FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB289H / SAP63H

Product name: Zeppos/Moxie

Chemical active substance(s):

Iodosulfuron-methyl-sodium, 6 g/kg
Mesosulfuron-methyl, 30 g/kg
Safener: Mefenpyr-diethyl, 90 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: GLOBAHCEM NV / ASCENZA Agro S.A.

Submission date: December 2019

MS Finalisation date: 08/2021 ; 01/2022 ; 03/2022 ; 09/2022

Version history

When	What
December 2019	V0 - Original version from applicant for submission to zRMS POLAND in the frame of new PPP registration
08/2021	Assessment
01/2022	Final version of the RR after Commenting period
03/2022	Final version of the RR after Commenting period - Moxie
09/2022	Information added by zRMS

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The product contains 2 active substances (iodosulfuron-methyl-sodium and mesosulfuron-methyl) and Mefenpyr-diethyl as a safener.

Note (03/2022): Assessment after comments (Moxie) is marked in blue.

Storage stability

Iodosulfuron-methyl-sodium
A new stability studies on iodosulfuron-methyl and triazine amine residues in cereals were presented in the framework of this application because data gap was identified in this area during the renewal of approval process (EFSA Journal 2016;14(4):4453).
The studies are accepted.
Based on the results obtained, it can be concluded that the residues for iodosulfuron-methyl in wheat (grain and straw), are stable for 190 days when stored in a freezer at or below -20 ºC.
The residues for triazine amine in wheat (grain and straw), lettuce and radish (leaves with tops and roots), are stable for 220 days when stored in a freezer at or below -20 ºC.
The residue trials on the intended use presented in this dossier are valid in regard to storage stability data.

Mesosulfuron-methyl
No new studies submitted in the framework of this application. Stability of residues has been evaluated during the Peer review (EFSA Journal 2016;14(10):4584). Mesosulfuron-methyl is stable for 40 months in wheat shoot, grain and straw. The residue trials on the intended use presented in this dossier are valid in regard to storage stability data.

Mefenpyr-diethyl
Additional data are not required.

Metabolism in plants and animals

Iodosulfuron-methyl-sodium
No new data submitted in the framework of this application.

EU Endpoints Plant	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not relevant
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016; Reg. (EU) No 289/2014)

Plant residue definition for risk assessment	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016) Triazine amine (IN-A4098) is a potential candidate for the plant residue definition for risk assessment, and a final decision is pending further clarification regarding the toxicological properties and the related consumer risk. Pending the conclusion on the IN-A4098 toxicity, also the metabolite AE 0031838 (hydroxymethyl triazine amine) observed up to 15% TRR in grain may require a reassessment.
Conversion factor from enforcement to RA	1 (EFSA, 2012, 2016)

Animal	
Animals covered	-
	-
Time needed to reach a plateau concentration	-
	-
Animal residue definition for monitoring	Not necessary (EFSA, 2012, 2016) Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (Reg. (EU) No 289/2014)
Animal residue definition for risk assessment	Not necessary (EFSA, 2012, 2016)
Conversion factor	-
Metabolism in rat and ruminant similar	-
Fat soluble residue	No

EFSA Journal 2020;18(3):6053 (Scientific Opinion of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the genotoxic potential of triazine amine (metabolite common to several sulfonylurea active substances): *Based on the overall weight of evidence, the Panel, in agreement with the cross-cutting Working Group Genotoxicity, concluded that there is no concern for the potential of triazine amine to induce gene mutations and clastogenicity; however, the potential to induce aneugenicity was not adequately investigated. For a conclusion, an in vitro micronucleus assay performed with triazine amine would be needed.*

Triazine amine (IN-A4098) was defined as a potential candidate for the plant residue definition for risk assessment after the renewal process of iodosulfuron. The final decision was left pending since further clarification regarding the toxicological properties and the related consumer risk assessment was required. This information was submitted by the main notifier and the Outcome in light of confirmatory data was published by EFSA in 2018 (*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 iodosulfuron and prosulfuron in light of confirmatory data. EFSA supporting publication 2018:EN-1470. 56pp*). The RMS concluded that there are no results supporting that triazine amine induces gene mutations or chromosome aberrations in mammalian cells in vitro. As a result, the genotoxicity of triazine amine could be concluded and no further information, particularly animal studies, was considered as further required.
Even if during the peer review there were some discussions regarding the gene mutation potential of the

metabolite in mammalian cells, the submitted trials demonstrate that residues of triazine amine are not expected to occur above the limit of quantification when the product SAP63H is applied according with the conditions proposed in the GAP. Therefore, the risk related to the presence of triazine amine can be disregarded.

No further data are required to support the proposed uses.

Mesosulfuron-methyl

No new data submitted in the framework of this application.

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not relevant
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	mesosulfuron-methyl (EFSA, 2016; Reg. (EU) No 289/2014)
Plant residue definition for risk assessment	mesosulfuron-methyl (EFSA, 2016)
Conversion factor from enforcement to RA	1 (EFSA, 2016)

Animals covered	Ruminant
	Poultry
Time needed to reach a plateau concentration	Egg yolks: day 10; egg whites: day 8;
	Milk : day 5
Animal residue definition for monitoring	Mesosulfuron-methyl (EFSA, 2016; Reg. (EU) No 289/2014)
Animal residue definition for risk assessment	Mesosulfuron-methyl (EFSA, 2016)
Conversion factor	1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

No further data are required to support the proposed uses.

Mefenpyr-diethyl

Plant residue definition for monitoring	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.
Plant residue definition for risk assessment	Mefenpyr-diethyl (AE F107892) and its metabolites AE

	F113225 and AE F094270 expressed as mefenpyr-diethyl.
Conversion factor from enforcement to RA	Not required.

Animal residue definition for monitoring	-
Animal residue definition for risk assessment	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.

Magnitude of residues in plants
Cereals (winter/spring soft wheat, winter/spring durum wheat, triticale, spelt and winter rye)

Iodosulfuron-methyl-sodium
Proposed GAP: 1 × 0.0006 – 0.003 kg as/ha, BBCH 21-32, PHI not relevant, outdoor.
Proposed application rate is less critical than application rate in the EU GAP.
EU GAP (EFSA Journal 2016;14(4):4453):
Wheat
1 × 0.010 kg as/ha, BBCH 13-32, PHI not relevant, outdoor.
Barley
1 × 0.0075 kg as/ha, BBCH 20-32, PHI not relevant, outdoor.

The results from studies evaluated on the EU level are all below LOQ (0.01 mg/kg). Differences due to formulations have not been observed. The residue data are valid with regard to storage stability. In some studies the applications were made at higher than proposed doses. Overdosed trials may be used to support a less critical GAP, when they indicate that no residues above the LOQ are to be expected.
New study (4 trials in Northern Europe) on the magnitude of residue has been submitted by the applicant in the framework of this application to support the proposed cGAP. This study is accepted.
Trials GAP: 1x 3g/ha, BBCH 32
The objective of the study was to generate samples for the determination of the residue levels of iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in wheat raw agricultural commodity (RAC) after one foliar application of the formulated product SAP63H (iodosulfuron-methyl-sodium 6 g/kg, mesosulfuron-methyl 30 g/kg, and mefenpyr-diethyl 90 g/kg WG) at the rate of 0.5 kg/ha. The wetting agent HAG 530 01 S was applied in tank mix at a dose rate of 200 ml/ha.
Results:
E=RA: 4x <0.01 mg/kg
TA: 4x <0.01mg/kg
Sufficient trials wheat are available to support the proposed uses.
Extrapolation from wheat to rye, spelt and triticale is possible (SANTE/2019/12752).
The residues arising from the proposed uses will not exceed the MRLs established for cereals (Commission Regulation (EU) No 289/2014).

Note:
Mefenpyr-diethyl was a component of the formulations used in the field trials.

Mesosulfuron-methyl
Proposed GAP: 1 × 0.003 – 0.015 kg as/ha, BBCH 21-32, PHI not relevant, outdoor.
EU GAP - representative uses (SANTE/11827/2016 Rev 2, 23 March 2017):
Wheat
1 × 0.015 kg as/ha, BBCH 20-32, PHI not relevant, outdoor.
Rye
1 × 0.006 kg as/ha, BBCH 20-32, PHI not relevant, outdoor.

GAP on which EU a.s. assessment is based: 1 x 15g as/ha, BBCH 37-47
Residues: E&RA: 9x<0.01 mg/kg
New study (4 trials in Northern Europe) on the magnitude of residue has been submitted by the applicant in the framework of this application to support the proposed cGAP. This study is accepted.
Trials GAP: 1x 15g/ha, BBCH 32
Residues: E&RA: 4x <0.01
Sufficient trials on wheat are available to support the proposed uses.
Extrapolation from wheat to rye, spelt and triticale is possible (SANTE/2019/12752).
The residues arising from the proposed uses will not exceed the MRLs established for cereals (Commission Regulation (EU) No 289/2014).

Note:
Mefenpyr-diethyl was a component of the formulations used in the field trials.

Mefenpyr-diethyl

Even though no studies assessing mefenpyr-diethyl and its metabolites are required, one study investigating the magnitude of residue has been submitted by the applicant in the framework of this application as additional data.
Trials GAP: 1x45g/ha, BBCH 29-32
Residues: 4x <0.050 mg/kg

Magnitude of residues in livestock

No livestock feeding studies to investigate the residue levels of iodosulfuron-methyl-sodium and mesosulfuron-methyl in food of animal origin are required as the calculated dietary burdens for all groups of livestock were found to be below the threshold intake for the submission of an animal study, 0.004 mg/kg bw/d (using the official spreadsheet "pesticides_mrl_guidelines_animal_model_2017.xls").
No new data are submitted in the framework of this application

The use of Moxie in a mixture with adjuvants, e.g. Actirob 842 EC has been accepted.

Magnitude of residues in processed commodities

Not required as significant residues are not expected to be found in cereals.

Magnitude of residues in representative succeeding crops

Iodosulfuron -methyl-sodium and mesosulfuron-methyl residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that they are applied in compliance with the GAPs of GLOB289H / SAP63H.

Consumer risk assessment

Iodosulfuron-methyl-sodium

Since the calculations (EFSA PRIMo v 3.0) for iodosulfuron-methyl-sodium and mesosulfuron methyl demonstrate a sufficient margins of safety, it was not deemed necessary to perform recalculations using EFSA PRIMo rev. 3.1 version.

TMDI (% ADI) according to EFSA PRIMo v3	6% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo v3	Not required, as TMDI is below 100%
IESTI (% ARfD) according to EFSA PRIMo v3	0.00% (wheat)

The proposed uses of iodosulfuron-methyl-sodium in the formulation GLOB289H / SAP63H do not represent unacceptable acute and chronic risks for the consumer.

Mesosulfuron-methyl

TMDI (% ADI) according to EFSA PRIMo v3	0.2% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo v3	Not relevant
IESTI (% ARfD) according to EFSA PRIMo v3	No ARfD derived, not necessary

The proposed uses of mesosulfuron-methyl in the GLOB289H / SAP63H do not represent unacceptable chronic risks for the consumer

Mefenpyr-diethyl
According with the European information available, mefenpyr-diethyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009.
However, no values above the LOQ have been found in any of the trials performed in grain. Taking this into account, it can be considered that the proposed uses of mefenpyr-diethyl in the formulation SAP63H do not represent unacceptable chronic and acute risks for the consumer.

Combined exposure and risk assessment
The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues.
Acute consumer risk assessment from combined exposure: not required

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation SAP63H are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU and SEU zones for wheat, rye, triticale and spelt. A list of all intended uses within CEU/SEU zones is given in Part B, Section 0.

The critical GAP consists in the application of SAP63H at a dose rate of 3 g a.s./ha of iodosulfuron-methyl-sodium, 15 g a.s./ha of mesosulfuron-methyl and 45 g a.s./ha of mefenpyr-diethyl.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for iodosulfuron-methyl and mesosulfuron-methyl as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of iodosulfuron-methyl and mesosulfuron-methyl residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France 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:
- No data gaps have been noticed.

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

GAP number 7 is the most critical GAP

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)**	**Conclu-sion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**num-ber min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**g as/ha min max**		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Cereals (winter/spring soft wheat 050090-002, winter/spring durum wheat 050090-001, triticale 050090-006, spelt 050090-005 and winter rye 050070)	PL	GLOB289H / SAP63H	F	Annual grassy weeds and Annual dicotyledonous weeds: CAPBP	WG	6 + 30 + 90 g/l[±]	Downward spraying	BBCH 21-32	1	N/A	0.1	100-400	0.6 + 3 + 9	N/A	A****
2	Cereals (winter/spring soft wheat 050090-002, winter/spring durum wheat 050090-001, triticale 050090-006, spelt 050090-005 and winter rye 050070)	PL	GLOB289H / SAP63H	F	Annual grassy weeds and Annual dicotyledonous weeds: VERPE CAPBP MATCH	WG	6 + 30 + 90 g/l[±]	Downward spraying	BBCH 21-32	1	N/A	0.2	100-400	1.2 + 6 + 18	N/A	A****
3	Cereals (winter/spring soft wheat 050090-002, winter/spring durum wheat 050090-001, triticale 050090-006, spelt 050090-005 and winter rye 050070)	PL	GLOB289H / SAP63H	F	Annual grassy weeds and Annual dicotyledonous weeds: APESV GALAP MATIN STEME CABP	WG	6 + 30 + 90 g/l[±]	Downward spraying	BBCH 21-32	1	N/A	0.3	100-400	1.8 + 9 + 27	N/A	A****

					POAAN											
4	Cereals (winter soft wheat 050090-002, winter durum wheat 050090-001, triticale 050090-006, spelt 050090-005 and winter rye 050070)	PL	GLOB289H / SAP63H	F	Annual grassy weeds and Annual dicotyledonous weeds: ALOMY AVEFA CHEAL PAPRH VIOAR	WG	6 + 30 + 90 g/l$^{\pm}$	Downward spraying	BBCH 21-32	1	N/A	0.4	100-400	2.4 + 12 + 36	N/A	A****
5	Cereals (winter/spring soft wheat 050090-002, winter/spring durum wheat 050090-001, triticale 050090-006, spelt 050090-005 and winter rye 050070)	BE, NL, DE, CZ	GLOB289H / SAP63H	F	Annual grassy weeds and Annual dicotyledonous weeds: POAAN PAPRH LAMPU APESV CHEAL MATIN STEME	WG	6 + 30 + 90 g/l$^{\pm}$	Downward spraying	BBCH 21-32	1	N/A	0.3	100-400	1.8 + 9 + 27	N/A	A****
6	Cereals (winter soft wheat 050090-002, winter durum wheat 050090-001, triticale 050090-006, spelt 050090-005 and winter rye 050070)	BE, NL, DE, CZ	GLOB289H / SAP63H	F	Annual grassy weeds and Annual dicotyledonous weeds: MATCH MATIN STEME	WG	6 + 30 + 90 g/l$^{\pm}$	Downward spraying	BBCH 21-32	1	N/A	0.4	100-400	2.4 + 12 + 36	N/A	A****
7	Cereals (winter soft wheat 050090-002, winter durum wheat 050090-001, triticale 050090-006, spelt 050090-005 and winter rye 050070)	BE, NL, DE, CZ	GLOB289H / SAP63H	F	Annual grassy weeds and Annual dicotyledonous weeds: ALOMY STEME MATIN GALAP VIOAR	WG	6 + 30 + 90 g/l$^{\pm}$	Downward spraying	BBCH 21-32	1	N/A	0.5	100-400	3 + 15 + 45	N/A	A****v most critical GAP

* 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

± Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr diethyl

**** The use of Moxie in a mixture with adjuvants, e.g. Actirob 842 EC has been accepted.

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 SAP63H is composed of iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr diethyl.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of iodosulfuron-methyl sodium and mesosulfuron-methyl

Reference value	Source	Year	Value	Study relied upon	Safety factor
Iodosulfuron-methyl					
ADI	EFSA	2016	0.03	Rat, 2 year	100
ARfD	EFSA	2016	3.15	Rat, developmental	100
Mesosulfuron-methyl					
ADI	EFSA	2016	1.0	Mouse, 18 months	100
ARfD	EFSA	2016	No ARfD derived, not necessary		
Mefenpyr-diethyl					
ADI	Mefenpyr DAR	2011	0.1	Anses proposal (co-RMS)	
ARfD	Mefenpyr DAR	2011	0.4	Anses proposal (co-RMS)	

7.1.2.1 Summary for iodosulfuron-methyl-sodium

Table 7.1-3: Summary for iodosulfuron-methyl-sodium

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	Winter (durum and soft) wheat (TRZAW-TRZDW) Triticale (TTLSS) Spelt (TRZSP) Winter rye (SECCW)	Yes	Yes (8)	Yes	Yes	Yes	No	No
2	Winter (durum and soft) wheat (TRZAW-TRZDW) Triticale (TTLSS) Spelt (TRZSP) Winter rye (SECCW)	Yes	Yes (8)	Yes	Yes	Yes		No
3	Spring (durum and soft) wheat (TRZAS-TRZDS)	Yes	Yes (8)	Yes	Yes	Yes		No

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

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

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

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

7.1.2.2 Summary for mesosulfuron-methyl

Table 7.1-4: Summary for mesosulfuron-methyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter (durum and soft) wheat (TRZAW-TRZDW) Triticale (TTLSS) Spelt (TRZSP) Winter rye (SECCW)	Yes	Yes (26)	Yes	Yes	Yes	No	No
2	Winter (durum and soft) wheat (TRZAW-TRZDW) Triticale (TTLSS) Spelt (TRZSP) Winter rye (SECCW)	Yes	Yes (26)	Yes	Yes	Yes		No
3	Spring (durum and soft) wheat (TRZAS-TRZDS)	Yes	Yes (26)	Yes	Yes	Yes		No

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

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

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

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

7.1.2.3 Summary for mefenpyr-diethyl

According with the European information available, mefenpyr-diethyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009.
Although in agreement with the Reg. 1107/2009 the safener should be evaluated, in the Regulation, it is stated "*In addition to active substance, plant protection products may contain safeners or synergistics for which similar rules should be provided. The technical rules necessary for the evaluation of such substances should be established. Substances currently on the market should only be evaluated after those rules have been established.*"

In addition, Article 26 is referred to safeners and synergists already on the market, and states: "*By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include the establishment of data requirements, including measures to minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.*"
This means that at this date, when evaluating a dossier which includes a safener, Member States should apply national rules. Being a zonal dossier, and knowing that the rules should be established soon, no particular evaluation of Mefenpyr-diethyl is made in this dossier. Nevertheless, we highlight that since Mefenpyr-diethyl is already included in the formulated product, its plant residue impacts are already accounted for on in the studies.

