FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: JME-HER 12 OD

Product name(s): -

Chemical active substance:

iodosulfuron-methyl-sodium, 2 g/L

mesosulfuron-methyl, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o.

Submission date: December 2023, revision: April 2024

MS Finalisation date: 03/10/2024

Version history

When	What
January 2024	Dossier sent for evaluation
04.2024	Update of dRR on evaluator's request
July 2024	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after Commenting period

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

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The Applicant did not provide any new data. dRR is based on data evaluated in the Atlantis 12 OD renewal Registration Report (zRMS PL, 2020). The dRR Part B7 assessment for Atlantis 12 OD has been made available by the Ministry of Agriculture and Rural Development for review by zRMS.

cGAP evaluated and accepted in dRR for Atlantis 12 OD and cGAP proposed for JME-HER 12 OD:

Crop	Application			PHI (days)	Remarks
	Timing / Growth stage of crop	Max. number a) per use b) per crop/ season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season		
Atlantis 12 OD					
Cereals	BBCH 12-39	1	2.4 iodosulfuron-methyl-sodium 12 mesosulfuron-methyl	-	plus 36 g mefenpyr-diethyl as a safener
JME-FER 12 OD					
Winter wheat	BBCH 21-31	1	2.4 iodosulfuron-methyl-sodium 12 mesosulfuron-methyl	-	plus 36 g mefenpyr-diethyl as a safener
Winter triticale					
Rye			0.9 iodosulfuron-methyl-sodium 4.5 mesosulfuron-methyl		

The cGAPs assessed and accepted for Atlantis 12 OD covers the cGAPs proposed for JME-HER 12 OD.

Since the assessment for Atlantis 12 OD, there have been no changes to the residue definitions of both active substances. The MRL values have also not changed, the MRL values in accordance with Reg. (EU) 289/2014 for both active substances still apply.

The residues arising from the proposed uses of iodosulfuron-methyl-sodium in JME-HER 12 OD (max: 1 × 2.4 g a.s./ha, BBCH 12-31, PHI not relevant) will not exceed the MRLs established for cereals (0.01 mg/kg according to the current Reg. (EU) No 289/2014 and not yet applicable Reg. (EU) 2024/1077 (will apply on 06/11/2024)).

The residues arising from the proposed uses of mesosulfuron-methyl in JME-HER 12 OD (max: 1 × 12 g a.s./ha, BBCH 12-31, PHI not relevant) will not exceed the MRLs established for cereals (0.01 mg/kg according to the current Reg. (EU) No 289/2014)

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 live-stock were found to be below the threshold intake for the submission of an animal study, 0.004 mg/kg bw/d.

Magnitude of residues in processed commodities are not required as significant residues are not expected to be found in cereals.

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 JME-HER 12 OD.

Mefenpyr used as a safener was not yet assessed at EU level nevertheless, it was assessed and accepted in national addendum for Atlantis 12 OD.

Consumer risk assessment

Chronic and acute exposure calculations were performed using EFSA PRIMo rev. 3.1.

Iodosulfuron-methyl-sodium

The potential chronic dietary exposure was compared to the ADI of 0.03 mg/kg bw/day and TMDI values were achieved. Input values for all commodities were derived from EU MRL, representing the worst-case scenario. The highest chronic exposure was calculated for NL toddler diet, representing 6% of the ADI.

The potential acute dietary exposure was compared to the ARfD of 3.15 mg/kg bw and IESTI values were achieved. Input values, for all commodities were derived from EU MRL, representing the worst-case scenario. With regard to the acute exposure, no exceedances of the ARfD are identified and IESTI values are below 100%.

The proposed uses of iodosulfuron-methyl-sodium in the formulation JME-HER 12 OD does not represent unacceptable acute and chronic risks for the consumer.

Mesosulfuron-methyl

The potential chronic dietary exposure was compared to the ADI of 1.0 mg/kg bw/day and TMDI values were achieved. Input values for all commodities were derived from EU MR, representing the worst-case scenario. The highest chronic exposure was calculated for NL toddler diet, representing 0.19% of the ADI.

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

The proposed uses of mesosulfuron-methyl in the formulation JME-HER 12 OD does not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification
The critical GAPs with respect to consumer intake and risk assessment for the preparation product code are presented in Table 7.1-1.

