals) which is not separated in this way.

According to Commission Regulation (EU) No. 283/2013 studies concerning the magnitude of residues in the various processed commodities are not required if the level of residues is less than 0.1 mg/kg and the commodity under consideration contributes less than 10% of ADI to the estimated theoretical maximum daily intake (TMDI) or less than 10% of ARfD to the estimated daily intake for any European consumer group diet.

No balance studies and no determination of concentration or dilution factors were conducted with maize treated with nicosulfuron since no significant residue (<0.1 mg/kg) was measured under the proposed conditions of use in field studies and the contribution of maize to the theoretical maximum daily intake TMDI) is less than 10% of the ADI. Therefore, no processing studies are necessary.

Default processing factors are available for calculation of dietary burden.

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

7.3.6 Magnitude of residues in representative succeeding crops

No data was submitted for evaluation of the magnitude of residues in succeeding crops in the DAR (RMS United Kingdom, 2006), its Addendum (RMS United Kingdom, 2007) or in the AIR dossier (2016) and no new data was submitted in the framework of this application.

Considering the conclusions drawn dealing with the nature of residues (see Point 7.3.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No data was submitted for evaluation of the magnitude of residues in succeeding crops in the DAR (RMS United Kingdom, 2006), its Addendum (RMS United Kingdom, 2007) or in the AIR dossier (2016) and no new data was submitted in the framework of this application.

For Annex I inclusion, studies addressing the phytotoxicity of nicosulfuron in field rotation trials and greenhouse bioassays using field aged soil were submitted. Nicosulfuron was applied to maize and in one study rotational crops were sown at 1 month (corn, sunflower and beans), 50 to 80 days (oilseed rape and barley) and 4 to 10 months (wheat and sugar beet). In the other study winter wheat was grown as rotational crop 5 months after harvest and removal of maize (field). In both studies bioassays were conducted in the greenhouse using oilseed rape, barley, sugar beet, oats, rye grass and red clover (first study), barley and sugar beet (second study).

In the first study, evidence of phytotoxicity in greenhouse tests was seen in all crops tested, apart from maize, in soil aged for 1 month. Some effects could be observed in oilseed rape, barley, sugar beet and rye grass after a 50 day plant back period, but none after 9 and 10 month plant back periods. Under field conditions no phytotoxicity to maize grown as a rotational crop, re-sown 1 month after application of nicosulfuron was observed, but damage was observed with other crops after longer plant back periods of up to 80 days. No phytotoxicity under field conditions to winter wheat sown 4 months or sugar beet sown 10 months after application of nicosulfuron was observed. In the second study, some evidence of phytotoxicity was seen in winter barley and sugar beet grown in soil aged for 3 and 4 months in greenhouse tests. Under field conditions no phytotoxicity to winter wheat as a rotational crop, sown 5 months after application of nicosulfuron to maize, was observed. Therefore in normal crop rotation, after ploughing, winter wheat, winter barley, winter rye, and triticale can be sown. All other crops can be sown in the following spring. In case of plant-back situation (crop failure), maize can be sown after ploughing.

Conclusion on rotational crops studies

Phytotoxicity data indicates that under field conditions the phytotoxicity of nicosulfuron limits the plant back interval to normal crop rotation. In case of crop failure only maize can be sown.

The intended critical dose rate (1 x 0.045 kg a.s./ha) is not more critical than the dose rate of the representative use supported during Annex I inclusion and subsequent EFSA MRL review. It was concluded that significant residues in rotational crops are not expected (EFSA conclusion, 2007 and EFSA MRL review of nicosulfuron, 2012). Residues in rotational crops above the EU MRL are therefore unlikely, provided that nicosulfuron is applied according to the proposed GAP.

zRMS comments:
Magnitude of residues in representative succeeding crops was evaluated at EU level. The available studies were considered sufficient by EFSA to demonstrate the absence of residues in rotational crops, provided that nicosulfuron is applied in compliance with the GAPs reported in EFSA Journal 2012;10(12):3048. GAP proposed for nicosulfuron in SAE 053H is less critical than GAP evaluated at EU level. Additional studies are not required.

7.3.7 Other / special studies (KCA 6.10)

No new data submitted in the framework of this application.

7.3.7.1 Effect on the residue level in pollen and bee products (KCA 6.10.1)

Nicosulfuron is applied early in the growing season when bee foraging activity is low. The treated crop is not foraged by bees, flowering weeds are unlikely to be in bloom at the time of application and are unlikely to mature following the application of a herbicide. The potential exposure to foraging bees is very low consequently the potential for residue detection in pollen and bee products, specifically honey, is zero. ~~Lastly, there is currently no implemented EU guidance for residue levels in pollen and bee products.~~ Therefore these data are not currently required.

zRMS commnets:
Not required. According to the Appendix II of *Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey*, SANTE/11956/2016 rev. 9, maize was considered a crop from which it is not possible to produce honey.

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).

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	
	Input value (mg/kg)	Comment
Risk assessment residue definition: nicosulfuron		
Maize / Corn	0.01	EU MRL
Other commodities of plant and animal origin	MRL	EU MRL

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.1 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	--

The proposed use of nicosulfuron in the formulation SAE053H/01 does not represent unacceptable chronic risks for the consumer.

zRMS comments:
TMDI calculation performed using EFSA PRIMo Rev. 3.0 covered all MRLs in force (Reg. (EU) 617/2014).
The highest chronic exposure was calculated for NL toddler, representing 0.1 % of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.
The use of nicosulfuron on maize according to the GAP proposed for SAE053H did not indicate a risk to consumers.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

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

7.4.1 Acute consumer risk assessment from combined exposure

Not relevant.

7.4.2 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.

7.5 References

AIR dossier 2016, Active substance: nicosulfuron, Document M-CA, Section 6 Residues in or on treated products, food and feed. Applicant: Nicosulfuron Task Force, 30 Jun 2016.

EFSA (European Food Safety Authority), 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance nicosulfuron. EFSA Scientific Report 2007; 120: 1-91 [91 pp.] Available online: www.efsa.europa.eu/efsa journal.

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for nicosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(12):3048. [27 pp.] doi:10.2903/j.efsa.2012.3048.
Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mesotrione according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3976, [36 pp.] doi:10.2903/j.efsa.2015.3976.
Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2016. Conclusion on pesticides peer review: Peer review of the pesticide risk assessment of the active substance mesotrione. EFSA Scientific Report 2016; 120: 1-103 [103 pp.] doi:10.2903/j.efsa.2016.4419.Available online: www.efsa.europa.eu/efsa journal.

EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mesotrione in light of confirmatory data. EFSA supporting publication 2018:EN-1527. 22 pp. doi:10.2903/sp.efsa.2018.EN-1527.

European Commission, 1997. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

European Commission, 2015. Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009, Mesotrione, Volume 3 – B.7 (AS), Rapporteur Member State: United Kingdom, Co-Rapporteur Member State: Belgium, 11 November 2015.

SANCO, 2003. Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC, Sanco/221/2000 – rev. 10 – final, 25 February 2003.

United Kingdom, 1999. ZA 1296 (ISO proposed name mesotrione), Volume 3, Annex B.7 to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8(1) of 91/414/EEC, December 1999.

United Kingdom, 2006. Draft Assessment Report, 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, June 2006.

United Kingdom, 2007. Final addendum to the Draft Assessment Report, 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, July 2007.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on (Mesotrione)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1/01 (KCA 6.3.1)	Semrau, J	2017	Determination of residues of mesotrione after one application of Mesotrione 80 g/L + Nicosulfuron 30 g/L OD in maize at 3 sites in Northern Europe 2015 Report No. S15-03081 GLP, unpublished	N	Sumi Agro Ltd
KCP 8.10/01 (KCA 6.10)	Bakker, F.	2016	Magnitude of mesotrione residues in maize plants following one application in Southern and Northern Europe in 2016 Report No.: JS001LRM GLP, unpublished	N	Sumi Agro Ltd
KCP 8.10/02 (KCA 6.10)	van de Sandt, H.J.	2019	Decline of mesotrione residues in maize plants following one application in The Netherlands – 2017 Report No. S17-05218 GLP, unpublished	N	Albaugh Europe Sàrl

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

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
CA 6.1	Wiebe L.A., Peyton C.S.	1999	ZA1296: Stability of ZA1296 & the Metabolite MNBA in Frozen Crops Report No. RR 97-042B GLP, unpublished	N	SYN*
CA 6.2.1	Wei Y., Dohn	1997	[cyclohexane-2-14C] ZA1296: Nature of the Residue in Corn (Zea mays)	N	SYN*

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
	D.R.		Report No. RR 96-026B GLP, unpublished		
CA 6.2.1	Tarr J.B., van Neste L.	1997	[phenyl-U-14C] ZA1296: Nature of the Residue in Corn Report No. RR 96-007B GLP, unpublished	N	SYN*
CA 6.2.3		1999	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow Report No. RJ2309B GLP, unpublished	Y	SYN*
CA 6.3.1	Barnes J., Chamier O., Wiebe L., Miller M.	1997	ZA1296: Residue levels in maize from trials carried out in Germany during 1996 (Postemergence) Report No. RR 97-048B GLP, not published	N	SYN*
CA 6.3.1	Barnes J. 1997a	1997a	ZA1296: Residue levels in maize from trials carried out in Germany during 1995 (WRC-96-114) Report No. RR 96-078B GLP, not published	N	SYN*
CA 6.3.1	Barnes J., Atger J., Wiebe L., Miller M.	1997	ZA1296: Residue levels in maize from trials carried out in France during 1996 (Postemergence) Report No. RR 97-045B GLP, not published	N	SYN*
CA 6.3.1	Barnes J.	1997	ZA1296: Residue levels in maize from trials carried out in France during 1995 (WRC-96-099) Report No. RR 96-071B GLP, not published	N	SYN*
CA 6.6.1	Gorder G.W.et al.	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate Report No. RR 96-084B	N	SYN*
CA 6.6.1	Spillner C. et al.	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate Report No. RR 95-042B GLP, not published	N	SYN*
CA 6.6.2	Barnes J.P., Wiebe L.A.	1997	ZA 1296: Residue levels on rotated crops from trials carried out in the United States during 1995-1996. Report No: RR 97-044B GLP, not published	N	SYN*

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

*Syngenta formerly Zeneca

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

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
CA 6.1	Schulz M., Ullrich-Mitzel A.	1995	Storage stability of SL-950 and its metabolites ASDM and ADMP in corn plants and ears Report No. 304762 GLP, unpublished	N	ISK
CA 6.2.1	Mamouni A.	1995	^{14}C-SL-950 (P): Plant metabolism study with corn in the greenhouse Report No. 272158 (and first amendment to report, dated 1996) GLP, unpublished	N	ISK
CA 6.2.1	Schanné C.	1991	^{14}C-SL-950 (Pm): Plant metabolism study with corn in the greenhouse Report No. 274173 GLP, unpublished	N	ISK
CA 6.2.2-6.2.5	xxx	1995a	^{14}C-SL-950 (P): Distribution, degradation, metabolism and excretion after repeated oral administration to a lactating goat Report No. 358323 GLP, unpublished	Y	ISK
CA 6.2.2-6.2.5	xxx	1995b	^{14}C-SL-950 (Pm): Distribution, degradation, metabolism and excretion after repeated oral administration to a lactating goat Report No. 358312 GLP, unpublished	Y	ISK
CA 6.2.2-6.2.5	xxx	1995c	^{14}C-SL-950 (Pm): Absorption, distribution and excretion after repeated oral administration to a lactating goat, based on an assumed daily intake of 0.15 mg/kg diet Report No. 367356	Y	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP, unpublished		
CA 6.3	Schulz H.	1993	Determination of the residues of SL-950 and its metabolites in corn (Germany, 1991) Report No. 310656 GLP, unpublished	N	ISK
CA 6.3	Ulrich C.	1994a	Nicosulfuron (4% w/v) – water miscible suspension (Code: HOE 1000063 00 SC04 A102) Field trials to generate samples for residue analysis following one application in maize Report No. ER 91 DEU 501 GLP, unpublished	N	ISK
CA 6.3	Schulz M.	1995a	Determination of the residues of SL-950 and its metabolites in fresh corn samples (Germany, 1992) Report No. 343528 GLP, unpublished	N	ISK
CA 6.3	Ulrich C.	1994b	Nicosulfuron (4% w/v) – water miscible suspension (Code: HOE 1000063 00 SC04 A102) Field trials to generate samples for residue analysis following one application in maize Report No. ER 92 DEU 501 GLP, unpublished	N	ISK
CA 6.3	Schulz H., Ullrich A.	1991a	Determination of the residues of SL-950 and its metabolites in corn Report to: Determination of residues of SL-950 in corn Report No. 272114 GLP, unpublished	N	ISK
CA 6.3	Schulz H., Ullrich A.	1991b	Determination of the residues of SL-950 and its metabolites in corn (dissipation study) Report to: Determination of residues of SL-950 in corn (dissipation study)N Report No. 272125 GLP, unpublished	N	ISK
CA 6.3	Schulz H..	1994	Determination of the residues of SL-950 and its metabolites in corn (Exp. No. S009KP, France 1991) Report No. 313964 GLP, unpublished	N	ISK
CA 6.5.2-6.5.3	Hesse B., Becker F.A.	1995	Investigation into the dissipation behaviour of nicosulfuron and its influence on rotational crops under field condition in the Federal Republic of Germany Report No. DE/HN/0191	N	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP, unpublished		
CA 6.5.2-6.5.3	Becker F.A., Raunft E.	1996	Phytotoxicity test of nicosulfuron on rotational crops under field conditions in Germany (trial period 1993/94) Report No. DE/HN/035/93 GLP, unpublished	N	ISK
CA 6.5.2-6.5.3	Schulz M.	1995	Analytical Phase: Analysis of soil residue samples – Analytical report to Evaluation of the phytotoxicity of nicosulfuron on subsequent crops under field conditions in Germany Report No. 350267 GLP, unpublished	N	ISK