Notifiers are aware that a national MRL is established for mefenpyr in France (Journal Officiel de la République Française » (JORF), 8th May 2008[1]). However, there are several products authorized in France that contain this safener and that are out of data protection rights. Products ATLANTIS WG and ENJEU are examples of this. Dose rates of mefenpyr authorized in these products are the same as the critical one proposed for SAP63H (45 g/ha). For the rest of countries to which this application is intended, technical rules necessary for the evaluation of safeners are not established yet. Hence, data for the mefenpyr-diethyl evaluation is not required according to the current legal framework of these countries.

However, new studies are submitted by the applicant as additional data for the evaluation of this dossier. Eight harvest trials have been carried out in order to determine the magnitude of mefenpyr-diethyl and its metabolites (AE F113225 and AE F094270) in wheat (grain and straw). Furthermore, a study to evaluate the stability of mefenpyr-diethyl and its metabolites under freezing storage conditions is being carried out at the moment of this submission. Magnitude results are exposed in Section 7.4.

7.1.2.4 Summary for SAP63H

Table 7.1-5: Information on SAP63H (KCA 6.8)

Crop	PHI for SAP63H proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for SAP63H proposed by zRMS	zRMS Comments (if different PHI proposed)
		Iodosulfuron-methyl-sodium	Mesosulfuron-methyl	Mefenpyr-diethyl		
Wheat, rye, triticale and spelt	F**	Yes	Yes	N/A		

* 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).

According with the OECD Guideline 509, "for a test substance which has a label recommendation for the use of a specific adjuvant, crop field trials should include the adjuvant, or another adjuvant with similar properties". Therefore, new residue data (4T NEU + 4T SEU) have been generated where SAP63H (Iodosulfuron 0.6% + Mesosulfuron 3% + Mefenepyr-diethyl 9% WG) has been applied along a non-ionic surfactant (Pottok) as an example molecule. As anticipated, no effect of Pottok on the residues was observed.
No trials are available for the combination of the PPP and Actirob. However:

- Non-ionic surfactants are used to reduce the surface tension and to improve spreading and plant

[1] Arrêté du 6 mai 2008 modifiant l'arrêté du 10 février 1989 relatif aux teneurs maximales en résidus de pesticides admissibles sur et dans les céréales destinées à la consommation humaine.

cuticle penetration, sticking and herbicide uptake during the application and in the plant. Esterified seed oils also reduce surface tension and boost the herbicide uptake by improving herbicide distribution on the leaf surface and keeping the leaf surface moist longer, allowing more time for the herbicide to be absorbed by the plant. Therefore, both of them show similar properties as they are used to improve the penetration of the active substance in the leaf surface.

- SAP63H is recommended to be applied early in the growing season (BBCH32 at the latest) when consumable parts of the crop are not present, being residue levels above the LOQ not expected. In fact, new data generated with applications of SAP63H and the non-ionic surfactant did not show residues above 0.01 mg/kg of iodosulfuron-methyl, mesosulfuron-methyl, triazine amine or mefenpyr-diethyl (including its metabolites AE F113225 and AE F094270) as it was expected according with data from the DAR of both active substances.

- According to SANCO 7525/VI/95 Rev. 10.3, special consideration should be given to changes in the content of adjuvants when the PHI < 7 days. However, our PPP is applied early in the season on a young crop. Therefore, no effects of the adjuvant are expected. An esterified rapeseed oil like Actirob is added to the WG formulation to mimic the effect of an OD formulation. In an OD or an Oil Dispersion formulation, solid active ingredients are dispersed in oil. The oil can vary from paraffinic to aromatic solvent types and vegetable oil or methylated seed oils. ODs have a better spray retention, spreading and foliar uptake as the carrier oil acts as an adjuvant.

- For the assessment of the effect of an oil like Actirob on the residue levels, reference is made to the unprotected residue trials in ALISTER (AMM N° 2060128).

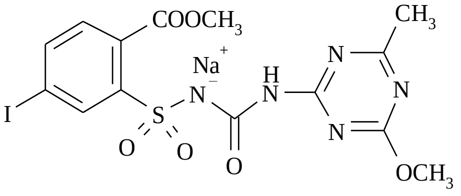
It can therefore be concluded that the available residue package of SAP63H is sufficient to recommend the use of a non-ionic surfactant and/or Esterified rapeseed oil to improve the efficacy of SAP63H, since no residues are expected according the proposed uses, the degradation in plant of both active substances is very fast and Pottok (non-ionic surfactant)/Actirob B (Esterified rapeseed oil) do not increase the residue level after application of SAP63H.

Assessment

7.2 Iodosulfuron-methyl-sodium

General data on Iodosulfuron-methyl-sodium are summarized in the table below (last updated 2019/06/12)

Table 7.2-1: General information on Iodosulfuron-methyl-sodium

Active substance (ISO Common Name)	Iodosulfuron Variant: iodosulfuron-methyl-sodium
IUPAC	Sodium ({[5-iodo-2-(methoxycarbonyl)phenyl]sulfonyl}carmamoyl)(4-methoxy-6-methyl-1,3,5-triazin-2-yl)azanide
Chemical structure	
Molecular formula	$C_{14}H_{13}IN_5NaO_6S$
Molar mass	529.27
Chemical group	Sulfonylurea
Mode of action (if available)	Acetolactate synthase (ALS) inhibitor acts on the target weeds both via the foliage and the soil, with a predominance of foliar action. After application to a fully developed plant leaf the active substance effectively inhibits the development of new leaves at the shoot apex, indicating that the herbicide has phloem-systemic properties. Translocation to the shoot base and the root is usually higher than translocation to the shoot parts above the treated leaf.
Systemic	Yes
Company (ies)	Bayer CropSciences
Rapporteur Member State (RMS)	Sweden
Approval status	Approved Date of (01/04/2017) and reference to decision (Regulation (EU) 2017/407 - Regulation (EU) No 540/2011).
Restriction	None
Review Report	SANTE/2016/11167 Rev 3 (7/12/2016)
Current MRL regulation	Regulation (EC) No 289/2014
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, 2016)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2012)
Current MRL applications on intended uses	None

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

New data regarding storage stability has been carried out and is submitted in the framework of this application. Summary of available data is included in table 7.2-2.

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			
Wheat Shoot	High water content	26 months	Sweden, 2016
Wheat Straw	No group	28 months	Sweden, 2016
Wheat Grain	Dry commodity	Up to 24 months	Sweden, 2016
New data			
Plant products			
Iodosulfuron-methyl			
Wheat Grain	High starch content	6 months	KCP 7.2.1/01 (Gordo, J., 2018)
Wheat Straw	No group	6 months	KCP 7.2.1/01 (Gordo, J., 2018)
Triazine amine			
Wheat Grain	High starch content	7.3 months	KCP 7.2.1/02 (Gordo, J., 2018)
Wheat Straw	No group	7.3 months	KCP 7.2.1/02 (Gordo, J., 2018)

Conclusion on stability of residues during storage

A new storage stability study on iodosulfuron-methyl residues in cereals was identified as a data gap in the peer review (EFSA, 2016). Concurrently, the storage stability of the metabolite triazine amine was also assessed.

Thus, new stability studies for both iodosulfuron-methyl and triazine amine have been submitted by the applicant, which are considered enough in order to support the findings in the residue trials submitted.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch does contain at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples are handled and stored in parallel. The recoveries in the fortified samples are within acceptable ranges, the stability of the sample extracts is considered as sufficiently proven.

Conclusion on stability of residues in sample extracts

No additional data required.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.
According to the RAR (Sweden, 2016) enough data was available from the first DAR (Germany, 2000). This data is currently out of data protection and can be used to support the requested uses. Summary of available metabolism data in plants is included in table 7.2-3.

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	Wheat	^{14}C-labelled in the 2-triazinyl-position (*)	Spray F	20 g/ha + mefenpyr diethyl safener ratio: 3/1	1	Forage: 3, 7 and 22 days Hay: 35 days Mature stage: 49 d Harvest: 77 days	Application at tillering stage	Germany, 2000 Braun, 1998,
		U-^{14}C-phenyl-labelled (**)	Spray G	20 g/ha + mefenpyr diethyl safener ratio: 3/1	1	Forage: 0, 20, 23 and 28 days Hay: 43 days Harvest: 87 days	Application at 3-4 leaf stage	Germany, 2000 Tarara, 1998,

Summary of plant metabolism studies reported in the EU

During the first inclusion process into Annex I of Directive 91/414/EEC, metabolism was investigated in wheat (cereal crop group) following foliar application using ^{14}C-Phenyl and ^{14}C-Triazinyl labelled iodosulfuron-methyl. The parent compound was a major residue in the cereal forage (40-68% TRR) for both labels and in straw of the phenyl label study (58% TRR). In the triazinyl label study in cereal straw there was almost equal distribution of the identified residues between five compounds (parent and the metabolites metsulfuron-methyl, AE F145741, AE 0031838, AE F059411 aka triazine amine) all of them individually accounting for 8 to 13% TRR. In grains, AE 0031838 was the major residue (15% TRR), the parent was recovered in very low proportions (0-3% TTR). The presence of the label specific metabolites AE F059411 and AE 0031838 in significant proportions indicated that cleavage of the sulfonylurea bridge is taking place (EFSA, 2016).

Summary of new plant metabolism studies

No new data is required.

Conclusion on metabolism in primary crops

Considering the representative use in cereals, the relevant residue for both enforcement and risk assessment on this crop group was proposed by default as sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl.
In view of the triazine amine metabolite (AE F059411) which is a common metabolite to a number of sulfonylurea herbicides, it is recommended to consider in a comprehensive consumer risk assessment the different possible sources of exposure and to address the potential transfer to livestock matrices, i.e. AE F059411 is provisionally a candidate for inclusion in the risk assessment definition, also pending the full clarification with regard to its toxicological properties.
Pending the conclusion on the triazine amine toxicity, also the metabolite AE 0031838 (hydroxymethyl triazine amine) observed up to 15% TRR in grain may require a reassessment (EFSA, 2016).

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

All crops under consideration may be grown in rotation but, according to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of iodosulfuron-methyl is expected to be lower than 49 days which is far below the trigger value of 100 days (Germany, 2000). Nevertheless, metsulfuron-methyl was identified as a relevant soil metabolite and for this compound DT_{90} values in the field ranged between 26 and 190 days. Nature and magnitude of residues in succeeding crops was therefore further investigated by means of a confined rotational crop study. A summary of available studies is included in table 7.2-4.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Spinach	^{14}C-labelled in the 2-triazinyl-position	Soil treatment	0.02	29 120 365	- - 408		Germany, 2000; Sweden, 2016; EFSA, 2016
Root and tuber vegetables	Carrot				29 120 365	- 252 464		
Cereals	Wheat				29 120 365	99 239 464		

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

Summary of plant metabolism studies reported in the EU

The study was carried out with one application of radiolabelled iodosulfuron-methyl-sodium at 20 g a.s./ha on a bare soil. Carrot, spinach and wheat were grown on the treated soil at three different plant-back intervals. The carrot planted 30 days after treatment as well as the spinach planted at 30 and 120 DAT, showed important signs of phytotoxicity and therefore were not considered. Total radioactive residues in mature carrot and spinach planted 1 year after treatment were too low for further characterisation (<0.05 mg eq/kg). Significant residues in rotational crops other than cereals are therefore not expected.
Total radioactive residues in cereal grains were found to be below 0.01 mg eq/kg at all plant-back inter-

vals. Total radioactive residues in cereal straw ranged between 0.1 and 0.5 mg eq/kg depending on the plant-back interval. However, the main metabolites identified were also identified in the primary crop metabolism (iodosulfuron triazine and iodosulfuron-demethyl-hydroxy-triazine) and the metabolic pattern for primary crops and rotational crops were concluded to be similar (Germany, 2000).

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops

Considering that, in studies conducted to assess nature of residue in rotational crops, individual metabolite fractions are not expected to exceed 0.05 mg/kg (=LOQ for cereal straw), that the rotational crop study was carried out on a bare soil with more than 6 times the most critical application rate and that the primary use of this active substances is authorized on cereal crops, particular risk mitigating measures for rotational crops are not deemed necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

The effect of processing on the nature of iodosulfuron-methyl was not investigated during the peer review (Germany, 2000; Sweden, 2016) and no new studies have been submitted in the framework of this application. Therefore, no data on the effect of processing on iodosulfuron-methyl are available.
No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

Specific studies to assess the magnitude of iodosulfuron-methyl and triazine amine residues during the processing of cereals are not necessary as the residue levels in raw agricultural commodities did not exceed the trigger value of 0.01 mg/kg.

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 (Wheat)
Rotational crops covered	Root/tuber crops (carrot) Leafy crops (spinach) Cereal (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (based on residue identification in rotational cereal straw only)
Processed commodities	Not available.
Residue pattern in processed commodities similar to pattern in raw commodities?	Quantifiable residues of iodosulfuron-methyl are not expected in the cereal grains, therefore there is no need to investigate the effect of industrial and/or household processing (EFSA, 2016).
Plant residue definition for monitoring	Iodosulfuron-methyl (sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl) (Regulation n°289/2014)

	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (only applicable to cereals) (EFSA 2016)
Plant residue definition for risk assessment	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (only applicable to cereals) (EFSA 2016) Triazine amine (IN-A4098) is a potential candidate for the plant residue definition for risk assessment, and a final decision is pending furhter clarification regarding the toxicological properties and the related consumer risk. Pending the conclusion on the IN-A4098 toxicity, also the metabolite AE 0031838 (hydroxymethyl triazine amine) observed up to 15 % TRR in grain may require a reassessment. (EFSA, 2016)
Conversion factor from enforcement to RA	Not necessary (EFSA, 2016)

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

Available data

For the first approval of iodosulfuron-methyl-sodium, metabolism studies in livestock were not performed as the use of iodosulfuron-methyl-sodium according to the good agricultural practice does not lead to significant residues in livestock feed and has no accumulation potential.

During the renewal process, one study in poultry and one study in ruminants were provided and assessed.

Summary of animal metabolism studies reported in the EU

Metabolism of AE F115008 in the dairy cow shows O-demethylation to AE F145741 and hydroxylation to AE F168532. AE F145741 is dehalogenated to AE F161778. Both AE F145741 and AE F168532 lose the triazinyl group to form AE C627337, which is then further metabolised to AE F114368, which is cyclised to AE F143133 (see figure below for a proposed metabolic pathway).
The major portion of AE F115008 is excreted unchanged, the mean daily recovery of the administered dose in excreta (faeces and urine) after 7 days was 91.79%.
AE F115008 does not accumulate in milk or edible tissues of the dairy cow, the plateau residue level is low, approximately 0.01 mg/kg (0.006-0.017 mg/kg).
The highest residues of AE F115008 and its metabolites in edible tissue were seen in kidney (0.100 mg eq/kg) and liver (0.061mg eq/kg). Residues in renal fat, heart and subcutaneous fat were 0.022, 0.008 and 0.008 mg eq/kg. Residue levels in omental fat and muscle were 0.007 and 0.002 - 0.004mg eq/kg (Sweden, 2016).