Overall conclusion
This is the application for registration of a plant protection product under working name JME-HER 12 OD according to Article 33 and Article 34 of Regulation 1107/2009. JME-HER 12 OD is an oil dispersion formulation, containing 2 g/L of iodosulfuron-methyl-sodium and 10 g/L of mesosulfuron-methyl to be used as a herbicide to protect cereals.

In respect to the above and taking into account Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant do not provide residue data and apply for using unprotected data of Atlantis 12 OD.

This document has been prepared by copying the risk assessments and summary of studies included in the Atlantis 12 OD renewal Registration Report (zRMS: Poland, MS finalisation: 12/02019). The information and studies used in this document are not protected in accordance with Art. 59 Reg. 1107/2009 and can be used for purpose of JME-HER 12 OD registration.

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

PPP (product name/code):	JME-HER 12 OD	Formulation type:	OD
Active substance 1:	iodosulfuron-methyl-sodium	Conc. of as 1:	2 g/L
Active substance 2:	mesosulfuron-methyl	Conc. of as 2:	10 g/L
Safener:	mefenpyr-diethyl	Conc. of safener:	30 g/L
Synergist:	-	Conc. of synergist:	-
Applicant:	Pestila sp. z o. o.	Professional use:	☒
Zone(s):	central	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**~~water L/ha~~ ~~min max~~ g as/ha a) max. rate per appl. b) max. total rate per crop/season**	**~~kg as/ha~~ ~~min max~~ water L/ha min max**		
1	Winter wheat	C-EU	JME-HER 12 OD	F	Please refer to Part A	OD	iodosulfuron-methyl-sodium, 2 g/L mesosulfuron-methyl, 10 g/L	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	-	a) 2.4 - iodosulfuron 12 - mesosulfuron b) same as a)	200-300	-	A

2	Winter triticale	C-EU	JME-HER 12 OD	F	Please refer to Part A	OD	iodosulfuron-methyl-sodium, 2 g/L mesosulfuron-methyl, 10 g/L	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	-	a) 2.4 - iodosulfuron 12 - mesosulfuron b) same as a)	200-300	-	A
3	Winter wheat	C-EU	JME-HER 12 OD	F	Please refer to Part A	OD	iodosulfuron-methyl-sodium, 2 g/L mesosulfuron-methyl, 10 g/L	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	-	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	-	A
4	Winter triticale	C-EU	JME-HER 12 OD	F	Please refer to Part A	OD	iodosulfuron-methyl-sodium, 2 g/L mesosulfuron-methyl, 10 g/L	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	-	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	-	A
5	Rye	C-EU	JME-HER 12 OD	F	Please refer to Part A	OD	iodosulfuron-methyl-sodium, 2 g/L mesosulfuron-methyl, 10 g/L	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	-	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	-	A

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

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

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation JME-HER 12 OD is composed of iodosulfuron-methyl-sodium and mesosulfuron-methyl.

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

Reference value	Source	Year	Value mg/kg bw (per day)	Study relied upon	Safety factor
Iodosulfuron-methyl					
ADI	EFSA	2016	0.03	Rat, 2 years	100
ARfD	EFSA	2016	3.15	Rat, developmental	100
Mesosulfuron-methyl					
ADI	EFSA	2016	1.0	Mouse, 18 months	100
ARfD	EFSA	2016	NR	No ARfD derived, not necessary.	NR

7.1.2.1 Summary for iodosulfuron-methyl-sodium

~~Iodosulfuron-methyl-sodium data is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

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?*
1-5	*Cereals*	*Yes*	*Yes (22 number of trials)*	*NR*	*Yes **	*Yes*	*No*	*No*

* *Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1*
** *The report of a new storage stability (intended by EFSA 2016) is presented in this dossier.*
NR not relevant