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Active substance 1 – Mesotrione

A 2.1.1 Stability of residues

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

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

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

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Maize

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applica-tions	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015) EU GAP, SANTE/11654/2016 23 March 2017, EFSA Journal 2016;14(3):4419	1 1	150 g a.s./ha 120 to 150 g a.s./ha	Not applicable Not applicable	19 18	Not applicable Not applicable
Intended cGAP (number 1)	1	120 g a.s./ha	Not applicable	19	Not applicable
GAP for SAE 053H in Part B, Section 0	1	96 g a.s./ha	Not applicable	19	Not applicable

~~* 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:	Four trials were conducted on maize during 2015 in Austria, Denmark and the United Kingdom. One application was performed at BBCH 15-18 at a nominal rate of 1.5 L/ha (120 g mesotrione plus 45 g nicosulfurone/ha). The GAP proposed for SAE 063H (Part B, section 0) is less critical: 1 appl., BBCH 12-19, max appl. rate 1.2 L/ha (96 g mesotrione/ha plus 36 g nicosulfurone/ha). Specimen extraction and determination of residues were performed according to multi-residue method QuEChERS. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for mesotrione in maize matrices with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The mean recoveries at each fortification level in all specimens (maize grain, rest of plant and whole plant) were in the range of 70 - 110 % with RSD ≤ 20 % - see Part B, Section 5. Procedural recoveries were handles and stored in the same way and the same time period as the analytical specimen extracts. The following procedural recovieries were obtained:

Mesotrione (Procedural Recoveries)				
Matrix	**Fortification Level (mg/kg)**	**Procedural Recovery (%)**	**Overall Mean Recovery (%)**	**Overall Rel. Std. Dev. (%)**
Mass Transition 338→291 m/z				
Maize (whole plant)	0.01 (LOQ)	70	75	8.5
	0.10	76		
	1.0	84		
	8.0	71		
Maize (grain)	0.01 (LOQ)	71	77	12
	0.10	72		
	1.0	87		
Maize (rest of plant)	0.01 (LOQ)	71	77	7.8
	0.10	83		
	1.0	78		

Max. storage time for samples (< -18 °C) was 211 days (sampling to extraction) - it is covered by stability of mesotione (42 months for grain and 31 days for forage).
No residues of mesotrione above the LOD were detected in any of the untreated specimens. Metabolite AMBA has not been considered.

The study is accepted.

Reference:	7.2.3 / KCP 8.3.1 (KCA 6.3.1)
Report	Determination of residues of mesotrione after one application of Mesotrione 80 g/L + Nicosulfuron 30 g/L OD in maize at 4 sites in Northern Europe 2015, Semrau, J. 2017, Report No. S15-03081
Guideline(s):	Yes Regulation (EC) 1107/2009 and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 SANCO/3029/99 rev. 4 Guideline 7029/VI/95 (rev. 5) OECD Guideline 509
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

In the growing season 2015 four residue field trials have been performed in Northern Europe on maize (Austria, Denmark, United Kingdom). At each trial site one treated plot of approximately 45 – 90 m² and one untreated plot were marked. Plots were sown with maize (ZEAMX) at a rate of 85,000 – 160,000 seeds/ha. At BBCH ~~12~~ 15-18, the treated plots at each trial site were treated once with a Mesotrione 80 g/L + Nicosulfuron 30 g/L OD at a rate of 1.5 L/ha product, equivalent to 0.120 kg mesotrione/ha and 0.045 kg nicosulfuron/ha using a spray volume (nominal) of 200-400 L/ha.

Samples of crop were taken before application (control sample, maize whole plant), following application but prior to normal commercial harvest (NCH) (maize whole plant, maize forage and maize silage, trials 3 and 4 only) and at NCH (maize grain and maize rest of plant). Treated samples and untreated specimens were maintained in deep frozen condition during storage and shipment to the analytical site and at the analytical site (prior to extraction for analysis).

Residues of mesotrione have been analysed according to the multi-residue QuEChERS method, which was previously validated according to SANCO/3029/99 in study S15-04204 "Validation of the Analytical Method QuEChERS for the Determination of Mesotrione in Maize Matrices" (Schernikau, N., Suaza Colorado, C., 2016). For detailed information please refer to Section 4 analytical methods. In summary, water was added if required, then specimen material was extracted with acetonitrile, a salt mixture was added, extract was centrifuged and clean-up was carried out with dispersive SPE with primary/secondary amine (PSA). Detection was carried out with liquid chromatography and mass spectrometric detection (LC-MS/MS). The limit of quantification (LOQ) for mesotrione was 0.01 mg/kg, the LOD was set at 0.003 mg/kg.

Results and discussions

No residues above the limit of detection were found in any of the untreated specimens.

Residues of mesotrione were below the limit of detection in all sampled crop commodities starting 14 days after sampling.