Summary of new animal metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in livestock

During the peer review it was concluded that, the calculated dietary burden showed that the residues from the representative GAP would not exceed the threshold of 0.004 mg/kg bw/day. Therefore, the study was not required according to the data requirements.
Same conclusion can be applied to the present submission and therefore, no further data is required.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin

(KCA 6.7.1)

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

	Endpoints
Animals covered	Goat/cow
	Laying hens
Time needed to reach a plateau concentration	4 days in milk
	5 days in eggs
Animal residue definition for monitoring	Iodosulfuron-methyl (sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl) (Regulation n°289/2014)
Animal residue definition for risk assessment	Study not triggered considering residues of parent iodosulfuron-methyl. Not further assessed (EFSA 2016).
Conversion factor	NA
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

Southern Europe
In the monograph, 10 trials were performed in the 1995 and 1996 in Southern Europe on cereals.
They were conducted on wheat at a growth stage from BBCH 39 to BBCH 51, with an application rate of 15 g as/ha, and a PHI of 51 to 96 days. Moreover, among these trials, 5 were realized in combination with the safener mefenpyr-diethyl. As a consequence, they are suitable to support the use requested for this plant protection product. In these trials, the crop was treated at a later stage and the application rate used is always higher than the one requested for this plant protection product, but the residue trials can be taken in account as it represents a worse case for residue evaluation. At harvest residues in grain and straw were always less than the respective limits of quantification (0.01 mg/kg for grain and 0.05 mg/kg for straw).

Northern Europe
In the monograph, 10 trials were performed in 1995 and 1996 in Northern Europe on cereals.
They were conducted on wheat, winter rye and spring barley, at a growth stage from BBCH 39 to BBCH 53, with an application rate of 15 g as/ha, and a PHI of 59 to 95 days. Moreover, among these trials, 5 were realized in combination with the safener mefenpyr-diethyl. As a consequence, they are suitable to support the use requested for this plant protection product. In these trials, the crop was treated at a later stage and the application rate used is always higher than the one requested for this plant protection product, but the residue trials can be taken into account as it represents a worse case for residue evaluation.
At harvest residues in grain and straw were always less than the respective limits of quantification (0.01 mg/kg for grain and 0.05 mg/kg for straw).
Before analysis the samples were stored frozen for up to 818 days for shoot, 481 days for grain and 699 days for straw. This maximum storage period is covered by the storage stability study. No residues above the LOQ of 0.01 mg/kg could be detected in any of the control samples.
Residue levels in treated samples are summarised hereafter.

Nevertheless, during the peer review EFSA pointed out three data gaps which affected the aforementioned residue trials (EFSA, 2016). First, the storage stability studies that were used to validate these residue trials were not clear enough to draw a conclusion on iodosulfuron-methyl stability. Second, in some cases, information on the experimental designs required to fully validate the residue trials (storage temperature prior to analysis) was missing. Finally, the metabolite triazine amine (AE F059411) was proposed as a candidate for inclusion in the risk assessment definition of the residue.

Consequently, new residue trials investigating the magnitude of residues of iodosulfuron-methyl and triazine amine have been carried out and are summarized in table 7.2-7. These new residue trials are submitted by the applicant in this dossier. In each trial one plot was treated once at BBCH 32 with SAP63H at the application rate of 0.5 kg/ha (3 g iodosulfuron-methyl-sodium/ha, 15 g mesosulfuron-methyl/ha and 45 g mefenpyr-diethyl/ha), whereas one plot remained untreated. These application parameters are equal to the most critical GAP proposed. The wetting agent HAG 530 01 S (Pottok)was applied in tank mix at a dose rate of 200 ml/ha. In all trials (4 in Northern Europe, and 4 in Southern Europe) samples of grain and straw were taken at maturity of the crop (BBCH 89).

Table 7.2-7: Summary of EU reported and new data supporting the intended uses of SAP63H 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 TA = Triazine amine (AE F059411)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calcula-tor MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Cereals grain	Monograph	N-EU	Trials GAP: 1x 15g/ha, BBCH 39-53, PHI=59-95 10x <0.01	N/A				
	Monograph	S-EU	Trials GAP: 1x 15g/ha, BBCH 39-51, PHI=51-96 10x <0.01					
	Overall supporting data for cGAP**	EU	Trials GAP: 1x 15g/ha, BBCH 39-53, PHI=51-96 20x <0.01	0.01*	0.01*	0.01*	0.01*	Yes
	New trials	N-EU	Trials GAP: 1x 3g/ha, BBCH 32, PHI=63-84 E=RA: 4x <0.01 TA: 4x <0.01	N/A				
	New trials	S-EU	Trials GAP: 1x 3g/ha, BBCH 32, PHI=70-90 E=RA: 4x <0.01 TA: 4x <0.01					
	Overall supporting data for cGAP**	EU	Trials GAP: 1x 3g/ha, BBCH 32, PHI=63-90 E=RA: 8x <0.01 TA: 8x <0.01	0.01*	0.01*	0.01* (0.01*)	0.01*	Yes
Cereals straw	Monograph	NEU	Trials GAP: 1x 15g/ha, BBCH 39-53, PHI=59-95 10x <0.05	N/A				
	Monograph	SEU	Trials GAP: 1x 15g/ha, BBCH 39-51, PHI=51-96 10x <0.05					
	Overall supporting data for cGAP**	EU	Trials GAP: 1x 15g/ha, BBCH 39-53, PHI=51-96 20x <0.05	0.05	0.05	N/A		
	New trials	N-EU	Trials GAP: 1x 3g/ha, BBCH 32, PHI=63-84 E=RA: 4x <0.01	N/A				

			TA: 4x <0.01			
	New trials	S-EU	Trials GAP: 1x 3g/ha, BBCH 32, PHI=70-90 E=RA: 4x <0.01 TA: 4x <0.01			
	Overall supporting data for cGAP**	EU	Trials GAP: 1x 3g/ha, BBCH 32, PHI=63-90 E=RA: 8x <0.01 TA: 8x <0.01	0.01*	0.01*	N/A

* Source of EU MRL: Regulation (EU) No 289/2014

** Residue data from both NEU and SEU have been pooled together since, according to Mann-Whitney U test, both populations can be considered as similar.

7.2.3.2 Conclusion on the magnitude of residues in plants

Wheat and rye are considered as major crops in both Northern and Southern Europe. Triticale and spelt are considered minor crops, however, data from wheat can be extrapolated to both. Residue trials are requested both in north and south for France. Therefore, 8 trials performed in each zone are required.

The magnitude of both iodosufluron-methyl and triazine amine was determined concurrently in each sample. As it could be demonstrated, all residue results were found to be below the LOQ. According the Table 2 of the EU guideline 7525/VI/95 rev. 10.3, («Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs») 4 trials in each zone are enough to support the whole group if residues are lower than the LOQ.

In addition, according to the aforementioned guideline, extrapolation from any one of the following barley / oats / rye / triticale / wheats to the remaining four crops is possible as long as the last application is done before consumable parts of the crops have started to form (BBCH 51). Considering the intended uses (until BBCH 32) the extrapolation is possible. Therefore, data from trials performed in wheat can be used to support the proposed use in winter rye, spelt and triticale.

A total of 8 new trials (4 N-EU and 4 S-EU) assessing the magnitude of iodosulfuron-methyl and triazine amine have been submitted to support the intended uses. The GAP at which they were carried out is equal to the intended cGAP. As already stated in section 7.2.1, new stability studies to cover the storage stability of both iodosulfuron-methyl and triazine amine were also carried out and are submitted in this dossier.

Finally, as reported in Section 7.1.2.4, the available residue package of SAP63H is sufficient to recommend the use of a non-ionic surfactant and/or Esterified rapeseed oil to improve the efficacy of SAP63H. No residues are expected according the proposed uses, the degradation in plant of both active substances is very fast and Pottok (non-ionic surfactant)/Actirob B (Esterified rapeseed oil) do not increase the residue level after application of SAP63H.

The number of residue trials is sufficient to conclude that MRL will not be exceeded according when SAP63H is used according to the intended GAP.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Input values used in the dietary burden calculation are included in table 7.2-8 for iodosulfuron-methyl and table 7.2-9 for triazine amine. Results of the calculation performed are included in table 7.2-10 for iodosulfuron-methyl and 7.2-11 for triazine amine.

Table 7.2-8: Input values for the iodosulfuron-methyl dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl				
Maize silage	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)
Cereal grain	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Cereal bran (wheat, milled by-pdts)	0.07	Median residue grain x 7 (EFSA, 2012)	0.07	Median residue grain x 7 (EFSA, 2012)
Cereal straw	0.05	Highest residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)
Brewer’s grain (dried)	0.03	Median residue grain x 3.3	-	-
Distiller’s grain (dried)	0.03	Median residue grain x 3.3	-	-
Wheat gluten (meal)	0.02	Median residue grain x 1.8	-	-

Table 7.2-9: Input values for the triazine amine dietary burden calculation (considering the uses under consideration)*

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Triazine amine				
Cereal grain	0.010	Mean residue (trials)	0.010	Highest Residue (trials)
Cereal straw	0.010	Mean residue (trials)	0.010	Highest Residue (trials)
Brewer’s grain (dried)	0.03	Mean residue grain x 3.3	-	-
Distiller’s grain (dried)	0.03	Mean residue grain x 3.3	-	-
Wheat gluten (meal)	0.02	Mean residue grain x 1.8	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat (milled by-pdts)	0.07	Mean residue grain x 7	-	-

The input values used are the following:
- The residue values (median and highest value) have been calculated from the available studies submitted in the dossier where triazine amine has been quantified (KCP 7.2.3/01b).
- The processing factor values are the default values included in the Excel spreadsheets for animal intake calculations (EFSA, 2015).

Table 7.2-10: Results of the iodosulfuron-methyl dietary burden calculation

Animal species	Most critical diet	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl						
Cattle (all diets)	Dairy cattle	0.004	0.004	Corn, field, Forage/silage	0.12	N
Cattle (dairy only)	Dairy cattle	0.004	0.004	Corn, field, Forage/silage	0.10	N
Sheep (all diets)	Lamb	0.003	0.003	Wheat, milled bypdts	0.07	N
Sheep (ewe only)	Ram/Ewe	0.002	0.002	Wheat, milled bypdts	0.07	N
Swine (all diets)	Swine (breeding)	0.002	0.002	Corn, field, Forage/silage	0.07	N
Poultry (all diets)	Poultry layer	0.002	0.002	Poultry layer, Corn, field	0.04	N
Poultry (layer only)	Poultry layer	0.002	0.002	Poultry layer, Corn, field	0.04	N

Table 7.2-11: Results of the triazine amine dietary burden calculation

Animal species	Most critical diet	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)
Triazine amine						
Cattle (all diets)	Dairy cattle	0.001	0.001	Wheat, milled bypdts	0.03	N
Cattle (dairy only)	Dairy cattle	0.001	0.001	Wheat, milled bypdts	0.03	N

Animal species	Most critical diet	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)
Sheep (all diets)	Lamb	0.002	0.002	Wheat, milled bypdts	0.05	N
Sheep (ewe only)	Ram/Ewe	0.001	0.001	Wheat, milled bypdts	0.04	N
Swine (all diets)	Swine (finishing)	0.001	0.001	Wheat, milled bypdts	0.05	N
Poultry (all diets)	Poultry layer	0.002	0.002	Wheat, milled bypdts	0.03	N
Poultry (layer only)	Poultry layer	0.002	0.002	Wheat, milled bypdts	0.03	N

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Based on the dietary burden calculation performed, the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.004 mg/kg bw/d. Further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Available data

No new data were submitted in the framework of this application.
No study has been submitted at European level either.

Conclusion on feeding studies

The requested uses and the new mode of calculation do not modify the theoretical maximum daily intake for animals, there is no risk for animal MRL to be exceeded.

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

The effect of processing on the nature of iodosulfuron-methyl was not investigated during the peer review and no new studies have been submitted in the framework of this application. Therefore, no data on the effect of processing on iodosulfuron-methyl are available.

Available data for all crops under consideration

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

Conclusion on processing studies

Specific studies to assess the magnitude of iodosulfuron-methyl residues during the processing of cereals are not necessary as the residue levels in raw agricultural commodities did not exceed the trigger value of 0.1 mg/kg and the total theoretical maximum daily intake (TMDI) is far below the trigger value of 10 % of the ADI and 10% of the ARfD.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2.2.3), no study dealing with magnitude of residues in succeeding crops is needed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

According with the conclusions of the RAR, three of the four confined rotational studies (B.7.4.2.2), were carried out on a bare soil with 20 g a.s./ha (twice the normal application rate). The fourth study was performed with rates (wheat 8.1 g a.s./ha) which is expected to match more closely the residues in soil in a rotational situation (2 to 3 g a.s./ha).
The conclusion was that, based on these studies, the individual metabolite fractions are not expected to exceed 0.05 mg/kg (LOQ for cereal straw). Considering that it was carried out on a bare soil with up to twice the normal application rate and that the representative uses, assessed during the RAR, were winter barley and winter wheat, it was concluded that iodosulfuron-methyl residue levels in rotational commodities were not expected to exceed 0.01 mg/kg, provided that iodosulfuron-methyl-sodium is applied in compliance with the representative GAPs (Sweden, 2016).

Same conclusion can be applied to the present submission and therefore, no further data is required.

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

A technical guideline for the determination of the magnitude of pesticide residues in honey is currently available (SANTE/11956/2016 rev. 9 – 14 September 2018). According to this guideline, a crop can be considered melliferous if, besides being attractive to bees, it provides enough pollen, nectar, propolis and/or honeydew to enable honeybees to yield honey from that crop. A comprehensive list of crops' melliferous capacity is included, in which all crops under consideration are described as no melliferous. Since the active substance is intended to be applied on crops from which it is not possible to produce honey, residues in honey are therefore not expected.

Furthermore, the aforementioned guideline is not in force at the time of the present submission, as it will be implemented by January 1st, 2020. Hence, residue data related to bee and bee products is neither needed nor required.

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of SAP63H. Therefore, other special studies are not needed.

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

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

7.2.8.1 Input values for the consumer risk assessment

The calculation of the TMDI was performed taking into account all the crops to which iodosulfuron-methyl-sodium may be applied.
Consumer risk assessment was performed using EFSA PRIMo-rev. 3 model. For chronic risk assessment, MRLs as set in Reg. (EU) No. 289/2014 were used as input values.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl				
Wheat Triticale Spelt	0.01	STMR	0.01	HR
Rye	0.01	STMR	0.01	HR
Rest of plant and animal comodities	MRL	Reg. (EU) No 289/2014		

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.
A summary of the results is included in table 7.2-13.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	6% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Assessment not required.
IESTI (% ARfD) according to EFSA PRIMo*	Wheat: 0.0 % (for all the groups tested)
NTMDI (% ADI) **	Assessment not required.
NEDI (% ADI)**	Assessment not required.
NESTI (% ARfD) **	Assessment not required.

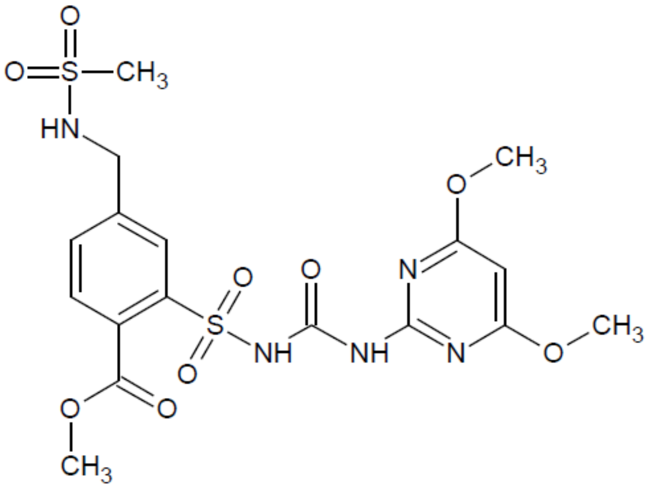
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of iodosulfuron-methyl-sodium in the formulation SAP63H do not represent unacceptable acute and chronic risks for the consumer.