Following the EFSA conclusion (doi:10.2903/j.efsa.2016.4453) on the iodosulfuron risk assessment regarding the triazine amine (AE F059411, a metabolite of iodosulfuron), additional data are required in post-registration depending on its toxicological profile. AE F059411 (also known as triazine amine or aminotriazine, or by company codes IN-A4098, or CGA150829) is a common metabolite of five sulfonylurea herbicide active substances (metsulfuron-methyl, thifensulfuron-methyl, tribenuron-methyl, prosulfuron, and iodosulfuron-methyl-sodium) currently at few different stages of renewal in Europe. A decision on the genotoxic potential of the triazine amine could not be taken at the EU level at the time of preparation of this dossier. Applicants of the different actives, part of the triazine amine Task Force, submitted a Weight of Evidence assessment as joint confirmatory data for Iodosulfuron and Prosulfuron a based on all available genotoxicity studies, including studies of other notifiers outside of the Task force. Based on the extensive genotoxicity data package available for this metabolite and using a Weight of Evidence approach, the Task Force concluded that the triazine amine is not genotoxic. This was

fully supported by the Swedish authority KEMI as RMS of Iodosulfuron. Nevertheless, reviewers are still in a process to reach a consensus regarding the final conclusion. To date, it remains unclear on what next additional steps should be triggered to reach a final agreement among the authorities as no firm conclusion could be drawn regarding the gene mutation potential of the triazine amine (EFSA; 2018 EN-1470). It is now in the hand of the European Commission to initiate the next steps such as mandating the EFSA to conduct a peer review meeting for example. Therefore, since no consensus was reached, Bayer maintains his position that with the overwhelming data provided (18 studies) in the form of a WoE assessment report it can be concluded that the triazine amine is not genotoxic. As the EFSA peer review process is on-going, this WoE assessment report has not been provided in this dossier but will be made available to the zRMS upon request.

Nevertheless, pending the outcome of the triazine amine toxicological profile final evaluation from the EU authorities, a package of field trials on various formulations containing iodosulfuron was performed to determine the magnitude of AE F059411 residues. The applications were made at different doses (from 1.5 to 10 g/ha) and at different growth stages (BBCH 32 to 39) in order to cover the various intended uses in the EU. The results of available data performed in the northern zone are presented in this dossier.

As residues of iodosulfuron-methyl-sodium 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

~~Mesosulfuron-methyl data is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

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?***
1-5	*Cereals*	*Yes*	*Yes (42 number of trials)*	*NR*	*Yes*	*Yes*	*No*	*No*

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

As residues of mesosulfuron 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 JME-HER 12 OD

~~Iodosulfuron-methyl-sodium and mesosulfuron-methyl data is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Table 7.1-5: Information on IMS+MSM+MPR OD 42 (2+10+30) / JME-HER 12 OD (KCA 6.8)

Crop	*PHI for IMS+MSM+MPR OD 42 / JME-HER 12 OD proposed by applicant*	*PHI/ Withholding period* sufficiently supported for*		*PHI for IMS+MSM+MPR OD 42 / JME-HER 12 OD proposed by zRMS*	*zRMS Comments (if different PHI proposed)*
		Iodosulfuron-methyl-sodium	*Mesosulfuron-methyl*		
Cereals	*NR*	*NR*	*NR*	*NR*	

NR: not relevant
** Purpose of withholding period to be specified*

Table 7.1-6: Waiting periods before planting succeeding crops

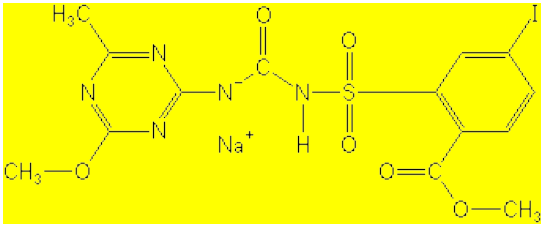
Waiting period before planting succeeding crops			*Overall waiting period proposed by zRMS for IMS+MSM+MPR OD 42 / JME-HER 12 OD*
Crop group	*Led by Iodosulfuron-methyl-sodium*	*Led by Mesosulfuron-methyl*	
NR	*NR*	*NR*	NR

NR: not relevant

7.2 Iodosulfuron-methyl-sodium

General data on iodosulfuron-methyl-sodium are summarized in the table below.