Concurrent with the routine analysis of the specimens, recovery experiments were carried out within the analytical series. The mean procedural recoveries were between 70% and 110% demonstrating the validity of the analytical method.

The maximum storage interval on the residue samples is covered by the storage stability data of mesotrione.

Table A 2: Summary of the study 1 trials

Reference: Determination of residues of mesotrione after one application of Mesotrione 80 g/L + Nicosulfuron 30 g/L OD in maize at 3 sites in Northern Europe 2015, Semrau, J. 2017, Report No. S15-03081

GLP:	Yes	**Sample storage conditions:**	Maximum of 211 days at -18°C (or less)
Crop/crop group:	Maize / maize plant	**Analytical method:**	Multi-residue Method QuEChERS
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	OD	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	80 g/L mesotrione (nominal) 84.0 g/L mesotrione (actual) Other active substances in the formulation: 30 g/L nicosulfuron (nominal) 32.0 g/L nicosulfuron (actual)	**Residues calculated as:**	Mesotrione

Trial No./ Location/ EU zone/ Year	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 (hours, in decimal notation) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mesotrione		
S15-03081-01 8200 Gleisdorf, Styria, Austria / Northern Zone / 2015	Maize/ ZEAMX/ Alberto	1) 23 Apr 2015 2) 15 Jul to 15 Aug 2015 3) 16 Sep 2015	0.124	309	0.040	09 Jun 2015	17	Grain Rest of plant	< 0.003 < 0.003	99 99	Stored deep frozen (< -18 °C for 133 days (sampling to extraction) Foliar application boom sprayer equipped with DG11002VS Teejet flat fan nozzles
S15-03081-02 5474 Veflinge, South Denmark, Denmark / Northern Zone / 2015	Maize/ ZEAMX/ Yukon	1) 16 May 2015 2) n/r 3) 05 Nov 2015	0.128	213	0.060	26 Jun 2015	15	Grain Rest of plant	< 0.003 < 0.003	132 132	Stored deep frozen (< -18 °C for 83 days (sampling to extraction) Foliar application boom sprayer equipped with AiXR11002VP Teejet reduced drift fan nozzles
S15-03081-03 5580 Nørre Åby, South Denmark, Denmark / Northern Zone / 2015	Maize/ ZEAMX/ LG 30.211	1) 02 May 2015 2) n/r 3) 19 Nov 2015	0.119	199	0.060	30 Jun 2015	16	Whole plant Whole plant Whole plant (forage) Whole plant (silage) Grain Rest of plant	5.0 < 0.003 < 0.003 < 0.003 < 0.003 < 0.003	0 13 41 87 142 142	Stored deep frozen (< -18 °C for 211 days (sampling to extraction) Foliar application boom sprayer equipped with AiXR11002VP Teejet reduced drift fan nozzles

S15-03081-04 WN6 9QG Wigan, Lancashire, United Kingdom / Northern Zone / 2015	Maize/ ZEAMX/ Activate	1) 04 Jun 2015 2) n/r 3) 29 Oct 2015	0.126	418	0.030	21 Jul 2015	18	Whole plant Whole plant Whole plant (forage) Whole plant (silage) Grain Rest of plant	4.5 < 0.003 < 0.003 < 0.003 < 0.003 < 0.003	0 13 42 83 100 100	Stored deep frozen (< -18 °C for 190 days (sampling to extraction) Foliar application boom sprayer equipped with LD03F110 Lumark flat fan nozzles

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

A 2.1.4 Magnitude of residues in livestock

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

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

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

A 2.1.6 Magnitude of residues in representative succeeding crops

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

A 2.1.7 Other/Special Studies

A 2.1.7.1.1 Study 1

Comments of zRMS:	The study was not used in this evaluation (Part B, Section 7), hovewer provides additional information that can be used for the evaluation the potential exposure of wildlife (e.g. birds and mammals) to residues of mesotrione in maize seedlings as food items. The study was conducted in 3 trials in south West France and 3 trials in The Netherlands. Residues of mesotrione were determined in maize seedlings after treatment with 0.150 kg a.s./ha at BBCH 12-18. Specimen extraction were performed according to the QuEChERS. Quantification was performed by use of LC-MS/MS detection. The analytical method used in the study was fully validated. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). Residues declined rapidly in all trials. Residue kinetics were modelled with a Simple First Order (SFO) model in order to derive DT_{50} and DT_{90} values. DT_{50}-values ranging from 0.329 to 0.693 days were obtained for the France trials, but for the trials in The Netherlands 0.0463 to 0.45 days. DT_{90}-values ranged from 1.1 to 2.3 days in France and from 0.15 to 1.5 days in The Netherlands.

Reference: 7.3.7 / KCP 8.10 (KCA 6.10)

Report: Magnitude of mesotrione residues in maize plants following one application in Southern and Northern Europe in 2016, Bakker, F., 2016, Report No. JS001LRM

Guideline(s): Yes
EFSA Guidance document on risk assessment for Birds and Mammals (2009)
Regulation (EC) 1107/2009 and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
SANCO/3029/99 rev. 4
SANCO/825/00 rev. 8.1
Guideline 7029/VI/95 (rev. 5)

OECD Guideline 509

Deviations: Yes

1) The analytical phase was started (05 July 2016) before the Analytical Phase Plan was formally incorporated into the study plan (18 July 2016) in order to make sure that all samples were performed within 30 days after sampling. This was evaluated to have no impact.
[comment: Analytical PI and Test site address were already defined in the Study Plan and the Analytical Phase Plan was finalized by the time the Phase was started]
2) One trial had to be restarted. Therefore, plot sizes were reduced from 1000 m² to 600m² because there was insufficient test item to conduct the application on plots of 1000 m² for each trial. This was evaluated to have no impact.
3) Due to failure of the tractor mounted boom sprayer for trial -05 the application was conducted with a hand carried spray boom. This was evaluated to have no impact.
4) HPPD inhibitors tembotrione and topramezone have been applied once at the test locations -04, -05 and -06 shortly before start of the trials. It was unknown that other HPPD inhibitors had been applied as the pre-study questionnaire only considered mesotrione and sulcotrione. This was evaluated to have no impact.
5) During transport from field to freezer, samples were transported at ambient conditions instead of chilled as stated in the study plan. Test sites -04 and -06 were within 1 hour driving distance from the test facility, test site -05 less than 10 minutes. For this reason the chilling was considered redundant. The impact on the outcome of the study was evaluated to be unknown but most likely not important.
6) During transport from field to freezer, temperature was not registered by a data logger according to test site SOP. This was evaluated to have no impact.
7) During shipment of the samples to the analytical test site, temperature was > -18°C for a period of 12 hours. Temperature condition during transport was fluctuating, probably as a result of loading and unloading of the freezer truck. This was evaluated to have no impact.