7.3 Mesosulfuron-methyl

General data on mesosulfuron are summarized in the table below (last updated 2018/08/07)

Table 7.3-1: General information on mesosulfuron

Active substance (ISO Common Name)	Mesosulfuron-methyl
IUPAC	Mesosulfuron-methyl: methyl-2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]- α-(methanesulfonamido)-p-toluate Mesosulfuron: 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-αmethanesulfonamido-p-toluic acid
Chemical structure	
Molecular formula	$C_{17}H_{21}N_5O_9S_2$
Molar mass	503.51 g/mol
Chemical group	Sulfonylurea
Mode of action (if available)	The primary biochemical target site of mesosulfuron is the enzyme acetohydroxyacid synthase in the aliphatic amino acid pathway. Biosynthesis of the essential amino acids, valine and isoleucine, is inhibited which stops cell division and plant growth (EFSA, 2012).
Systemic	Yes, mesosulfuron-methyl is absorbed by the foliage and, to a lesser extent, the roots. It is systemically active being translocated in the phloem and xylem (EFSA, 2012)
Company (ies)	Bayer Cropscience AG
Rapporteur Member State (RMS)	France
Approval status	Approved Date of (01/07/2017) and reference to decision (Commission Implementing Regulation (EU) 2017/755)
Restriction	-
Review Report	SANTE/11827/2016 Rev 2 23 March 2017
Current MRL regulation	Regulation (EU) No 289/2014
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, 2016)

EFSA Journal: conclusion on article 12	Yes (EFSA, 2012)
Current MRL applications on intended uses	None

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

Stability data was submitted and evaluated during the first inclusion process of the active substance mesosulfuron-methyl (France, 2001). Since the protection of these data has expired, they can be used to support the product SAP63H. No further data is required.

No new data submitted in the framework of this application.
Summary of available data is included in table 7.3-2.

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			
Cereals, shoots	High water content	13 months	France, 2001
Cereals, straw	Dry commodities	13 months	France, 2001
Cereals, grain	High starch content	24 months	France, 2001

Conclusion on stability of residues during storage

The studies determined the stability of residues of mesosulfuron-methyl in wheat grain, wheat straw and wheat shoots during storage under deep freezing conditions for up to 24 months. However, the data assessed during the first inclusion process covered a period of 13 months. Therefore, in the framework of the first inclusion, storage stability of mesosulfuron-methyl was demonstrated for a period of 13 months at -18ºC in wheat grain, wheat straw and wheat shoots.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch does contain at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples are handled and stored in parallel. The recoveries in the fortified samples are within acceptable ranges, the stability of the sample extracts is considered as sufficiently proven.

Conclusion on stability of residues in sample extracts

No additional data required.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Two metabolism studies were submitted and assessed during the first inclusion process. Since their protection has expired, both can be used to support the product SAP63H.
No new data submitted in the framework of this application.
Summary of available data is included in table 7.3-3

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	^{14}C-pyridimidyl label	F	10 g a.s./ha	1 2	0, 35, 49, 95	Foliar application in advanced tillering stage	France, 2001 France, 2015
	Wheat	^{14}C-phenyl label	F	30 g a.s./ha	1 2	0, 41/42, 57/58, 103/104	Foliar application in advanced tillering stage	France, 2001 France, 2015

Summary of plant metabolism studies reported in the EU

The metabolism of mesosulfuron-methyl was investigated upon foliar application at the tillering stage (growth stages of mono- and dicotyledonous plants (BBCH) 29) in cereals (wheat) using, respectively, 2-14C-pyrimidyl and U-14C-phenyl labelling.
The total radioactive residues (TRRs) accounted for 0.018 mg eq/kg in forage, 0.0112 mg eq/kg in hay, 0.0012–0.0014 mg eq/kg in grain and 0.019–0.045 mg eq/kg in straw for both labelling forms indicating a limited translocation of the radioactivity throughout the whole plant. Metabolites' identification was not attempted in grain in view of the very low recovered residue levels. The parent compound was recovered at significant proportions in wheat forage and hay (23% TRR and 15% of TRR, respectively) and occurred only at a level of up to 3% TRR in straw. In wheat forage, hay and straw, mesosulfuron-methyl was shown to be degraded into metabolites identified as AE F160459 (3.7–14% TRR), AE F140584 (8.8–10% TRR) and AE F147447 (5–18% TRR). These metabolites accounted for a residue concentration <0.01 mg eq/kg. The major part of the radioactivity in these plant parts was characterised as polar fractions that globally accounted for 22–34% TRR and were constituted of several components that did not exceed each 0.004 mg eq/kg. The identity of these compounds was not further investigated (EFSA, 2016).

Summary of new plant metabolism studies

New data has not been submitted.

Conclusion on metabolism in primary crops

Since all the identified and characterised metabolites were recovered at very low concentrations (< 0.01

mg eq/kg) in wheat forage, hay and straw and in rotational crops, the residue definition for monitoring and risk assessment is proposed as mesosulfuron-methyl for cereals following post-emergence foliar application (EFSA, 2016).

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Two metabolism studies were submitted and assessed during the first inclusion process. Since their protection has expired, both can be used to support the product SAP63H.
No new data submitted in the framework of this application.
Summary of available data is included in table 7.3-4.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	**Rate (kg a.s./ha)**	**Sowing intervals (DAT)**	**Harvest Intervals (DAT)**	**Remarks**	
EU data								
Leafy vegetables	Spinach	^{14}C-pyrimidyl and ^{14}C-phenyl	Bare soil, F	~~0.0015~~ 0.015	32, 120, 365	162, 411	32 DAT spinach was not harvested	France, 2001 France, 2015
Root and tuber vegetables	Carrot					139, 237, 487		
Cereals	Wheat					131, 238, 482		

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

Summary of plant metabolism studies reported in the EU

A confined rotational crop metabolism study was conducted with a bare soil application of mesosulfuron-methyl labelled, respectively, on the pyrimidyl ring and on the phenyl ring at a dose rate of 15 g a.s./ha (1N rate). Spinach, carrot and wheat were sown at plant-back intervals (PBIs) of 30, 120 and 365 days. The total residues in all plant parts and at all PBIs were below 0.01 mg/kg, except in wheat straw where TRRs accounted for up to 0.022 mg eq/kg (30-day-PBI), 0.012 mg eq/kg (120-day-PBI) and 0.014 mg eq/kg (365-day-PBI) for both labelling forms. The radioactive residues in wheat straw at the 30-day-PBI were constituted of a major polar fraction (34% TRR) besides numerous minor polar fractions and a major metabolite identified as AE F147447 (31% TRR) (EFSA, 2016).

Summary of new plant metabolism studies

New data has not been submitted.

Conclusion on metabolism in rotational crops

Hence, the metabolic pathway in the rotational crops is deemed to be similar to that depicted in the primary crops and residues are not expected to be present in rotational crops (> 0.01 mg/kg), providing that mesosulfuron-methyl is applied according to the representative uses.
Since all the identified and characterised metabolites were recovered at very low concentrations (< 0.01 mg eq/kg) in wheat forage, hay and straw and in rotational crops, the residue definition for monitoring

and risk assessment is proposed as mesosulfuron-methyl for cereals following post-emergence foliar application (EFSA, 2016).

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

As residues in wheat grain are below the LOQ (<0.01 mg/kg) at the intended maximum application rate (15 g/ha), studies on the effects of processing on the nature of the residue are not required.
No data is available at European level.
No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

Data regarding the nature of residues in processed commodities is not available. However, is not required to support the proposed use in SAP63H.

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

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

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Data not available
Residue pattern in processed commodities similar to pattern in raw commodities?	-
Plant residue definition for monitoring	Mesosulfuron-methyl (Regulation (EU) n° 289/2014)
Plant residue definition for risk assessment	Mesosulfuron-methyl (EFSA, 2016)
Conversion factor from enforcement to RA	Not applicable

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

Available data

Metabolism studies in poultry and ruminants were submitted and assessed during the first inclusion process. Since their protection has expired, both can be used to support the product SAP63H.
No new data submitted in the framework of this application.
Summary of available data is included in table 7.3-6.

Table 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	U-^{14}C-phenyl	1	0.417 mg/kg bw/day	5	Milk	twice daily	France, 2001 France, 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hen	U-^{14}C-phenyl	6	0.758 mg/kg bw/day	14	Eggs	Twice daily	France, 2001 France, 2015
						Excreta	Daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

According with the conclusions of the peer review (EFSA, 2016), although livestock metabolism studies were not triggered according to the representative uses assessed during the first inclusion process and the renewal process, poultry and ruminant metabolism studies conducted with the U-^{14}C-phenyl labelling form only were submitted.

The parent compound was the predominant compound of the total residues in milk (23% TRR), liver (21–52% TRR), kidney (41% TRR) and in fat (20–70% TRR). Other compounds that occur at significant proportions, such as the alcohol metabolite AE F0195141 in fat (27% TRR), mesosulfuron-methyl or AE F140584 in poultry liver (18% TRR) and AE F140584 or AE F160459 in milk (17% TRR), accounted for a very low concentration (< 0.01 mg/kg) in all matrices at the calculated dietary burden.

Metabolites’ identification was not attempted in eggs and in the muscle because of the low recovered residue levels (0.012 and 0.004 mg eq/kg, respectively).

On the basis of the available metabolism studies in lactating ruminants and laying hens conducted with U-^{14}C-phenyl labelled mesosulfuron-methyl only, the residue definition for both monitoring and risk assessment for animal commodities is proposed as mesosulfuron-methyl only (EFSA, 2016).

Summary of new animal metabolism studies

New data has not been provided.

Conclusion on metabolism in livestock

Mesosulfuron-methyl was identified as the predominant compound of the total residues in milk, liver, kidney and fat. No metabolites’ identification was attempted in eggs and in muscle due to the very low recovered residues (0.012 and <0.01 mg eq./kg, respectively). The identified metabolites were recovered at very low concentrations in all matrices (<0.01 mg/kg) (EFSA, 2016).

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	5 days in milk
	10 days in eggs
Animal residue definition for monitoring	Mesosulfuron-methyl (Regulation (EU) n° 289/2014)
Animal residue definition for risk assessment	Mesosulfuron-methyl (EFSA, 2016)
Conversion factor	Not applicable
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

Southern Europe
In the monograph, 9 trials were performed in 1997 and 1998 in Southern Europe on cereals (3 in winter wheat, 3 in wheat durum, 2 in wheat soft and 1 in triticale).
They were conducted on cereals at a growth stage from BBCH 39 to BBCH 47, with an application rate of 15 g as/ha, and a PHI of 42 to 90 days. Moreover, all of them were realized in combination with the safener mefenpyr-diethyl. As a consequence, they are suitable to support the use requested for this plant protection product. In these trials, the crop was treated at a later stage than the one requested for this plant protection product, but the residue trials can be taken in account as it represents a worse case for residue evaluation.
At harvest residues in grain were always less than the respective limits of quantification (0.01 mg/kg for grain) in straw, only one trial was above the LOQ (0.09 mg/kg).

Northern Europe
In the monograph, 9 trials were performed in 1997 and 1998 in Northern Europe on cereals (4 in winter wheat, 4 in wheat soft and 1 in rye).
They were conducted on wheat and rye at a growth stage from BBCH 39 to BBCH 47, with an application rate of 15 g as/ha, and a PHI of 80 to 103 days. Moreover, all of them were realized in combination with the safener mefenpyr-diethyl. As a consequence, they are suitable to support the use requested for this plant protection product. In these trials, the crop was treated at a later stage than the one requested for this plant protection product, but the residue trials can be taken in account as it represents a worse case for residue evaluation.
At harvest residues in grain and straw were always less than the respective limits of quantification (0.01 mg/kg for grain and 0.05 mg/kg for straw).
No residues above the LOQ of 0.01 mg/kg could be detected in any of the control samples.

Even though the available data from the DAR can be considered enough to support the intended uses, new residue trials have been provided as additional data. In each trial one plot was treated once at BBCH 32 with SAP63H at the application rate of 0.5 kg/ha (3 g iodosulfuron-methyl-sodium/ha, 15 g mesosulfuron-methyl/ha and 45 g mefenpyr-diethyl/ha). One plot remained untreated. These application parameters are equal to the most critical GAP proposed. The wetting agent HAG 530 01 S (Pottok) was applied in tank mix at a dose rate of 200 ml/ha. In all trials (4 in Northern Europe, and 4 in Southern Europe) samples of grain and straw were taken at maturity of the crop (BBCH 89). Residue levels in treated samples are summarised in table 7.3-8.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of SAP63H 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
Cereals grain	France, 2001 France, 2015	N-EU	GAP on which EU a.s. assessment is based: 1 x 15g as/ha, BBCH 37-47 E&RA: 9x<0.01 mg/kg	N/A				
		S-EU	GAP on which EU a.s. assessment is based: 1 x 15g as/ha, BBCH 39-47 E&RA: 9x<0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	E&RA: 18x<0.01 mg/kg	E&RA: 0.01	E&RA: 0.01	0.01	0.01*	yes
	New trials	N-EU	Trials GAP: 1x 15g/ha, BBCH 32, PHI=63-84 E&RA: 4x <0.01	N/A				
	New trials	S-EU	Trials GAP: 1x 15g/ha, BBCH 32, PHI=70-90 E&RA: 4x <0.01					
	Overall supporting data for cGAP**	EU	Trials GAP: 1x 15g/ha, BBCH 32, PHI=63-90 E&RA: 8x <0.01	0.01*	0.01*	0.01* (0.01*)	0.01*	Yes
Cereals straw	France, 2001 France, 2015	N-EU	GAP on which EU a.s. assessment is based: 1 x 15g as/ha, BBCH 37-47 E&RA: 9x<0.01 mg/kg	N/A				
		S-EU	GAP on which EU a.s. assessment is based: 1 x 15g as/ha, BBCH 39-47 E&RA: 8x<0.05, 0.09 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	E&RA: 17x<0.05, 0.09 mg/kg	E&RA: 0.05	E&RA: 0.09	-	-	-

	New trials	N-EU	Trials GAP: 1x 15g/ha, BBCH 32, PHI=63-84 E&RA: 4x <0.01	N/A		
	New trials	S-EU	Trials GAP: 1x 15g/ha, BBCH 32, PHI=70-90 E&RA: 4x <0.01			
	Overall supporting data for cGAP**	EU	Trials GAP: 1x 15g/ha, BBCH 32, PHI=63-90 E&RA: 8x <0.01	0.01*	0.01*	N/A

* Source of EU MRL: Regulation (EU) No 289/2014

** Residue data from both NEU and SEU have been pooled together since, according to Mann-Whitney U test, both populations can be considered as similar.

7.3.3.2 Conclusion on the magnitude of residues in plants

Wheat and rye are considered as major crops in both Northern and Southern Europe. Triticale and spelt are considered minor crops, however, data from wheat can be extrapolated to both. Residue trials are requested both in north and south for France. Therefore, 8 trials performed in each zone are required.

According to EU guideline 7525/VI/95 rev.9, Appendix D (EC, 2017), extrapolation from any one of the following barley/oats/rye/triticale/wheats to the remaining four crops if the last application is before consumable parts of the crops have started to form (BBCH 51). Considering the intended uses (until BBCH 32) the extrapolation is possible. Therefore, data from trials performed in cereals can be used to support the proposed use in wheat (winter and spring), winter rye, spelt and triticale.

Trials from the DAR were performed with an OD formulation and SAP63H corresponds to a WG formulation. Even if formulations are not the same, differences in the residue levels are not expected. According to EU guideline 7525/VI/95 rev.9, Appendix D (EC, 2017) if the treatments are made to the soil the formulation is not relevant. In the same way, if the treatments are made to a very young crop the effect of co-formulants is likely to be minimal. These two conditions are fulfilled in the proposed uses of SAP63H.

A total of 18 DAR residue trials (9 NEU and 9 SEU) are available to support the intended uses. Although trials were conducted at a more critical GAP: with a later application growth stage (BBCH 37-47 instead BBCH 32), all 18 trials can be used to support the intended GAP. Residue levels are all below the LOQ (0.01 mg/kg) in grain and only one residue level is above the LOQ in straw.

Furthermore, 8 new residue trials (4 NEU and 4 SEU) have been submitted for this application as additional data. These trials were conducted at a comparable GAP to the one suggested, and thus are suitable to support the intended uses. Residue levels are all below the LOQ (0.01 mg/kg) in both grain and straw.

Finally, as already stated in Section 7.1.2.4, the available residue package of SAP63H is sufficient to recommend the use of a non-ionic surfactant and/or Esterified rapeseed oil to improve the efficacy of SAP63H. No residues are expected according the proposed uses, the degradation in plant of both active substances is very fast and Pottok (non-ionic surfactant)/Actirob B (Esterified rapeseed oil) do not increase the residue level after application of SAP63H.