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

Active substance (ISO Common Name)	iodosulfuron-methyl-sodium
IUPAC	sodium ({[5-iodo-2-(methoxycarbonyl)phenyl]sulfonyl} carbamoyl)(4-methoxy-6-methyl-1,3,5-triazin-2-yl)azanide
Chemical structure	
Molecular formula	$C_{14}H_{13}IN_5NaO_6S$
Molar mass	529.24
Chemical group	Sulfonylurea
Mode of action (if available)	Selective to cereals. Inhibits plant amino acid synthesis - acetohydroxyacid synthase AHAS
Systemic	Yes
Company (ies)	Bayer Crop Science*
Rapporteur Member State (RMS)	Sweden (Renewal)
Approval status	Date of approval:01/01/2004 Date of renewal: 01/04/2017 Expiration of approval: 31/03/2032 Commission Implementing Regulation (EU) 2017/407 of 8 March 2017 renewing the approval of the active substance iodosulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1490351291552&uri=CELEX:32017R0407
Restriction	see Regulation
Review Report	SANTE/2016/11167 Rev 3, 7 December 2016
Current MRL regulation	Reg. (EU) No 289/2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes. EFSA 2012
EFSA Journal: Conclusion on the peer review	EFSA Journal 2016; 14(4):4453
EFSA Journal: Conclusion on article 12	EFSA Journal 2012; 10(11):2974
Current MRL applications on intended uses	NR

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

7.2.1 Stability of Residues (KCA 6.1)

~~Data on stability of residues is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

7.2.1.1 Stability of residues during storage of samples

Available data

The report from a new stability study is submitted in the framework of this application. Indeed, a new storage stability study on iodosulfuron-methyl residues was requested during the Peer Review of the AIR of iodosulfuron to support the findings in the residue trials (EFSA Journal 2016;14(4):4453). The request was motivated by the fact that a distinct conclusion regarding the stability of iodosulfuron-methyl residues in cereals was not possible on the basis of the available studies. The intended matrices for the new study are cereal shoot, grain and straw. The detailed assessment of this study are presented in Appendix 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			
Animal Products			
Not applicable			*EFSA Journal 2016;14(4):4453*
New data			
Plant products			
Wheat green material	*High water content*	*24 months*	*Kaussmann M.; 2019 M-635482-02-1*
Wheat grain	*High starch content*	*24 months*	*Kaussmann M.; 2019 M-635482-02-1*
Wheat straw	*Other*	*24 months*	*Kaussmann M.; 2019 M-635482-02-1*

Conclusion on stability of residues during storage

The storage stability data were not considered acceptable during the Peer Review and a data gap was set (EFSA Journal 2016;14(4):4453).
The storage stability report shows that iodosulfuron-methyl and its metabolites AE F059411 and AE 0031838 are stable in wheat grain, green material and straw for at least 24 months (721 days) under deep-freezer storage conditions (≤-18°C) except for AE 0031838 in wheat, green material (68% recovery after 24 months) for which it is recommended to analyse the residues within 587 days. The residue trials on the intended uses presented in this dossier are covered by the storage stability study and had a storage period up to 468 days (see Appendix 2).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Stability of residues in matrix solutions and standard solvents (RAR, RMS Sweden, 2015)

Tests of stability of residues in matrix solutions and standard solvents have been conducted with iodosulfuron-methyl.

The stability of residues in matrix solutions were conducted on lemon fruit, flax grain, oilseed rape, wheat grain, wheat green material, wheat straw, sugar beet body and sugar beet leaf. The results indicate significant deviations between initial and re-analysis which were observed especially for the matrices lemon fruit, oilseed rape, sugar beet body and sugar beet leaf. The matrix solutions of flax grain, wheat grain, wheat green material and wheat straw shows less deviation. However, the general conclusion is that the analysis of the samples should be analysed as soon as possible after preparation and within one day.

The stability of residues in standard solvents was found to be stable in the standard solvent for at least two months.

Conclusion on stability of residues in sample extracts

The analysis of cereal samples should be done as soon as possible after preparation of matrix solutions and within one day.

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)

~~Data on nature of residue in primary crops is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	*Wheat*	*[2-^{14}C]-triazinyl*	*Foliar, F*	*0.02*	*1*	*Forage: 3, 7, 22 Hay: 35 Leaves/ears/stem: 49 Grain, straw: 77*	*Active applied with non-labelled safener mefenpyr-diethyl*	*Braun, P. J.; Brueckner, H.; Voelkl, S. (1998), M-182772-01-1 EFSA, 2012*
		[U-^{14}C]-phenyl	*Foliar, G*	*0.02*	*1*	*Forage: 0, 20, 23, 28 Hay: 43 Grain, straw: 87*		*Tarara, G.; Brueckner, H. (1998), M-148037-01-1 EFSA, 2012*

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
a.s: active substance

Summary of plant metabolism studies reported in the EU

As stated in EFSA Journal 2016; 14(4):4453:
"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.