GLP: Yes

Acceptability: Yes

Materials and methods

In the growing season 2016 six residue field trials have been performed in Southern and Northern Europe on maize (3 trials in Southern France, 3 trials in the Netherlands). At each trial site one treated plot of approximately 600 m² was marked; each plot was divided into five subplots of 120 m² each. Plots were sown with maize at a rate of 85,000 seeds/ha. At BBCH 16-18, the treated plots at each trial site were treated once with a 10% SC product containing nominally 100 g/L mesotrione at a rate of 1.5 L/ha, equivalent to 0.150 kg a.s./ha using a spray volume of 200 L/ha. No other formulations containing mesotrione or sulcotrione were applied during the trial and for three years before start of the trial. However, for trials 4 – 6) two other HPPD-inhibitors were applied shortly before the study start. These were tembotrione (trials 4 – 6) and topramezone (trials 4 and 6).

Samples of crop (maize leaves, 3x50 g per sample taken from 12 random locations across each subplot) were taken before application (control sample) and following application nine samples were taken over a period of 4 days. Treated samples of trials 1-3 were kept at chilled conditions during transport and were deep frozen within maximum of 0:30 – 1:30 hours (Trial 1), 0:44 – 1:20 hours (Trial 2) and 1:15 – 1:55 hours (Trial 3) after start of sampling at the test site freezer. Treated samples were kept at ambient temperatures during transport and were deep frozen within 1:36 – 3:50 hours (Trial 4), 0:35 – 0:49 hours (Trial 5) and 1:14 – 2:00 hours after start of sampling at the test site freezer.

Residues of mesotrione have been analysed according to the modified multi-residue QuEChERS method, which was validated within the analytical phase. (for detailed information please refer to information please refer to Section 4 analytical methods). In summary, water was added if required, then specimen material was extracted with acetonitrile, a salt mixture was added and extract was centrifuged. Detection was carried out with liquid chromatography and mass spectrometric detection (LC-MS/MS). The limit of quantification (LOQ) for mesotrione was 0.01 mg/kg, the LOD was set at 0.003 mg/kg.

In addition to residue analyses, time weighted averages were calculated in Excel for Windows, residue values were plotted against time as average values (n=5) (± standard deviation) and residue kinetics were modelled with a Single First Order (SFO) model in order to derive DT_{50} and DT_{90} values.

Results and discussions

Results may be used to evaluate the potential exposure of wildlife (e.g. birds and mammals) to residues of mesotrione in maize seedlings as food items. The application rate was performed within the 25% difference of the critical GAP (120 g/ha mesotrione).

No residues above the limit of quantitation were found in any of the untreated specimens.

With the exception of the lower residue value in trial 1, the three trials in France (trials 1-3) showed consistent and largely overlapping residue decline patterns. This was not the case for the three trials in The Netherlands (trials 4-6), where trials 4 and 5 yielded starting values were comparable to those reported in France but indicated much faster residue decline. Trial 6 had lower starting values, but decline kinetics was comparable to results obtained from the trials performed in France.

In the Northern Zone trials, the residue values measured 1 hour after application were fairly homogenous between sites and ranged from 10.6 to 21.8 mg/kg. Residues then decreased rapidly in all trials. The four day time weighted averages for the Dutch trials were: 0.84, 0.67 and 1.77 mg/kg. Using a Simple First Order kinetics model DT_{50}-values ranging from 0.0463 to 0.45 days were obtained for the Dutch trials. The low value came from a trial where extremely fast degradation was observed (decline rate constant (k)=15 versus 1.0 to 4.3 for the other trials).The residues at day 0 for this trial were comparable to the other trials and also at 1 hour after application. This indicates that the application was correct, but rapid degradation quickly occurred. From the available environmental data there is no obvious reason why degradation in this trial was faster than in the other trials, as such the results are considered relevant. DT 90 -values ranged from 0.15 to 1.5 days in The Netherlands. Residue values were homogeneous between replicates of the same sample and with 5 replicates per sample the error rates were very low (4.6%-16%), with the exception of 1 trial in The Netherlands that had an error rate of 60%, mainly due to very high residue values 4 hours after application.

In the Southern Zone trials, the residue values measured 1 hour after application ranged from 12.42 to 23.0 mg/kg. Residues declined rapidly in all trials. The four day time weighted averages for the French trials were higher than those in the Dutch trials: 3.278, 3.362 and 2.954 mg/kg. Using a Simple First Order kinetics model DT_{50}-values ranging from 0.330 to 0.702 days were obtained for the French trials.

Concurrent with the routine analysis of the specimens, recovery experiments were carried out within the analytical series. The mean procedural recoveries were between 70% and 110% demonstrating the validity of the analytical method.

The maximum storage interval on the residue samples is 151 days which is covered by the storage stability data of mesotrione (at least 42 months).

Table A 3: Summary of the study 1 trials

Reference:	Magnitude of mesotrione residues in maize plants following one application in Southern and Northern Europe in 2016, Bakker F., 2016, Report No. JS001LRM		
GLP:	Yes	**Sample storage conditions:**	Maximum of 151 days at -18°C (or less)
Crop/crop group:	Maize / maize seedlings	**Analytical method:**	Multi-residue Method QuEChERS
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	100 g/L mesotrione (nominal) 98.7 g/L mesotrione (actual)	**Residues calculated as:**	Mesotrione