The number of residue trials is sufficient to conclude that MRL will not be exceeded according when SAP63H is used according to the intended GAP.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Dietary burden calculation has been performed using EFSA's animal model (EFSA, 2017). Input values are included in table 7.3-9. Values calculated in table 7.3-8 have been used since they represent a worst case compared with the values used by EFSA in its review of the existing MRLs for mesosulfuron (EFSA, 2012).
Results of the calculation performed with these data are included in table 7.3-10.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Mesosulfuron-methyl				
Rye, triticale and wheat grain	0.01	Median residue	0.01	Median residue
Rye, triticale and wheat straw	0.05	Median residue	0.09	Highest residue
Distiller's grain (dried)	0.03	Median residue x PF	0.03	Median residue x PF
Wheat gluten (meal)	0.02	Median residue x PF	0.02	Median residue x PF
Wheat milled by-pdts	0.07	Median residue x PF	0.07	Median residue x PF

Table 7.3-10: Results of the dietary burden calculation

<table>
<tr><th rowspan="3">Relevant groups</th><th colspan="4">Dietary burden expressed in</th><th rowspan="3">Most critical diet (a)</th><th rowspan="3" colspan="2">Most critical commodity (b)</th><th>Trigger exceeded (Yes/No)</th></tr>
<tr><th colspan="2">mg/kg bw per day</th><th colspan="2">mg/kg DM</th><th>0.004</th></tr>
<tr><th>Median</th><th>Max.</th><th>Median</th><th>Max.</th><th>mg/kg bw</th></tr>
<tr><td>Cattle (all diets)</td><td>0,002</td><td>0,002</td><td>0,04</td><td>0,05</td><td>Dairy cattle</td><td>Rye</td><td>straw</td><td>No</td></tr>
<tr><td>Cattle (dairy only)</td><td>0,002</td><td>0,002</td><td>0,04</td><td>0,05</td><td>Dairy cattle</td><td>Rye</td><td>straw</td><td>No</td></tr>
<tr><td>Sheep (all diets)</td><td>0,003</td><td>0,003</td><td>0,06</td><td>0,08</td><td>Lamb</td><td>Rye</td><td>straw</td><td>No</td></tr>
<tr><td>Sheep (ewe only)</td><td>0,002</td><td>0,003</td><td>0,06</td><td>0,08</td><td>Ram/Ewe</td><td>Rye</td><td>straw</td><td>No</td></tr>
<tr><td>Swine (all diets)</td><td>0,001</td><td>0,001</td><td>0,05</td><td>0,05</td><td>Swine (finishing)</td><td>Wheat</td><td>milled bypdts</td><td>No</td></tr>
<tr><td>Poultry (all diets)</td><td>0,002</td><td>0,002</td><td>0,03</td><td>0,03</td><td>Poultry layer</td><td>Wheat</td><td>straw</td><td>No</td></tr>
<tr><td>Poultry (layer only)</td><td>0,002</td><td>0,002</td><td>0,03</td><td>0,03</td><td>Poultry layer</td><td>Wheat</td><td>straw</td><td>No</td></tr>
</table>

No exceedance of the trigger value of 0.004 mg/kg bw/day is expected.
No further data is required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Conclusion on feeding studies

Same conclusions as were defined during the renewal process are applicable in the assessment of SAP63H:

Residue studies with mesosulfuron at application rates up to 15 g a.s./ha in Europe show that no residue levels are expected in animal feed commodities. Rare cases have shown some residues above the LOQ in straw (0.09 mg/kg).
Metabolism, distribution and expression studies in rats and livestock showed that mesosulfuron-mehtyl was rapidly absorbed and excreted, mainly via the faeces. No indications of cumulative properties were seen. Therefore, it was concluded that residues in edible parts of livestock at or above a reasonable limit of quantification will not occur and feeding studies are not deemed necessary.

Moreover, dietary burden calculations showed, in all animals, levels <0.004 mg/kg bw/day.
It can be therefore concluded that the use of mesosulfuron-methyl followed by the use of the produced grain, bran and wheat straw as animal feed will not lead to detectable residues in food of animal origin. Consequently, there is no need to conduct livestock feeding studies (France 2015).

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

7.3.5.1 Available data for all crops under consideration

Residues in wheat grain are below the LOQ (<0.01 mg/kg) at the intended maximum application rate (15 g/ha). Since the residue levels in raw agricultural commodities did not exceed the trigger value of 0.1 mg/kg and the total theoretical maximum daily intake (TMDI) is far below the trigger value of 10 % of the ADI and 10% of the ARfD, studies on the effects of processing on the magnitude of the residue are not required.
No data is available at European level.
No new data submitted in the framework of this application.

7.3.5.2 Conclusion on processing studies

Data regarding the magnitude of residues in wheat grain processed commodities is not available. However, it is not required to support the proposed use in SAP63H.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No data is available at EU level.
No new data submitted in the framework of this application.

Conclusion on rotational crops studies

Same conclusions as were defined during the renewal process are applicable in the assessment of SAP63H:

Metabolism studies on rotational crops have shown that no residues at or above the limit of quantification (<0.01 mg/kg) can be expected in succeeding crops. Therefore, no field trials on representative crops are necessary (France, 2015).

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

A technical guideline for the determination of the magnitude of pesticide residues in honey is currently available (SANTE/11956/2016 rev. 9 – 14 September 2018). According to this guideline, a crop can be considered melliferous if, besides being attractive to bees, it provides enough pollen, nectar, propolis and/or honeydew to enable honeybees to yield honey from that crop. A comprehensive list of crops' melliferous capacity is included, in which all crops under consideration are described as no melliferous. Since the active substance is intended to be applied on crops from which it is not possible to produce honey, residues in honey are therefore not expected.

Furthermore, the aforementioned guideline is not in force at the time of the present submission, as it will be implemented by January 1st, 2020. Hence, residue data related to bee and bee products is neither needed nor required.

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of SAP63H. Therefore, other special studies are not needed.

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

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

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

7.3.8.1 Input values for the consumer risk assessment

For the consumer risk assessment, the EFSA version 3 of the PRIMo model has been used (EFSA, 2018). Input values used in the consumer risk assessment are included in table 7.3-11.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Mesosulfuron-methyl				
Wheat Triticale Spelt	0.01	STMR Regulation (EU) No 289/2014	-	-
Rye	0.01	STMR Regulation (EU) No 289/2014	-	-
Rest of products of plant and animal origin	EU MRL	Regulation (EU) No 289/2014	-	-

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.
Summary of the results are included in table 7.3-12.

Table 7.3-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.2% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Assessment not required.

IESTI (% ARfD) according to EFSA PRIMo*	Assessment not required.
NTMDI (% ADI) **	Assessment not required.
NEDI (% ADI)**	Assessment not required.
NESTI (% ARfD) **	Assessment not required.

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

The proposed uses of mesosulfuron-methyl in the formulation SAP63H do not represent unacceptable chronic risks for the consumer.

7.4 Mefenpyr-diethyl

According with the European information available, mefenpyr-diethyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009.
Although in agreement with the Reg. 1107/2009 the safener should be evaluated, in the Regulation, it is stated "*In addition to active substance, plant protection products may contain safeners or synergists for which similar rules should be provided. The technical rules necessary for the evaluation of such substances should be established. Substances currently on the market should only be evaluated after those rules have been established.*"
In addition, Article 26 is referred to safeners and synergists already on the market, and states: "*By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include the establishment of data requirements, including measures to minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.*"
This means that at this date, when evaluating a dossier which includes a safener, Member States should apply national rules. Being a zonal dossier, and knowing that the rules should be established soon, no particular evaluation of Mefenpyr-diethyl is made in this dossier. Nevertheless, we highlight that since Mefenpyr-diethyl is already included on the formulated product, its plant residue impacts are already accounted for in the studies.

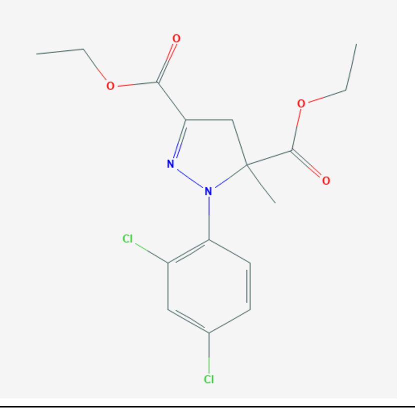
Notifiers are aware that a national MRL is established for mefenpyr in France (Journal Officiel de la République Française » (JORF), 8th May 2008[2]). However, there are several products authorized in France that contain this safener and that are out of data protection rights. Products ATLANTIS WG and ENJEU are examples of this. Dose rates of mefenpyr authorized in these products are the same as the critical one proposed for SAP63H (45 g/ha). For the rest of countries to which this application is intended, technical rules necessary for the evaluation of safeners are not established yet. Hence, data for the mefenpyr-diethyl evaluation is not required according to the current legal framework of these countries.

Despite the aforementioned reasonings, new studies are submitted by the applicant as additional data for the evaluation of this dossier. Eight harvest trials have been carried out in order to determine the magnitude of mefenpyr-diethyl and its metabolites (AE F113225 and AE F094270) in wheat (grain and straw). Furthermore, a study to evaluate the stability of mefenpyr-diethyl and its metabolites under freezing storage conditions is being carried out at the moment of this submission. Magnitude results are exposed in sections below.

General data on mefenpyr-diethyl are summarized in the table below (last updated 2019/09/30)

[2] Arrêté du 6 mai 2008 modifiant l'arrêté du 10 février 1989 relatif aux teneurs maximales en résidus de pesticides admissibles sur et dans les céréales destinées à la consommation humaine.

Table 7.4-1: General information on mefenpyr-diethyl

Active substance (ISO Common Name)	Mefenpyr-diethyl
IUPAC	diethyl 1-(2,4-dichlorophenyl)-5-methyl-4H-pyrazole-3,5-dicarboxylate
Chemical structure	
Molecular formula	$C_{16}H_{18}Cl_2N_2O_4$
Molar mass	373.2 g/mol
Chemical group	Unclassified
Mode of action (if available)	Enhances the metabolism of mesosulfuron-methyl and iodosulfuron-methyl.
Systemic	Not required.
Company (ies)	Not required.
Rapporteur Member State (RMS)	Not required.
Approval status	Not required.
Restriction	Herbicide safener with no herbicidal activity.
Review Report	Not required.
Current MRL regulation	MRLs established at national level in France.
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Not required.
EFSA Journal : Conclusion on the peer review	Not required.
EFSA Journal: conclusion on article 12	Not required.
Current MRL applications on intended uses	Not required.

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

Even though no studies assessing mefenpyr-diethyl and its metabolites are required, one new stability study has been submitted by the applicant in the framework of this application as additional data. Results are summarized in the Table below. The detailed assessment of this study is presented in Appendix 2.

Table 7.4-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
New data			
Plant products			
Wheat grain	High water content	Ongoing study	KCP 7.4.1/01 (Gaffney, V., 2019)
Wheat straw	Unspecific	Ongoing study	KCP 7.4.1/01 (Gaffney, V., 2019)

Conclusion on stability of residues during storage

One study to evaluate the stability of mefenpyr-diethyl and its metabolites (AE F113225 and AE F094270) in wheat is ongoing. Freezing storage conditions are equal or below to -18 ºC. The stability is expected to be demonstrated for a period of 100 days (3.3 months). This study is intended to support the data obtained from the additional harvest trials.

7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

Relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch does contain at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples are handled and stored in parallel. The recoveries in the fortified samples are within acceptable ranges, the stability of the sample extracts is considered as sufficiently proven.

Conclusion on stability of residues in sample extracts

No additional data required.

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

Unprotected data available. No new data is required or submitted in the framework of this application.

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Unprotected data available. No new data is required or submitted in the framework of this application.

7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

No residues above the LOQ have been found in the parts of the crops intended for processing. Since residues do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

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

Table 7.4-3: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered*	Barley
Rotational crops covered*	Spinach, radish, carrot, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Unprotected data available. No new data is required or submitted in the framework of this application.
Processed commodities	Not required.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not required.
Plant residue definition for monitoring*	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.
Plant residue definition for risk assessment*	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.
Conversion factor from enforcement to RA	Not required.

* There are several products authorized in France that contain this safener and that are out of data protection rights. See ATLANTIS WG and ENJEU.

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

Unprotected data available. No new data is required or submitted in the framework of this application.

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

Table 7.4-4: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered*	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	-
	-
Animal residue definition for monitoring	-
Animal residue definition for risk assessment*	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.
Conversion factor	Not required.
Metabolism in rat and ruminant similar	-

Fat soluble residue	-

* There are several products authorized in France that contain this safener and that are out of data protection rights. See ATLANTIS WG and ENJEU.

7.4.3 Magnitude of residues in plants (KCA 6.3)

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

Even though no studies assessing mefenpyr-diethyl and its metabolites are required, one study investigating the magnitude of residue has been submitted by the applicant in the framework of this application as additional data. This study is summarized in the Table below. The detailed assessment of this study is presented in Appendix 2.

In each trial one plot was treated once at BBCH 32 with SAP63H at the application rate of 0.5 kg/ha (3 g iodosulfuron-methyl-sodium/ha, 15 g mesosulfuron-methyl/ha and 45 g mefenpyr-diethyl/ha). One plot remained untreated. These application parameters are equal to the most critical GAP proposed. The wetting agent HAG 530 01 S was applied in tank mix at a dose rate of 200 ml/ha. In all trials (4 in Northern Europe, and 4 in Southern Europe) samples of grain and straw were taken at maturity of the crop (BBCH 89).

Table 7.4-5: Summary of EU reported and new data supporting the intended uses of SAP63H 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 FR-MRL[3] (mg/kg) *	MRL compliance*
Wheat grain	New trials	N-EU	Trials GAP: 1x45g/ha, BBCH 29-32, PHI 64-82 4x <0.050	N/A				
	New trials	S-EU	Trials GAP: 1x45g/ha, BBCH 29-32, PHI 62-88 4x <0.050					
	Overall supporting data for cGAP**	EU	8x <0.050	<0.050*	<0.050*	<0.050*	<0.050*	Yes
Wheat straw	New trials	N-EU	Trials GAP: 1x45g/ha, BBCH 29-32, PHI 64-82 3x <0.10; 0.10	N/A				
	New trials	S-EU	Trials GAP: 1x45g/ha, BBCH 29-32, PHI 62-88 4x <0.10					
	Overall supporting data for cGAP**	EU	7x <0.10; 0.10	0.10	0.10	N/A		

* Not applicable at EU level: Mefenpyr-diethyl is a safener, not a PPP. The MRL depicted is the current value at national level for France.
** Residue data from both NEU and SEU have been pooled together since, according to Mann-Whitney U test, both populations can be considered as similar.
*** Results are expressed as mefenpyr-diethyl (sum of mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl).

[3] Arrêté du 6 mai 2008 modifiant l'arrêté du 10 février 1989 relatif aux teneurs maximales en résidus de pesticides admissibles sur et dans les céréales destinées à la consommation humaine.

7.4.3.2 Conclusion on the magnitude of residues in plants

Mefenpyr-diethyl is categorized as a safener. According to the European information available, mefenpyr-diethyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009. Similarly, there are no MRLs set for the enforcement of mefenpyr-diethyl since PPP regulations such as Reg. (EC) Nº 396/2005 do not apply to this substance.

According to the EU guideline 7525/VI/95 rev. 10.3, extrapolation from any one of the following barley / oats / rye / triticale / wheats to the remaining four crops is possible as long as the last application is done before consumable parts of the crops have started to form (BBCH 51). Considering the intended uses (until BBCH 29) the extrapolation is possible.

Taking this into account, residue levels above the LOQ are not expected in cereal grains as demonstrated by the new trials submitted. For cereal straw, a result above the LOQ of <0.10 mg/kg was found. However, and as previously stated, these data can only be considered as confirmatory since no EU-MRLs are set for the enforcement of straw commodities since, according with Regulation (EU) No 396/2005, no MRLs are stablished for feeding commodities. Furthermore, unprotected data is available and can be used to support the intended cGAP, as there are several products authorized in France that contain this safener and are out of data protection rights (for instance ATLANTIS WG and ENJEU).

Finally, as already stated in Section 7.1.2.4, the available residue package of SAP63H is sufficient to recommend the use of a non-ionic surfactant and/or Esterified rapeseed oil to improve the efficacy of SAP63H. No residues are expected according the proposed uses, the degradation in plant of both active substances is very fast and Pottok (non-ionic surfactant)/Actirob B (Esterified rapeseed oil) do not increase the residue level after application of SAP63H.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

Unprotected data available. No new data is required or submitted in the framework of this application.

7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Unprotected data available. No new data is required or submitted in the framework of this application.

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

Available data for all crops under consideration

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

Conclusion on processing studies

No residues above the LOQ have been found in the parts of the crops intended for processing. Since residues do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

7.4.6 Magnitude of residues in representative succeeding crops

Unprotected data available. No new data is required or submitted in the framework of this application.

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

Unprotected data available. No new data is required or submitted in the framework of this application.

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

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

According with the European information available, mefenpyr-diethyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009.

Furthermore, there is no data available for the applicant indicating in which crops mefenpyr is authorised. Hence, a risk assessment cannot be properly carried out.

However, no values above the LOQ have been found in any of the trials performed in grain. Taking this into account, it can be considered that the proposed uses of mefenpyr-diethyl in the formulation SAP63H do not represent unacceptable chronic and acute risks for the consumer.

7.5 Combined exposure and risk assessment

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

7.5.1 Acute consumer risk assessment from combined exposure

Not required.

7.5.2 Chronic consumer risk assessment from combined exposure

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

7.6 References

Iodosulfuron:

European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for iodosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(11):2974. [28 pp.]

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance iodosulfuron-methyl-sodium approved as iodosulfuron). EFSA Journal 2016;14(4):4453, 111 pp.

Germany, 2000. Draft assessment report on the active substance iodosulfuron-methyl-sodium prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, May 2000.

Sweden 2016. Revised renewal assessment report (RAR) on iodosulfuron-methyl-sodium, February 2016.

Mesosulfuron-methyl:

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mesosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(11):2976, 27 pp. doi:10.2903/j.efsa.2012.2976

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance mesosulfuron (variant evaluated mesosulfuron-methyl). EFSA Journal 2016;14(10):4584, 26 pp. doi:10.2903/j.efsa.2016.4584

France, 2001. Draft assessment report on the active substance mesosulfuron prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, December 2001.

France, 2015. Renewal assessment report (RAR) on the active substance mesosulfuron-methyl prepared by the rapporteur Member State France, in the framework of Commission Implementing Regulation (EU) No 844/2012, October 2015. Available online: www.efsa.europa.eu

General documents:

EC (European Comission), 2017. Guidance document. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95 rev.10.3.

EFSA (European Food Safety Authority), 2017. Animal Model 2017. Available at:
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_animal_model_2017.xls
(consulted: 08/08/2018)

EFSA (European Food Safety Authority), 2018. EFSA calculation model Pesticide Residue Intake Model "PRIMo" revision 3. Available at:
https://www.efsa.europa.eu/sites/default/files/applications/EFSA_PRIMo_rev3.xlsm
(consulted: 08/08/2018)

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.3/01a	Perny, A.	2019	Generation of samples for the determination of Iodosulfuron-methyl-sodium, Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) residues in wheat following foliar application with SAP63H under field conditions in Northern and Southern Europe in 2018. Perny, A., 2019. Report nº R B8019. GLP, unpublished	N	ASCENZA / GLOBACHEM
KCP 7.2.3/01b	Arias, A.	2019	Determination of residues of Iodosulfuron-methyl (and its meatabolite Triazine Amine), Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in wheat after one foliar application of SAP63H in Northern and Southern Europe. Report nº QUT20/18 GLP, unpublished	N	ASCENZA / GLOBACHEM
KCP 7.2.1/01 (KCA 6.1)	Gordo, J.	2019	Stability Study of Iodosulfuron-methyl Residues in Wheat Stored Under Deep Freezing Conditions. Report nº EST51/18 GLP, unpublished	N	ASCENZA
KCP 7.2.1/02 (KCA 6.1)	Gordo, J.	2019	Stability Study of Triazine amine (AE F059411) Residues in Wheat, Lettuce and Radish Stored Under Deep Freezing Conditions. Report nº EST50/18 GLP, unpublished	N	ASCENZA
KCP 7.4.1/01 (KCA 6.1)	Gaffney, V.	Ongoing	Stability study of Mefenpyr-diethyl and its Metabolites AE F113225 and AE F094270 Residues in Wheat (Grain and Straw) Stored Under Deep Freezing Conditions. Study Plan Report nº EST16/19 GLP, unpublished	N	ASCENZA

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1 /01	Wrede, A.	1998a	Stability of AE F115008 in wheat grain during deep freeze storage of 24 months Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C001041, Edition Number: M-181689-01-1 EPA MRID No.: 45108918 Date: 1998-10-05 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.1 /02	Wrede, A.	1998b	Stability of AE F115008 in wheat straw during deep freeze storage of 24 months (interim report) Code: AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C000983, Report includes Trial Nos.: CR96/018 Edition Number: M-181582-01-1 Date: 1998-09-30 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.1 /03	Wrede, A.	1998c	Stability of AE F115008 in wheat shoot during deep freeze storage of 24 months (interim report) Code: AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C000985, Report includes Trial Nos.: CR96/017 Edition Number: M-181587-01-1 Date: 1998-09-30 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.2.1 /01	Braun, P. J.; Brueckner, H.; Voelkl, S.	1998	Metabolism in wheat (Triticum aestivum) after treatment at a nominal rate of 1 x 20 g a.s./ha 2-triazinyl-14C-AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C001497,	N	Bayer Crop-Science

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
			Edition Number: M-182772-01-1 EPA MRID No.: 45108921 Date: 1998-11-16 GLP/GEP: yes, unpublished		
KCA 6.2.1 /02	Tarara, G.; Brueckner, H.	1998	Metabolism in wheat (Triticum aestivum) after single treatment at a nominal rate of 20 g a.s./ha U-phenyl-14C-AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A67671, Edition Number: M-148037-01-1 EPA MRID No.: 45108922 Date: 1998-11-04 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.2.2 /01	-	1999	Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues Code: (14C)-AE F115008 Bayer CropScience, Report No.: C005548, Report includes Trial Nos.: TOX95291 Edition Number: M-192269-01-1 EPA MRID No.: 45108923 Date: 1999-10-11 GLP/GEP: yes, unpublished	Y	Bayer Crop-Science
KCA 6.2.3 /01	-	1999	Ruminant - Metabolism, distribution and nature of residues in milk and edible tissues (14C) AE F115008 Code: AE F115008 Bayer CropScience, Report No.: C005678, Report includes Trial Nos.: TOX95290 Edition Number: M-192483-01-1 EPA MRID No.: 45108924 Date: 1999-12-15 GLP/GEP: yes, unpublished	Y	Bayer Crop-Science
KCA 6.3.1 /01	Helgers, A.	1998a	AE F115008 00 WG20 A103 WG (wettable granule) 200 g/kg in tank mix with two different formulations of the safener AE F107892 (AE F107892 00 WG15 A101 and AE F107892 00 EC10 A102) Residue trials on wheat to determine residue decline of AE F115008 and AE F107892 following 1 application; European Union (northern zone)	N	Bayer Crop-Science

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
			1995 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A56709, Edition Number: M-140498-01-1 Date: 1998-05-18 GLP/GEP: yes, unpublished		
KCA 6.3.1 /02	Helgers, A.	1998b	AE F115008 00 WG20 A103 WG (wettable granule) 200 g/kg in tank mix with two different formulations of the safener AE F107892 (AE F107892 00 WG15 A101 and AE F107892 00 EC10 A102) Residue trials on wheat to determine residue decline of AE F115008 and AE F107892 following 1 application; European Union (southern zone), 1995 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A56708, Edition Number: M-140497-01-1 Date: 1998-05-18 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.3.1 /03	Helgers, A.	1998c	AE F115008 and AE F107892 EG (emulsifiable granule) and WG (water dispersible granule) 50 and 150 g/kg Code: AE F115008 02 EG20 A401 and Code: AE F115008 02 WG20 A903 Residue trials on cereals with two different coformulations to determine a residue decline of AE F115008 and AE F109872 following 1 application; European Union (southern zone) 1996 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A59542, Edition Number: M-143213-02-1 Date: 1998-03-27 ...Amended: 1999-06-11 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.3.1 /04	Helgers, A.	1998d	AE F115008 and AE F107892 EG (emulsifiable granule) and WG (water dispersible granule) 50 and 150 g/kg Code: AE F115008 02 EG20 A401 and Code: AE F115008 02 WG20 A903 Residue trials on cereals with two different coformulations to determine a residue decline of AE F115008 and AE F107892 following 1 application; European Union (Northern zone), 1996 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience,	N	Bayer Crop-Science

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
			Report No.: A59541, Edition Number: M-143212-01-1 Date: 1998-05-18 GLP/GEP: yes, unpublished		
KCA 6.6.2 /01	Buerkle, L. W.	1998	Residues in rotated crops sown 29 days after application to bare soil at a rate of 20 g a.s./ha AE F115008-triazinyl 2-14C Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C000833, Edition Number: M-181318-01-1 EPA MRID No.: 45108927 Date: 1998-08-25 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.6.2 /02	Buerkle, L. W.; Kellner, G.; Voelkl, S.	1998a	Residues in rotated crops sown 120 days after application to bare soil at a rate of 20 g a.s./ha AE F115008-triazinyl 2-14C Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C001454, Edition Number: M-182667-01-1 EPA MRID No.: 45108928 Date: 1998-10-06 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.6.2 /03	Buerkle, L. W.; Kellner, G.; Voelkl, S.	1998b	Residues in rotated crops sown 1 year after application to bare soil at a rate of 20 g a.s./ha AE F115008-triazinyl 2-14C Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C001331, Edition Number: M-182374-01-1 EPA MRID No.: 45108929 Date: 1998-10-06 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCA 6.6.2 /05	Meyer, B. N.; Tull, P. J.	1999	Uptake of [14C]-AE F115008 residues from soil by rotational wheat, soybeans and sugarbeets under confined conditions AgrEvo USA Company, Environmental Chemistry, Pikeville, NC, USA	N	Bayer Crop-Science

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
			Bayer CropScience, Report No.: B002595, Report includes Trial Nos.: 511BY Edition Number: M-238341-01-1 EPA MRID No.: 45108930 Date: 1999-12-09 GLP/GEP: yes, unpublished		
KCA 6.1/01	Wrede, A.	2000	Stability of AE F130060 in wheat grain during deep freeze storage Code: AE F130060 Interim report Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C015808, Edition Number: M-198607-03-1 Date: 2000-08-29 ...Amended: 2001-09-24 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.1 /02	Wrede, A.	2000	Stability of AE F130060 in wheat straw during deep freeze storage Mesosulfuron-methyl Code: AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C028927, Edition Number: M-198612-03-1 EPA MRID No.: 46229003 Date: 2000-08-29 ...Amended: 2003-01-27 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.1 /03	Wrede, A.	2000	Stability of AE F130060 in wheat shoot during deep freeze storage Mesosulfuron-methyl Code: AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C028928, Edition Number: M-198617-03-1 EPA MRID No.: 46229002 Date: 2000-08-29 ...Amended: 2003-01-27 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.1 /05	Wrede, A.	2003	Stability of AE F130060 in wheat grain during deep freeze storage Mesosulfuron-methyl Code: AE F130060	N	Bayer

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
			Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C028926, Edition Number: M-216176-01-1		CropScience
KCA 6.2.1 /01	Braun, P. J.; Koehn, D. M.; Buerkle, L. W.; Buerkle, L.	2000	Metabolism in wheat (Triticum aestivum) following single and double treatment at a nominal application rate of 10 g a.s./ha each Code: (2-14C-pyrimidyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008761, Edition Number: M-197766-02-1 Date: 2000-08-14 ...Amended: 2001-10-26 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.1 /02	Koehn, D. M.; Selzer, J.; Buerkle, L. W.	2000	Metabolism in wheat (Triticum aestivum) following single and double treatment at a nominal application rate of 30 g a.s./ha Each Code: (U-14C-phenyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C009588, Edition Number: M-198861-01-1 Date: 2000-09-12 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.1 /03	Gildemeister, H.	2003	Comparison of the two wheat metabolism studies with 14C-AE F130060 Bayer CropScience Deutschland GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: M-260002-01-1, Edition Number: M-260002-01-1 Date: 2003-02-11 GLP/GEP: n.a., unpublished	N	Bayer CropScience
6.2.2 /01	-	1999	Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues Code: AE F130060 Bayer CropScience, Report No.: C005417, Edition Number: M-192019-01-1 Date: 1999-09-16 GLP/GEP: yes, unpublished	Y	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.3 /01	-	1999	Ruminant - Metabolism, distribution and nature of the residues in milk and edible tissues Code: AE F130060 Bayer CropScience, Report No.: C005418, Edition Number: M-192023-01-1 Date: 1999-09-16 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCA 6.3.1 /01	Helgers, A.; Wrede, A.; Neuss, B.	2000	Decline of residues in cereals European Union (northern zone) 1997 AE F130060 and AE F107892 (mefenpyr-diethyl) oil flowable 30 and 90 g/L Code: AE F130060 01 1K12 A201 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C006208, Edition Number: M-193491-01-1 Date: 2000-01-24 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.1 /02	Davies, P.	2000	Residues at harvest in wheat European Union (northern zone) 1998 AE F130060 and mefenpyr-diethyl oil flowable 30 + 90 g/L Code: AE F130060 01 1K12 A701 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C007152, Edition Number: M-195315-01-1 Date: 2000-08-18 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.1 /03	Helgers,	200	Decline of residues in cereals European Union (southern zone) 1997 AE F130060 and AE F107892 (mefenpyr-diethyl) oil flowable 30 and 90 g/L Code: AE F130060 01 1K12 A201 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C006209, Edition Number: M-193494-01-1 Date: 2000-01-27 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.1 /04	Davies, P.; Wrede, A.	2000	Residues at harvest in cereals European Union (southern zone) 1998 AE F130060 + mefenpyr-diethyl oil flowable 30 + 90 g/L Code: AE F130060 01 1K12 A701 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience,	N	Bayer CropScience

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
			Report No.: C008074, Edition Number: M-197167-01-1 Date: 2000-08-18 GLP/GEP: yes, unpublished		
KCA 6.6.2 /01	Frey, J. A.; Harri-son, C. L.; Buerkle, L. W.	2000	Residues in rotated crops sown 31 days after application to bare soil at a rate of 15 g a.s./ha (2-14C-pyrimidyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008238, Edition Number: M-197310-01-1 Date: 2000-08-09 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.6.2 /02	Frey, J. A.; Harri-son, C. L.; Buerkle, L. W.	2000	Residues in rotated crops sown 32 days after application to bare soil at a rate of 15 g a.s./ha (U-14C-phenyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008240, Edition Number: M-197312-01-1 Date: 2000-08-09 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.6.2 /03	Frey, J. A.; Harri-son, C. L.	2000	Residues in rotated crops sown 4 months after application to bare soil at a rate of 15 g a.s./ha Code: (2-14C-pyrimidyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008242, Edition Number: M-197314-01-1 EPA MRID No.: 45386506 Date: 2000-09-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.6.2 /04	Frey, J. A.; Harri-son, C. L.	2000	Residues in rotated crops sown 4 months after application to bare soil at a rate of 15 g a.s./ha Code: (U-14C-phenyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008243,	N	Bayer CropScience

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
			Edition Number: M-197315-01-1 Date: 2000-09-13 GLP/GEP: yes, unpublished		
KCA 6.6.2 /05	Frey, J. A.; Harri-son, C. L.	2000	Residues in rotated crops sown 1 year after application to bare soil at a rate of 15 g a.s./ha Code: (2-14C-pyrimidyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008239, Edition Number: M-197311-01-1 Date: 2000-09-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.6.2 /06	Frey, J. A.; Harri-son, C. L.	2000	Residues in rotated crops sown 1 year after application to bare soil at a rate of 15 g a.s./ha Code: (u-14C-phenyl)-AE F130060 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C008241, Edition Number: M-197313-01-1 Date: 2000-09-13 GLP/GEP: yes, unpublished	N	Bayer CropScience

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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
			Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished		

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Iodosulfuron-methyl-sodium

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	KCP 7.2.1/01
Report	Stability Study of Iodosulfuron-methyl Residues in Wheat Stored Under Deep Freezing Conditions. Gordo, J., 2018. Report nº EST51/18
Guideline(s):	Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). Directive 2004/10/EC (codified version) of European Parliament and Council of 11 February 2004. Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Samples preparation was done previously to this study. The homogeneous matrices were kept frozen at or below -20 ºC. The amount required by the analytical method, 5 g, was weighed from the homogeneous matrix into 50 mL falcon tubes.

Three replicates per target day and matrix were supplemented by adding an aliquot of iodosulfuron-methyl solution in acetonitrile, in order to fortify at 0.10 mg/kg. After that the analytical portions were shaken in order to homogenize.
Some extra portions were weighed and kept frozen without supplementation to be analysed as control samples and spiked for procedural recovery tests in each extraction day.
Other extra analytical portions were weighed and spiked to repeat if needed.

The methods used to determine the magnitude of iodosulfuron-methyl residues in wheat, were the validated in GLP Study VAL19/17 and VAL04/18 for grain and straw respectively.

Residues of iodosulfuron-methyl were extracted from the matrices in study with acetonitrile and depending on the matrix to analyse, the analytical portion was weighted, water was added and clean up steps were performed. The analyses were carried out by UPLC-TQ-S-micro. This method is based on Quechers method. The standard solutions were prepared using reference item from Labor Dr. Ehrenstorfer, with internal codes SR297/18.