Trial No./ Location/ EU zone/ Year	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 (hours, in decimal notation) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mesotrione		
JS001LRM Trial 1 47170 Mezin, Lot-et-Garonne, France / Southern Zone / 2016	Maize/ ZEAMX/ Fuxxtur	1) 24 Apr 2016 2) not relevant 3) not relevant	144.1	192.1	75.01	03 Jun 2016	17	Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves	12.42 14.60 11.88 10.10 5.52 2.36 1.54 0.24 0.05	1.4 4.4 8.5 12.6 24.5 36.4 50.3 80.2 97.5	Stored deep frozen (< -18 °C for 33 days (sampling to extraction) Foliar application with tractor mounted 10 m boom sprayer equipped with 20 Albuz, AVI IS 110 02 nozzles
JS001LRM Trial 2 40310 Parelboscq, Landes, France / Southern Zone / 2016	Maize/ ZEAMX/ Pioneer Groupe 3	1) 27-28 Apr 2016 2) not relevant 3) not relevant	137.7	183.6	75.00	07 Jun 2016	16-17	Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves	22.60 19.60 14.08 12.06 3.38 1.66 1.05 0.20 0.10	1.9 5.1 8.7 12.4 25.1 37.0 50.0 71.3 96.6	Stored deep frozen (< -18 °C for 34 days (sampling to extraction) Foliar application with tractor mounted 10 m boom sprayer equipped with 20 Albuz, AVI IS 110 02 nozzles

JS001LRM Trial 3 47160 St. Leger, Lot-et-Garonne, France / Southern Zone / 2016	Maize/ ZEAMX/ DK5632	1) 27 Apr 2016 2) not relevant 3) not relevant	144.6	192.8	75.00	08 Jun 2016	16	Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves	23.00 17.00 10.96 9.02 3.42 1.74 1.22 0.14 0.01	1.2 4.1 8.2 12.3 24.3 35.9 53.1 79.2 100.7	Stored deep frozen (< -18 °C for 33 days (sampling to extraction) Foliar application with tractor mounted 10 m boom sprayer equipped with 20 Albuz, AVI IS 110 02 nozzles
JS001LRM Trial 4 7025 CS Halle, Gelderland, Netherlands / Northern Zone / 2016	Maize/ ZEAMX/ Megusto	1) 13 May 2016 2) not relevant 3) not relevant	146.2	197.5	74.03	27 Jun 2016	17-18	Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves	16.50 17.04 0.83 0.32 0.14 0.07 0.04 0.02 0.01	1.0 4.1 8.3 12.0 24.1 35.9 48.3 72.4 98.5	Stored deep frozen (< -18 °C for 151 days (sampling to extraction) Foliar application with tractor mounted 15 m boom sprayer equipped with 30 drift reducing nozzles TEEJET AIXR 110.03VS
JS001LRM Trial 5 6662 PK Elst, Gelderland, Netherlands / Northern Zone / 2016	Maize/ ZEAMX/ Ricodino	1) 27 May 2016 2) not relevant 3) not relevant	150.3	203.0	74.04	05 Jul 2016	16	Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves	22.83 3.18 1.60 1.23 0.41 0.29 0.24 0.08 0.04	2.2 5.2 8.9 12.6 25.1 36.6 49.1 72.6 96.5	Stored deep frozen (< -18 °C for 143 days (sampling to extraction) Foliar application with 3 m handheld boom sprayer equipped with 6 nozzles XR 110.02VS
JS001LRM Trial 6 69 PH Erp/Nistelrode, Brabant, Netherlands / Northern Zone / 2016	Maize/ ZEAMX/ Ridocino	1) 11 May 2016 2) not relevant 3) not relevant	149.0	201.3	74.02	29 Jun 2016	16-17	Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves Maize leaves	10.62 9.50 7.04 5.13 2.34 1.37 0.44 0.14 0.08	1.3 4.4 8.6 12.2 24.8 35.9 48.6 72.6 96.6	Stored deep frozen (< -18 °C for 33 days (sampling to extraction) Foliar application with tractor mounted 15 m boom sprayer equipped with 30 drift reducing nozzles TEEJET AIXR 110.03VS

(a) According to EPPO 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
(*) Average residue calculated from 5 replicates

Study 2

Comments of zRMS:	The study was not used in this evaluation (Part B, Section 7), hovewer provides additional information that can be used for the evaluation the potential exposure of wildlife (e.g. birds and mammals) to residues of mesotrione in maize seedlings as food items. The study was conducted in 4 trials in The Netherlands. Residues of mesotrione were determined in maize seedlings after treatment with 0.150 kg a.s./ha at BBCH 12-18. Specimen extraction were performed according to the QuEChERS. Quantification was performed by use of LC-MS/MS detection. The analytical method used in the study was fully validated. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The residues of mesotrione in the treated maize (whole plants w/o roots) samples taken from all trials at: 1 hour after application (HAA) were in the range 2.5 to 22 mg/kg, 4 HAA were in the range 0.98 to 17 mg/kg, 8 HAA were in the range 0.61 to 20 mg/kg, 12 HAA were in the range 0.61 to 13 mg/kg, 24 HAA were in the range 0.43 to 12 mg/kg, 36 HAA were in the range 0.28 to 8.0 mg/kg, 2 days after application (2 DAA) were in the range 0.23 to 2.6 mg/kg, 3 DAA were in the range 0.05 to 1.4 mg/kg 4 DAA were in the range 0.02 to 0.49 mg/kg.

Reference: 7.3.7 / KCP 8.10 (KCA 6.10)

Report: Decline of mesotrione residues in maize plants following one application in The Netherlands - 2017, van de Sandt, H.J., 2019, Report No. S17-05218

Guideline(s): Yes
EFSA Guidance document on risk assessment for Birds and Mammals (2009)
Regulations (EU) 283/2013 and 284/2013 amending Regulation (EC) 1107/2009
SANCO/3029/99 rev. 4
Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market
Guideline 7029/VI/95 (rev. 5)

Deviations: Yes
During sample storage period the maximum temperature rose above -18ºC for a short period

GLP: Yes

Acceptability: Yes

Materials and methods

In 2017, four residue field trials were performed with the herbicide mesotrione in maize in The

Netherlands. Trials were set up as single plot design with 5 replicates within the treated plot. Untreated samples were taken before application. Plot size in each trial was 1080 m². At crop stage BBCH 14-15, a single application of mesotrione 100 g/L SC was applied at a rate of 1.5 L/ha, equivalent to 0.150 kg a.s./ha using a spray volume of 200 L/ha.

Untreated samples were taken before application at 0 DBA (Days Before Application). Treated samples were taken at: 1 HAA (Hours After Application), 4 ±0.5 HAA, 8 ±1 HAA, 12 ±1 HAA, 24 ±1 HAA, 36 ±1 HAA, 2 DAA (Days After Application), 3 DAA, 4 DAA, 7 DAA and 14 DAA.