In order to prepare a stock solution at approximately 1 µg/µL of iodosulfuron-methyl in acetonitrile, a certain quantity of reference item was weighed on a five decimal places balance, after correction for the purity of the reference item.
Spiking solution at 5 ng/µL was prepared by dilution with acetonitrile of the stock solution.

Results and discussions

Blank samples of each matrix used in this study were analysed in order to evaluate the absence of interferences. No residues above the limit of detection were found in the samples selected. The target level chosen for supplementation and procedural recoveries was 0.10 mg/kg.

Table A 1: Summary of concurrent recoveries of iodosulfuron-methyl from wheat grain and straw

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Iodosulfuron-methyl					
Wheat grain	0.10	0	3	88.7	80.2 ± 10.6
				80.1	
				71.7	
		63	3	97.6	97.8 ± 0.39
				98.2	
				97.5	
		119	3	100.1	100.5 ± 0.60
				100.2	
				101.2	
		187	3	97.2	95.9 ± 1.2
				95.5	
				95.0	
Wheat straw	0.10	0	3	82.3	83.0 ± 0.72
				83.2	
				83.5	
		70	3	82.5	83.5 ± 1.4
				83.2	
				84.8	
		126	3	112.0	107.5 ± 5.5
				100.8	
				109.6	

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
		193	3	112.5	109.5 ± 2.4
				107.5	
				108.7	

Table A 2: **Stability of iodosulfuron-methyl residues in wheat grain and straw following storage at ≤ -20 °C, corrected for recovery.**

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
Iodosulfuron-methyl				
Wheat grain	0.10	0	0.12	122.0
			0.11	110.2
			0.099	98.6
	0.10	63	0.086	86.5
			0.087	87.1
			0.086	86.5
	0.10	119	0.099	99.3
			0.099	99.4
			0.10	100.4
	0.10	187	0.099	99.3
			0.098	97.6
			0.097	97.1
Wheat straw	0.10	0	0.099	99.5
			0.10	100.6
			0.10	100.8
	0.10	70	0.088	88.5
			0.089	89.2
			0.091	90.9
	0.10	126	0.11	111.0
			0.10	99.9
			0.11	108.6
	0.10	193	0.11	107.5
			0.10	102.8
			0.10	103.9

Conclusion

The magnitude of iodosulfuron-methyl residues in supplemented samples was determined in order to evaluate the stability of iodosulfuron-methyl residues in wheat (grain and straw) stored at or below -20 ºC. Based on the results obtained, it can be concluded that the residues for iodosulfuron-methyl in wheat (grain and straw), are stable for 190 days when stored in a freezer at or below -20 ºC.

A 2.1.1.1.1.2 Study 2

Comments of zRMS:	Study is accepted

Reference:	KCP 7.2.1/02
Report	Stability Study of Triazine amine (AE F059411) Residues in Wheat, Lettuce and Radish Stored Under Deep Freezing Conditions, Gordo, J., 2018. Report nº EST50/18
Guideline(s):	Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). Directive 2004/10/EC (codified version) of European Parliament and Council of 11 February 2004. Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Samples preparation was done previously to this study. The homogeneous matrices were kept frozen at or below -20 ºC. The amount required by the analytical method (5 g or 10 g, described in point 5.8) was weighed from the homogeneous matrix into 50 mL falcon tubes.

Three replicates per target day and matrix were supplemented by adding an aliquot of triazine amine solution in acetonitrile, in order to fortify at 0.10 mg/kg. After that the analytical portions were shaken in order to homogenize. Some extra portions were weighed and kept frozen without supplementation to be analysed as control samples and spiked for procedural recovery tests in each extraction day. Other extra analytical portions were weighed and spiked to repeat if needed.

The methods used to determine the magnitude of triazine amine residues in wheat (grain and straw), lettuce and radish (leaves with tops and roots) were the validated in GLP Study VAL02/18.

Residues of triazine amine were extracted from the matrices in study with acidified acetonitrile and depending on the matrix to analyse, the analytical portion was weighted, water was added and clean up steps were performed. The analyses were carried out by UPLC-TQ-S-micro. This method is based on acidified Quechers method. The standard solutions were prepared using reference item from Labor Dr. Ehrenstorfer, with internal codes SR321/18.

In order to prepare a stock solution at approximately 1 µg/µL in H2O / 0.1 M hydrochloric acid, a certain quantity of triazine amine was weighed on a five decimal places balance, after correction for the purity of reference item.

Spiking solution at 5 ng/µL was prepared by dilution with acetonitrile of the stock solution.

Results and discussions

Blank samples of each matrix used in this study were analysed in order to evaluate the absence of interferences. No residues above the limit of detection were found in the samples selected. The target level chosen for supplementation and procedural recoveries was 0.10 mg/kg.

The analytical results obtained from supplemented and procedural samples are in the following table:

Table A 3: Summary of concurrent recoveries of triazine amine from wheat grain, straw, lettuce, radish (leaves with tops) and radish (roots).

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Triazine amine					
Wheat grain	0.10	0	3	78.7	74.6 ± 4.8
				71.8	
				73.4	
	0.10	91	3	102.1	102.6 ± 2.2
				105.1	
				100.8	
	0.10	221	3	102.0	101.0 ± 2.8
				103.3	
				97.8	
Wheat straw	0.10	0	3	91.5	84.5 ± 7.3
				80.1	
				81.8	
	0.10	92	3	96.6	95.4 ± 1.8
				93.4	
				96.1	
	0.10	222	3	101.8	102.1 ± 0.33
				102.1	
				102.4	
Lettuce	0.10	0	3	90.4	90.6 ± 0.49
				91.0	
				90.2	
	0.10	91	3	89.9	83.2 ± 7.0
				79.2	
				80.6	
	0.10	221	3	101.4	99.0 ± 2.1
				98.2	
				97.5	

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Radish (leaves with tops)	0.10	0	3	81.5	83.8 ± 2.6
				85.8	
				84.1	
	0.10	92	3	89.8	89.2 ± 1.1
				88.0	
				89.8	
	0.10	222	3	90.5	90.8 ± 0.44
				91.2	
				90.6	
Radish (roots)	0.10	0	3	93.0	94.2 ± 1.3
				94.0	
				95.4	
	0.10	92	3	81.0	81.8 ± 2.6
				80.2	
				84.2	
	0.10	221	3	99.1	101.5 ± 3.0
				104.9	
				100.5	

Table A 4: Stability of triazine amine residues in wheat grain, straw, lettuce, radish (leaves with tops) and radish (roots) following storage at ≤ -20 °C, corrected for recovery.

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
Triazine amine				
Wheat grain	0.10	0	0.098	97.7
			0.089	89.1
			0.091	91.1
	0.10	91	0.10	99.5
			0.10	102.5
			0.098	98.2
	0.10	221	0.10	100.4
			0.10	101.6
			0.096	96.3
Wheat straw	0.10	0	0.11	110.9
			0.097	97.1

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
			0.099	99.2
	0.10	92	0.10	100.0
			0.097	96.7
			0.099	99.4
	0.10	222	0.097	97.1
			0.097	97.5
			0.098	97.8
Lettuce	0.10	0	0.10	102.7
			0.10	103.4
			0.10	102.5
	0.10	91	0.095	95.4
			0.084	84.0
			0.085	85.4
	0.10	221	0.10	104.0
			0.10	100.7
			0.10	100.0
Radish (leaves with tops)	0.10	0	0.093	92.8
			0.098	97.7
			0.096	95.8
	0.10	92	0.10	101.6
			0.10	99.6
			0.10	101.5
	0.10	222	0.10	102.1
			0.10	103.0
			0.10	102.2
Radish (roots)	0.10	0	0.092	91.9
			0.093	92.8
			0.094	94.2
	0.10	92	0.099	99.4
			0.098	98.4
			0.10	103.4
	0.10	221	0.099	98.8
			0.10	104.6
			0.10	100.2

Conclusion

The magnitude of triazine amine residues in supplemented samples was determined in order to evaluate the stability of triazine amine residues in wheat (grain and straw), lettuce and radish (leaves with tops and roots) stored at or below -20 ºC.
Based on the results obtained, it can be concluded that the residues for triazine amine in wheat (grain and straw), lettuce and radish (leaves with tops and roots), are stable for 220 days when stored in a freezer at or below -20 ºC.

A 2.1.1.1.2 Storage stability of residues in animal products

New data has not been provided.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

New data has not been provided.

A 2.1.2.1.2 Nature of residue in rotational crops

New data has not been provided.

A 2.1.2.1.3 Nature of residues in processed commodities

New data has not been provided.

A 2.1.2.2 Nature of residues in livestock

New data has not been provided.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Cereals

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g/ha)	Interval between application	Growth stage at last application	PHI (days)
EFSA, 2012 NEU	1	10	-	BBCH 13-37	-
EFSA, 2012 SEU	1	10	-	BBCH 13-37	-
EU (DAR)- EU N and S	1	7.5-10	-	BBCH 13-32	-
Intended cGAP (1)	1	3	-	BBCH 21-32	-

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference: KCP 7.2.3/01a

Report: Generation of samples for the determination of Iodosulfuron-methyl-sodium, Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) residues in wheat following foliar application with SAP63H under field conditions in Northern and Southern Europe in 2018. Perny, A., 2019, report nº R B8019.

Guideline(s): Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17)
Number 6, The Application of the GLP Principles to Field Studies (ENV/JM/MONO(99)22)
Number 13, The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies (ENV/JM/MONO(2002)9)

Deviations: No impact deviations

GLP: Yes

Acceptability: Yes

The objective of the study was to generate samples for the determination of the residue levels of iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in wheat raw agricultural commodity (RAC) after one foliar application of the formulated product SAP63H (iodosulfuron-methyl-sodium 6 g/kg, mesosulfuron-methyl 30 g/kg, and mefenpyr-diethyl 90 g/kg WG) at the rate of 0.5 kg/ha. The wetting agent HAG 530 01 S was applied in tank mix at a dose rate of 200 ml/ha.

The study consisted of the field phase and the sample preparation phase. The study was conducted under field conditions at 4 sites in Northern Europe and 4 sites in Southern Europe.

In each trial one plot was treated once at BBCH 32 with SAP63H at the application rate of 0.5 kg/ha (3 g iodosulfuron-methyl-sodium/ha, 15 g mesosulfuron-methyl/ha and 45 g mefenpyr-diethyl/ha). One plot remained untreated.

In seven trials (4 in Northern Europe, and 3 in Southern Europe) samples of grain and straw were taken at maturity of the crop (BBCH 89). In one trial in Southern Europe, a sampling of whole plant was done 7 days after the application. Samples of grain and straw were taken at maturity of the crop (BBCH 89).

After blending and homogenisation, all blended samples were sent to the ASCENZA AGRO laboratory.

Comments of zRMS:	Study is accepted

Reference:	KCP 7.2.3/01b
Report	Analytical phase: Determination of residues of Iodosulfuron-methyl (and its meatabolite Triazine Amine), Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in Wheat after one foliar application of SAP63H in Northern and Southern Europe. Arias, A., 2019. Report nº QUT20/18
Guideline(s):	Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). Directive 2004/10/EC (codified version) from European Parliament and Council of 11 February 2004. Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP).
Deviations:	No impact deviations
GLP:	Yes
Acceptability:	Yes

The objective of the current study was to determine the magnitude of iodosulfuron-methyl (sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl), 2-Amino-4-methoxy-6-methyl-1,3,5-triazine (hereinafter referred as triazine amine), mesosulfuron-methyl and mefenpyr-diethyl (sum of mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl), residues in wheat (grain and straw) after one foliar application of the formulated product SAP63H in eight harvest trials, with two modalities each, untreated and treated.

The analytical work was performed at LabResíduos under GLP study nº QUT20/18. The extraction procedure for the determination of iodosulfuron-methyl, triazine amine, mesosulfuron-methyl, mefenpyr-diethyl and its metabolites residues was based on QuEChERS method that was validated at LabResíduos under GLP studies VAL19/17, VAL02/18 and VAL25/18.
The concentration of all analytes in samples of grain and straw was measured in linear analytical calibration with matrix matched standards in the respective extracts. Recovery tests were extracted concurrently with the incurred samples, covering several concentration levels, depending on the matrix. The results obtained were in accordance with the requirements set on SANCO/825/00 and SANCO/3029/99.

Whole plant samples were used for a cross validation study directed by Mr. Alejandro Arias (ASCENZA AGRO S.A.) referenced VAL19/18 entitled: “Cross Validation of an Extraction Method based on Quechers Method vs. an Extraction Method Applied in ^{14}C-metabolism Studies for the determination of Mesosulfuron-methyl in Wheat (green material)”. However, the results of the VAL19/18 will not be discussed here. Grain and straw samples were analysed for determination of residues of iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270).

Final results are compiled in the table below.

Table A 6: Summary of the study 1 trials

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 (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Iodo	TA		
B8019 TL1 / Castelnau-d'Estrétefonds, Occitanie, France / S-EU / 2018	Winter wheat	1. 23/10/2017 2. N/A 3.	3.1	313	0.99	29/03/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	90 90	LOQiodo = 0.010 mg/kg LOQ_{TA} = 0.010 mg/kg Storage: Iodo (grain): 36 days Iodo (straw): 92 days TA (grain): 15 days TA (straw): 44 days QuEChERS method that was validated under GLP studies VAL19/17, VAL02/18 and VAL25/18
B8019 ND1 / Steenbecque, Hauts-de-France, France / N-EU / 2018	Winter wheat	1. 03/11/2017 2. N/A 3.	3.3	273	1.21	27/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	83 83	
B8019 CZ1 / Záměl, Hradec Králové, Czech Republic / N-EU / 2018	Spring wheat	1. 04/04/2018 2. N/A 3.	3.3	327	1.21	24/05/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	63 63	
B8019 PL1 / Moraków, Łódzkie, Poland / N-EU / 2018	Spring wheat	1. 11/04/2018 2. N/A 3.	3.3	435	0.76	22/05/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	66 66	
B8019 HU1 / Komárom, Central Transdanubia, Hungary / N-EU / 2018	Winter wheat	1. 03/11/2017 2. N/A 3.	2.9	293	0.99	24/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	84 84	
B8019 IT1 / Casei Gerola, Lombardia, Italy / S-EU / 2018	Spring wheat	1. 18/02/2017 2. N/A 3.	3.0	300	1.0	27/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	73 73	

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 (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Iodo	TA		
B8019 ES1 / Santa Cecília de Voltregà, Catalonia, Spain / S-EU / 2018	Winter wheat	1. 18/11/2017 2. N/A 3.	3.1	307	1.01	20/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	90 90	
B8019 GR1 / Galani, Western Macedonia, Greece / S-EU / 2018	Spring wheat	1. 31/01/2018 2. N/A 3.	3.0	303	0.99	26/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	<LOQ <LOQ	70 70	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
Iodo: Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (only applicable to cereals).
TA: Triazine amine (IN-A4098).

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

New data has not been provided.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

New data has not been provided.

A 2.1.5.2 Processing studies on a core set of representative processes

New data has not been provided.

A 2.1.6 Magnitude of residues in representative succeeding crops

New data has not been provided.

A 2.1.7 Other/Special Studies

New data has not been provided.

A 2.2 Mesosulfuron-methyl

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

New data has not been provided.

A 2.2.1.1.2 Storage stability of residues in animal products

New data has not been provided.

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

New data has not been provided.

A 2.2.2.1.2 Nature of residue in rotational crops

New data has not been provided.

A 2.2.2.1.3 Nature of residues in processed commodities

New data has not been provided.

A 2.2.2.2 Nature of residues in livestock

New data has not been provided.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Cereals

Table A 7: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
EFSA, 2012 (NEU)	1	0.02 kg a.i./ha	-	BBCH 13-32	90
EFSA, 2012 (SEU)	1	0.02 kg a.i./ha	-	BBCH 13-32	90
France, 2001 (DAR)	1	15 g/ha	-	BBCH 39-47	-
France, 2015 (RAR)	1	15 g/ha	-	BBCH 20-32	-
Intended cGAP (1)	1	3 g/ha	-	BBCH 21-32	-

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

A 2.2.3.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference: KCP 7.2.3/01a

Report: Generation of samples for the determination of Iodosulfuron-methyl-sodium, Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) residues in wheat following foliar application with SAP63H under field conditions in Northern and Southern Europe in 2018. Perny, A., 2019, report nº R B8019.

Guideline(s): Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17)
Number 6, The Application of the GLP Principles to Field Studies (ENV/JM/MONO(99)22)
Number 13, The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies (ENV/JM/MONO(2002)9)

Deviations: No impact deviations

GLP: Yes

Acceptability: Yes

See Section A 2.1.3.1.1 for details.