Residues of mesotrione were analysed according to the multi-residue QuEChERS method, which was validated within a separate study. The limit of quantification (LOQ) for mesotrione was 0.01 mg/kg; the LOD was set at 0.003 mg/kg (30 % of the LOQ).

Results and discussions

Results may be used to evaluate the potential exposure of wildlife (e.g. birds and mammals) to residues of mesotrione in maize seedlings as food items. The application rate was performed within the 25% difference of the critical GAP (120 g/ha mesotrione).

No residues above the limit of quantitation were found in any of the untreated specimens.

The residues of mesotrione in the treated maize (whole plants w/o roots) samples taken from all trials at 1 hour after application (HAA) were in the range 2.5 to 22 mg/kg, at 4 HAA were in the range 0.98 to 17 mg/kg, at 8 HAA were in the range 0.61 to 20 mg/kg, at 12 HAA were in the range 0.61 to 13 mg/kg, at 24 HAA were in the range 0.43 to 12 mg/kg, at 36 HAA were in the range 0.28 to 8.0 mg/kg, at 2 days after application (2 DAA) were in the range 0.23 to 2.6 mg/kg, at 3 DAA were in the range 0.05 to 1.4 mg/kg and at 4 DAA were in the range 0.02 to 0.49 mg/kg. The maize (whole plants w/o/ roots) sampling at 7 and 14 DAA were performed for contingency purposes; these samples were not analysed.

Concurrent with the routine analysis of the specimens, recovery experiments were carried out within the analytical series. The mean procedural recoveries were between 70% and 110% demonstrating the validity of the analytical method.

The maximum storage interval on the residue samples is 82 days which is covered by the storage stability data of mesotrione (at least 42 months).

Table A 41: Summary of the study 2 trials

Reference:	Decline of mesotrione residues in maize plants following one application in The Netherlands - 2017, van de Sandt, H.J., 2019, Report No. S17-05218		
GLP:	Yes	**Sample storage conditions:**	Maximum of 82 days at -18°C (or less)
Crop/crop group:	Maize / maize seedlings	**Analytical method:**	Multi-residue Method QuEChERS
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	100 g/L mesotrione (nominal) 96.83 g/L mesotrione (actual)	**Residues calculated as:**	Mesotrione

Trial No./ Location/ EU zone/ Year	**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 (hours, in decimal notation)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**				**Mesotrione**		
S17-05218-01 De Dries, 6662 PK Elst, Gelderland - The Netherlands / Northern Zone / 2017	Maize/ ZEAMX/ Millesim	1) 16 May 2017 2) not relevant 3) not relevant	144.06	199	72.39	12 Jun 2017	14	Maize whole plant without roots	12, 18, 22, 12, 17 10, 17, 17, 14, 17 11, 15, 20, 16, 16 10, 11, 13, 13, 10 11, 10, 11, 11, 12 4.3, 8, 5.8, 4.2, 4.2 2.2, 2.3, 2.6, 1.5, 2 0.97, 0.85, 1.4, 0.97, 0.89 0.37, 0.49, 0.42, 0.31, 0.36	1 4 8 12 24 36 48 72 96	Stored deep frozen (< -18 °C for 58 days (sampling to extraction)
S17-05218-02 Provincialeweg (against Meertenwei 5), 4033 BB Lienden, Gelderland - The Netherlands / Northern Zone / 2017	Maize/ ZEAMX/ Stabil	1) 28 Apr 2017 2) not relevant 3) not relevant	148.09	204	72.59	30 May 2017	14	Maize whole plant without roots	9.5, 8.3, 7.5, 12, 11 9, 9.4, 7.8, 10, 10 6.7, 5.9, 5.8, 8.5, 6.5 6.5, 7.9, 7.4, 8, 6.8 4.8, 5, 3.7, 5.1, 4.4 1.4, 1.7, 1.3, 2.6, 1.9 0.88, 0.79, 0.85, 1.3, 0.93 0.26, 0.3, 0.28, 0.28, 0.32 0.11, 0.1, 0.09, 0.14, 0.12	1 4 8 12 24 36 48 72 96	Stored deep frozen (< -18 °C for 76 days (sampling to extraction)

S17-05218-03 Babberichseweg 24, 6905 JV Zevenaar, Gelderland - The Netherlands / Northern Zone / 2017	Maize/ ZEAMX/ Millesim	1) 29 Apr 2017 2) not relevant 3) not relevant	145.40	201	72.34	31 May 2017	14	Maize whole plant without roots	17, 15, 10, 16, 13 13, 7.8, 7, 9.4, 9.5 7.4, 5.6, 6, 5.9, 5 5.5, 5.2, 5.3, 5.4, 5.5 4.9, 4.3, 4.8, 4.6, 4.9 1.4, 1.7, 0.98, 1.4, 1.4 1.1, 0.99, 1.2, 0.93, 1.2 0.36, 0.3, 0.59, 0.47, 0.42 0.06, 0.06, 0.07, 0.06, 0.09	1 4 8 12 24 36 48 72 96	Stored deep frozen (< -18 °C for 82 days (sampling to extraction)
S17-05218-04 Jonkerstraat, 5388 VR Nistelrode, Brabant - The Netherlands / Northern Zone / 2017	Maize/ ZEAMX/ Treillel	1) 25 April 2017 2) not relevant 3) not relevant	149.03	206	72.34	07 Jun 2017	14-15	Maize whole plant without roots	3.3, 2.8, 2.5, 2.7, 2.6 1.5, 1.4, 1.2, 0.98, 1.1 0.82, 0.79, 0.73, 0.65, 0.61 0.77, 0.83, 0.67, 0.63, 0.61 0.68, 0.54, 0.51, 0.55, 0.43 0.32, 0.28, 0.34, 0.37, 0.34 0.25, 0.23, 0.23, 0.24, 0.26 0.05, 0.05, 0.05, 0.05, 0.05 0.03, 0.02, 0.03, 0.02, 0.02	1 4 8 12 24 36 48 72 96	Stored deep frozen (< -18 °C for 76 days (sampling to extraction)

(a) According to EPPO 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
(*) Individual results from 5 replicate samples

A 2.2 Active substance 2 – Nicosulfuron

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

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Mesotrione

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.02
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
12%	NL toddler	1.24	6%	Milk: Cattle	1%	Apples	0.7%	Maize/corn	12%	12%
7%	NL child	0.67	2%	Milk: Cattle	0.8%	Sugar beet roots	0.6%	Apples	7%	7%
6%	DE child	0.64	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	6%	6%
6%	UK infant	0.61	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat	6%	6%
6%	FR toddler 2 3 yr	0.56	3%	Milk: Cattle	0.3%	Apples	0.3%	Wheat	6%	6%
6%	FR child 3 15 yr	0.55	2%	Milk: Cattle	0.5%	Wheat	0.4%	Sugar beet roots	6%	5%
5%	GEMS/Food G11	0.49	1%	Soyabeans	0.8%	Milk: Cattle	0.4%	Potatoes	4%	5%
4%	UK toddler	0.45	2%	Milk: Cattle	0.4%	Wheat	0.3%	Potatoes	4%	4%
4%	GEMS/Food G10	0.43	1.0%	Soyabeans	0.5%	Milk: Cattle	0.4%	Wheat	3%	4%
4%	GEMS/Food G07	0.42	0.6%	Milk: Cattle	0.5%	Soyabeans	0.4%	Wheat	4%	4%
4%	GEMS/Food G08	0.42	0.6%	Soyabeans	0.6%	Milk: Cattle	0.4%	Wheat	4%	4%
4%	GEMS/Food G15	0.42	0.7%	Milk: Cattle	0.5%	Soyabeans	0.5%	Wheat	4%	4%
4%	DK child	0.41	1%	Milk: Cattle	0.6%	Rye	0.4%	Wheat	4%	4%
4%	GEMS/Food G06	0.41	0.7%	Wheat	0.4%	Soyabeans	0.4%	Tomatoes	4%	4%
4%	RO general	0.38	1%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	4%
4%	ES child	0.38	1%	Milk: Cattle	0.4%	Wheat	0.3%	Cocoa beans	4%	4%
4%	SE general	0.37	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.4%	Potatoes	4%	4%
4%	DE women 14-50 yr	0.37	1%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Apples	4%	4%
4%	DE general	0.36	1%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Apples	4%	4%
4%	FI adult	0.35	3%	Coffee beans	0.1%	Potatoes	0.1%	Rye	4%	4%
3%	IE adult	0.33	0.4%	Milk: Cattle	0.4%	Sweet potatoes	0.2%	Wheat	3%	3%
3%	NL general	0.30	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Potatoes	3%	3%
3%	FR infant	0.29	2%	Milk: Cattle	0.2%	Potatoes	0.2%	Apples	3%	3%
2%	FR adult	0.22	0.4%	Milk: Cattle	0.2%	Wine grapes	0.2%	Wheat	2%	2%
2%	PT general	0.21	0.5%	Potatoes	0.4%	Wheat	0.2%	Wine grapes	2%	2%
2%	ES adult	0.21	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges	2%	2%
2%	FI 3 yr	0.18	0.5%	Potatoes	0.1%	Bananas	0.1%	Wheat	2%	2%
2%	IT toddler	0.16	0.7%	Wheat	0.2%	Other cereals	0.1%	Tomatoes	2%	2%
2%	DK adult	0.16	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	2%
2%	LT adult	0.16	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Apples	2%	2%
1%	UK vegetarian	0.15	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	1%
1%	FI 6 yr	0.14	0.4%	Potatoes	0.1%	Cocoa beans	0.1%	Wheat	1%	1%
1%	UK adult	0.14	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	1%
1%	IT adult	0.12	0.4%	Wheat	0.1%	Tomatoes	0.1%	Apples	1%	1%
1.0%	PL general	0.10	0.3%	Potatoes	0.2%	Apples	0.1%	Tomatoes	1.0%	1.0%
0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.8%

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

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Nicosulfuron

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC 2008/40	Source of ARfD:	
Year of evaluation:	2008	Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.1%	NL toddler	1.91	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Maize/corn	0.1%	0.1%
0.1%	UK infant	1.04	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Eggs: Chicken	0.1%	0.1%
0.0%	NL child	0.97	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.0%	0.0%
0.0%	FR toddler 2 3 yr	0.90	0.0%	Milk: Cattle	0.0%	Apples	0.0%	Wheat	0.0%	0.0%
0.0%	DE child	0.87	0.0%	Milk: Cattle	0.0%	Apples	0.0%	Wheat	0.0%	0.0%
0.0%	FR child 3 15 yr	0.85	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	0.0%
0.0%	UK toddler	0.69	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
0.0%	DK child	0.59	0.0%	Milk: Cattle	0.0%	Rye	0.0%	Swine: Muscle/meat	0.0%	0.0%
0.0%	GEMS/Food G11	0.58	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Potatoes	0.0%	0.0%
0.0%	ES child	0.56	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.0%	0.0%
0.0%	SE general	0.55	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes	0.0%	0.0%
0.0%	GEMS/Food G07	0.53	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
0.0%	RO general	0.53	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
0.0%	GEMS/Food G15	0.52	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
0.0%	DE women 14-50 yr	0.52	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.0%	0.0%
0.0%	GEMS/Food G08	0.52	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%
0.0%	LT adult	0.22	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Swine: Muscle/meat	0.0%	0.0%
0.0%	PT general	0.22	0.0%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.0%	0.0%
0.0%	UK vegetarian	0.18	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
0.0%	UK adult	0.18	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
0.0%	FI 3 yr	0.18	0.0%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.0%	0.0%
0.0%	IT toddler	0.17	0.0%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.0%	0.0%
0.0%	FI 6 yr	0.14	0.0%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.0%	0.0%
0.0%	IE child	0.12	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
0.0%	IT adult	0.12	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.0%	0.0%
0.0%	PL general	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.0%	0.0%

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

A 3.2 IEDI calculations

Not required. TMDI does not exceed ADI for mesotrione or nicosulfuron.

A 3.3 IESTI calculations - Raw commodities

Mesotrione

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

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

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Maize/corn	0.01 / 0.01	0.07	0.1%	Maize/corn	0.01 / 0.01	0.02
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Nicosulfuron

Not required for nicosulfuron, no ARfD set.

A 3.4 IESTI calculations - Processed commodities

Mesotrione

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Maize / oil	0.01 / 0.25	0.23	0.6%	Maize / oil	0.01 / 0.25	0.13
0.1%	Maize / processed (not spe	0.01 / 0.01	0.01				
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Mesotrione is unlike
For processed commodities, no exceedance of the ARfD/ADI was identified.

Nicosulfuron

Not required for nicosulfuron, no ARfD set.