Comments of zRMS:	Analytical phase is accepted

Reference:	KCP 7.2.3/01b
Report	Analytical phase: Determination of residues of Iodosulfuron-methyl (and its meatabolite Triazine Amine), Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in Wheat after one foliar application of SAP63H in Northern and Southern Europe. Arias, A., 2019. Report nº QUT20/18
Guideline(s):	Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). Directive 2004/10/EC (codified version) from European Parliament and Council of 11 February 2004. Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP).
Deviations:	No impact deviations
GLP:	Yes
Acceptability:	Yes

See Section A 2.1.3.1.1 for details.

Table A 8: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treat-ments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mesosulfuron-methyl		
B8019 TL1 / Castelnau-d'Estrétefonds, Occitanie, France / S-EU / 2018	Winter wheat	1. 23/10/2017 2. N/A 3.	15.7	313	5.02	29/03/2018	BBCH 32	Straw Grain	<LOQ <LOQ	90 90	LOQmeso = 0.010 mg/kg Storage (grain): 36 days Storage (straw): 92 days QuEChERS method that was validated under GLP studies VAL19/17, VAL02/18 and VAL25/18
B8019 ND1 / Steenbecque, Hauts-de-France, France / N-EU / 2018	Winter wheat	1. 03/11/2017 2. N/A 3.	16.4	273	6.0	27/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	83 83 83	
B8019 CZ1 / Záměl, Hradec Králo-vé, Czech Republic / N-EU / 2018	Spring wheat	1. 04/04/2018 2. N/A 3.	16.4	327	5.02	24/05/2018	BBCH 32	Straw Grain	<LOQ <LOQ	63 63	
B8019 PL1 / Moraków, Łódzkie, Poland / N-EU / 2018	Spring wheat	1. 11/04/2018 2. N/A 3.	16.3	435	3.75	22/05/2018	BBCH 32	Straw Grain	<LOQ <LOQ	66 66	
B8019 HU1 / Komárom, Central Transdanubia, Hungary / N-EU / 2018	Winter wheat	1. 03/11/2017 2. N/A 3.	14.7	293	5.02	24/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	84 84	
B8019 IT1 / Casei Gerola, Lombardia, Italy / S-EU / 2018	Spring wheat	1. 18/02/2017 2. N/A 3.	15.0	300	5.0	27/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	73 73	

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 (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mesosulfuron-methyl		
B8019 ES1 / Santa Cecília de Voltregà, Catalonia, Spain / S-EU / 2018	Winter wheat	1. 18/11/2017 2. N/A 3.	15.4	307	5.02	20/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	90 90	
B8019 GR1 / Galani, Western Macedonia, Greece / S-EU / 2018	Spring wheat	1. 31/01/2018 2. N/A 3.	15.2	303	5.02	26/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	70 70	

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

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

New data has not been provided.

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

A 2.2.5.1 Distribution of the residue in peel/pulp

New data has not been provided.

A 2.2.5.2 Processing studies on a core set of representative processes

New data has not been provided.

A 2.2.6 Magnitude of residues in representative succeeding crops

New data has not been provided.

A 2.2.7 Other/Special Studies

New data has not been provided.

A 2.3 Mefenpyr-diethyl

A 2.3.1 Stability of residues

A 2.3.1.1 Stability of residues during storage of samples

A 2.3.1.1.1 Storage stability of residues in plant products

A 2.3.1.1.1.1 Study 1

Comments of zRMS:	Study is ongoing (not considered)

Reference:	KCP 7.4.1/01 (KCA 6.1)
Report	Study plan: Stability Study of Mefenpyr-diethyl and its Metabolites AE F113225 and AE F094270 Residues in Wheat (Grain and Straw) Stored Under Deep Freezing Conditions. Gaffney, V., ongoing. Report nº EST16/19.
Guideline(s):	- OECD Series on Principles of GLP and Compliance Monitoring: Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). - Directive 2004/10/EC (codified version) of European Parliament and Council of 11 February 2004. - Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP).
Deviations:	Study ongoing.
GLP:	Yes
Acceptability:	Study ongoing.

Materials and methods

The objective of the current study is to evaluate the stability of mefenpyr-diethyl and its metabolites AE F113225 and AE F094270 in wheat (grain and straw) under freezing storage conditions (≤ -18 ºC) over a period of 100 days.

This study will be conducted by spiking untreated samples of wheat (grain and straw) at least ten times the limit of quantification of the method.

Internal samples will be available in order to perform the study. The absence of residues of mefenpyr-diethyl and its metabolites AE F113225 and AE F094270 in the samples will be checked prior to the quantification of the spiked samples.

Samples will be extracted following the analytical method validated at Laboratório de Resíduos under GLP Study Nº VAL25/18.

The quantification step will be done by a chromatographic technique coupled to tandem mass spectrometry.

The storage stability of mefenpyr-diethyl and its metabolites AE F113225 and AE F094270 in wheat (grain and straw) will be evaluated over a period of 100 ± 5 days.

Results and discussions

Study ongoing.

Conclusion

Study ongoing.

A 2.3.1.1.2 Storage stability of residues in animal products

New data has not been provided.

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

A 2.3.2.1 Nature of residue in plants

A 2.3.2.1.1 Nature of residue in primary crops

New data has not been provided.

A 2.3.2.1.2 Nature of residue in rotational crops

New data has not been provided.

A 2.3.2.1.3 Nature of residues in processed commodities

New data has not been provided.

A 2.3.2.2 Nature of residues in livestock

New data has not been provided.

A 2.3.3 Magnitude of residues in plants

A 2.3.3.1 Cereals

A 2.3.3.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	KCP 7.2.3/01a
Report	Generation of samples for the determination of Iodosulfuron-methyl-sodium, Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) residues in wheat following foliar application with SAP63H under field conditions in Northern and Southern Europe in 2018. Perny, A., 2019, report nº R B8019.
Guideline(s):	Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17) Number 6, The Application of the GLP Principles to Field Studies (ENV/JM/MONO(99)22) Number 13, The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies (ENV/JM/MONO(2002)9)
Deviations:	No impact deviations
GLP:	Yes
Acceptability:	Yes

See Section A 2.1.3.1.1 for details.

Comments of zRMS:	Study is accepted

Reference:	KCP 7.2.3/01b
Report	Analytical phase: Determination of residues of Iodosulfuron-methyl (and its meatabolite Triazine Amine), Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in Wheat after one foliar application of SAP63H in Northern and Southern Europe. Arias, A., 2019. Report nº QUT20/18
Guideline(s):	Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). Directive 2004/10/EC (codified version) from European Parliament and Council of 11 February 2004. Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP).

Deviations:	No impact deviations
GLP:	Yes
Acceptability:	Yes

See Section A 2.1.3.1.1 for details.

Table A 9: Summary of the study 1 trials

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 (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mefenpyr-diethyl		
B8019 TL1 / Castelnau-d'Estrétefonds, Occitanie, France / S-EU / 2018	Winter wheat	1. 23/10/2017 2. N/A 3.	47.0	313	15.02	29/03/2018	BBCH 32	Straw Grain	<LOQ <LOQ	90 90	LOQstraw = 0.10 mg/kg LOQgrain = 0.050 mg/kg Storage (grain): 36 days Storage (straw): 92 days QuEChERS method that was validated under GLP studies VAL19/17, VAL02/18 and VAL25/18
B8019 ND1 / Steenbecque, Hauts-de-France, France / N-EU / 2018	Winter wheat	1. 03/11/2017 2. N/A 3.	49.1	273	17.99	27/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	83 83	
B8019 CZ1 / Záměl, Hradec Králové, Czech Republic / N-EU / 2018	Spring wheat	1. 04/04/2018 2. N/A 3.	49.1	327	15.02	24/05/2018	BBCH 32	Straw Grain	0.10 <LOQ	63 63	
B8019 PL1 / Moraków, Łódzkie, Poland / N-EU / 2018	Spring wheat	1. 11/04/2018 2. N/A 3.	48.9	435	11.24	22/05/2018	BBCH 32	Straw Grain	<LOQ <LOQ	66 66	
B8019 HU1 / Komárom, Central Transdanubia, Hungary / N-EU / 2018	Winter wheat	1. 03/11/2017 2. N/A 3.	44.0	293	15.02	24/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	84 84	
B8019 IT1 / Casei Gerola, Lombardia, Italy / S-EU / 2018	Spring wheat	1. 18/02/2017 2. N/A 3.	45.0	300	15	27/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	73 73	

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 (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mefenpyr-diethyl		
B8019 ES1 / Santa Cecília de Voltregà, Catalonia, Spain / S-EU / 2018	Winter wheat	1. 18/11/2017 2. N/A 3.	46.1	307	15.02	20/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	90 90	
B8019 GR1 / Galani, Western Macedonia, Greece / S-EU / 2018	Spring wheat	1. 31/01/2018 2. N/A 3.	45.5	303	15.02	26/04/2018	BBCH 32	Straw Grain	<LOQ <LOQ	70 70	

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

A 2.3.4 Magnitude of residues in livestock

A 2.3.4.1 Livestock feeding studies

New data has not been provided.

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

A 2.3.5.1 Distribution of the residue in peel/pulp

New data has not been provided.

A 2.3.5.2 Processing studies on a core set of representative processes

New data has not been provided.

A 2.3.6 Magnitude of residues in representative succeeding crops

New data has not been provided.

A 2.3.7 Other/Special Studies

New data has not been provided.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations (Iodosulfuron-methyl):

efsa
European Food Safety Authority
EFSA PRIMo revision 3.0; 2017/12/11

Iodosulfuron-methyl

LOQs (mg/kg) range from: 0,01 to: 0,05

Toxicological reference values

ADI (mg/kg bw/day): 0,03 | ARfD (mg/kg bw): 3,15

Source of ADI: | Source of ARfD:

Year of evaluation: | Year of evaluation:

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
6%	NL toddler	1,90	4%	Milk: Cattle	0,4%	Apples	0,2%	Maize/corn	6%	6%
3%	UK infant	1,03	3%	Milk: Cattle	0,1%	Potatoes	0,1%	Eggs: Chicken	3%	3%
3%	NL child	0,97	2%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Apples	3%	3%
3%	FR toddler 2 3 yr	0,90	2%	Milk: Cattle	0,1%	Apples	0,1%	Wheat	3%	3%
3%	DE child	0,87	1%	Milk: Cattle	0,4%	Apples	0,1%	Wheat	3%	3%
3%	FR child 3 15 yr	0,84	2%	Milk: Cattle	0,2%	Wheat	0,1%	Sugar beet roots	3%	3%
2%	UK toddler	0,68	1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	2%	2%
2%	DK child	0,59	0,8%	Milk: Cattle	0,2%	Rye	0,1%	Swine: Muscle/meat	2%	2%
2%	GEMS/Food G11	0,58	0,5%	Milk: Cattle	0,2%	Soyabeans	0,1%	Potatoes	2%	2%
2%	ES child	0,56	0,8%	Milk: Cattle	0,1%	Wheat	0,1%	Bovine: Muscle/meat	2%	2%
2%	SE general	0,55	0,8%	Milk: Cattle	0,3%	Bovine: Muscle/meat	0,1%	Potatoes	2%	2%
2%	RO general	0,53	0,8%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	2%	2%
2%	GEMS/Food G07	0,52	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	2%	2%
2%	DE women 14-50 yr	0,52	0,8%	Milk: Cattle	0,2%	Sugar beet roots	0,1%	Apples	2%	2%
2%	GEMS/Food G15	0,52	0,5%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	2%	2%
2%	DE general	0,51	0,8%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Apples	2%	2%
2%	GEMS/Food G08	0,51	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Soyabeans	2%	2%
2%	GEMS/Food G10	0,51	0,4%	Milk: Cattle	0,2%	Soyabeans	0,1%	Wheat	2%	2%
2%	FR infant	0,47	1%	Milk: Cattle	0,1%	Potatoes	0,1%	Apples	2%	2%
1%	GEMS/Food G06	0,45	0,2%	Wheat	0,2%	Milk: Cattle	0,1%	Tomatoes	1%	1%
1%	NL general	0,43	0,6%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Potatoes	1%	1%
1%	IE adult	0,41	0,3%	Milk: Cattle	0,1%	Sweet potatoes	0,1%	Wheat	1%	1%
1%	FI adult	0,35	0,9%	Coffee beans	0,0%	Potatoes	0,0%	Rye	1%	1%
1,0%	FR adult	0,29	0,3%	Milk: Cattle	0,1%	Wine grapes	0,1%	Wheat	1,0%	0,9%
1,0%	ES adult	0,29	0,3%	Milk: Cattle	0,1%	Wheat	0,0%	Bovine: Muscle/meat	1,0%	0,9%
0,8%	DK adult	0,24	0,4%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,0%	Potatoes	0,8%	0,8%
0,7%	LT adult	0,22	0,3%	Milk: Cattle	0,1%	Potatoes	0,1%	Swine: Muscle/meat	0,7%	0,7%
0,7%	PT general	0,22	0,2%	Potatoes	0,1%	Wheat	0,1%	Wine grapes	0,7%	0,6%
0,6%	UK vegetarian	0,18	0,2%	Milk: Cattle	0,1%	Wheat	0,0%	Potatoes	0,6%	0,5%
0,6%	UK adult	0,18	0,2%	Milk: Cattle	0,1%	Wheat	0,0%	Potatoes	0,6%	0,6%
0,6%	FI 3 yr	0,18	0,2%	Potatoes	0,0%	Bananas	0,0%	Wheat	0,6%	0,6%
0,6%	IT toddler	0,17	0,2%	Wheat	0,1%	Other cereals	0,0%	Tomatoes	0,6%	0,3%
0,5%	FI 6 yr	0,14	0,1%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat	0,5%	0,5%
0,4%	IE child	0,12	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,4%	0,4%
0,4%	IT adult	0,12	0,1%	Wheat	0,0%	Tomatoes	0,0%	Apples	0,4%	0,3%
0,3%	PL general	0,10	0,1%	Potatoes	0,1%	Apples	0,0%	Tomatoes	0,3%	0,3%

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

A 3.2 TMDI calculations (Mesosulfuron-methyl):

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

mesosulfuron-methyl

LOQs (mg/kg) range from:	0,01	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	not necessry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0,2%	NL toddler	1,90	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Maize/corn	0,2%	0,2%
0,1%	UK infant	1,03	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Eggs: Chicken	0,1%	0,1%
0,1%	NL child	0,97	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,1%	0,1%
0,1%	FR toddler 2 3 yr	0,90	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Wheat	0,1%	0,1%
0,1%	DE child	0,86	0,0%	Milk: Cattle	0,0%	Apples	0,0%	Wheat	0,1%	0,1%
0,1%	FR child 3 15 yr	0,84	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Sugar beet roots	0,1%	0,1%
0,1%	UK toddler	0,68	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,1%	0,1%
0,1%	DK child	0,59	0,0%	Milk: Cattle	0,0%	Rye	0,0%	Swine: Muscle/meat	0,1%	0,1%
0,1%	GEMS/Food G11	0,58	0,0%	Milk: Cattle	0,0%	Soyabeans	0,0%	Potatoes	0,1%	0,1%
0,1%	ES child	0,56	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat	0,1%	0,1%
0,1%	SE general	0,55	0,0%	Milk: Cattle	0,0%	Bovine: Muscle/meat	0,0%	Potatoes	0,1%	0,1%
0,1%	RO general	0,53	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,1%	0,0%
0,1%	GEMS/Food G07	0,52	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,1%	0,0%
0,1%	DE women 14-50 yr	0,52	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,1%	0,0%
0,1%	GEMS/Food G15	0,52	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,1%	0,0%
0,1%	DE general	0,51	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples	0,1%	0,0%
0,1%	GEMS/Food G08	0,51	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Soyabeans	0,1%	0,0%
0,1%	GEMS/Food G10	0,51	0,0%	Milk: Cattle	0,0%	Soyabeans	0,0%	Wheat	0,1%	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	0,41	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	0,29	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 mesosulfuron-methyl is unlikely to present a public health concern.

A 3.3 IEDI calculations

Not required.

A 3.4 IESTI calculations - Raw commodities

Iodosulfuron-methyl:

Unprocessed commodities								
	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
	IESTI				**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)
	0,00%	Wheat	0,01 / 0,01	0,14	0,00%	Wheat	0,01 / 0,01	0,08
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.5 IESTI calculations - Processed commodities

Iodosulfuron-methyl:

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,0%	Wheat / milling (flour)	0,01 / 0,01	0,12	0,0%	Wheat / bread/pizza	0,01 / 0,01	0,04
0,0%	Wheat / milling (wholemeal)-l	0,01 / 0,01	0,06	0,0%	Wheat / pasta	0,01 / 0,01	0,04
				0,0%	Wheat / bread (wholemeal)	0,01 / 0,01	0,02
Expand/collapse list							

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

Mesosulfuron-methyl:
Not required