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."

Conclusion on metabolism in primary crops

Sufficient data have been provided to acknowledge the metabolism of iodosulfuron-methyl-sodium in cereal.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

~~Data on nature of residue in rotational crops is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

No new data submitted in the framework of this application.

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

Crop group	***Crop***	***Label position***	***Application and sampling details***					***Reference***
			Method, F or G *	**Rate (kg a.s./ha)**	**Sowing intervals (DAT)**	**Harvest Intervals (DAT)**	**Remarks**	
EU data								
Leafy vegetables	*Spinach*	*[2-14C]-triazinyl*	*Bare soil, F ***	*0.02*	*29, 120, 365*	*408*	*-*	*Buerkle, L. W. (1998), M-181318-01-1 EFSA, 2012*
Root and tuber vegetables	*Carrot*		*Bare soil, F ***	*0.02*	*29, 120, 365*	*252, 464*	*-*	*Buerkle, W. L.; Kellner, G.; Voelkl, S.; (1998), M-182667-01-1 EFSA, 2012*
	Sugarbeet		*Bare soil, G*	*0.0054*	*60*	*134, 233*	*Applied with a safener*	*Meyer, B. N.; Tull, P. J., (1999), M-238341-01-1*

							(isoxadifen-ethyl)	*EFSA, 2012, 2016*
Cereals	*Wheat*		*Bare soil, F* **	*0.02*	*29, 120, 365*	*99, 239, 464*	*-*	*Buerkle, W. L.; Kellner, G.; Voelkl, S.; (1998) M-182374-01-1, EFSA, 2012*
			Bare soil, G	*0.0081*	*65*	*210, 261*	*Applied with a safener (isoxadifen-ethyl)*	*Meyer, B. N.; Tull, P. J., (1999), 238341-01-1 EFSA, 2012, 2016*
Pulses and oilseeds	*Soybean*		*Bare soil, G*	*0.0054*	*7, 14*	*52, 56, 138, 145*	*Applied with a safener (isoxadifen-ethyl)*	*Meyer, B. N.; Tull, P. J., (1999), M-238341-01-1, EFSA, 2012, 2016*

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

Summary of plant metabolism studies reported in the EU

As stated in EFSA Journal 2012;10(11):2974:

"The carrots planted 30 DAT as well as the spinach planted at 30 and 120 DAT showed important signs of phytotoxicity and therefore were not further considered. Total radioactive residues in mature carrots and spinach planted one 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.

The TRR in cereal grains were found to be below 0.01 mg eq/kg at all plant-back intervals. In cereal straw, the TRR 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 triazin and iodosulfuron-demethyl-hydroxy-triazin) and the metabolic pattern for primary crops and rotational crops were concluded to be similar (Germany, 2000)."

And in EFSA Journal 2016; 14(4):4453:

"In confined rotational crop studies, the potential incorporation of soil residues into succeeding crops was investigated in sugar beet, carrot, spinach, soya bean and wheat using plant back intervals of 28 days, 120 days and 1 year. No metabolite identification was attempted except in wheat straw since the TRRs were relatively low in the other commodities. In rotational straw, metabolites AE F059411 and AE 0031838 were identified (0.03-0.04 mg/kg at a plant back interval of 1 year). However, to finalise the assessment of the potential enrichment of residues in rotational crops a data gap was set. The likely concentration of the triazine amine metabolite in soil in the rotational crop studies should be determined (or demonstrated in a soil experiment) and related to the calculated plateau level expected from the representative use in order to assess the residue transfer into relevant rotational commodities."

Conclusion on metabolism in rotational crops

The metabolism of iodosulfuron-methyl in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

~~Data on nature of residue in processed commodities is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

No new data submitted in the framework of this application.

As stated in EFSA, 2012:
"As quantifiable residues of iodosulfuron-methyl are not expected in edible part of crops and total chronic exposure represents less than 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing."
And in EFSA, 2016:
Investigations of the effect of industrial and/or household processing were not conducted and are not obligatory in view of the very low residues in grain.

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

~~Conclusion on the nature of residues in commodities of plant origin is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Table 7.2-5: 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	*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)*
Plant residue definition for risk assessment	*Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016)*
Conversion factor from enforcement to RA	*1 (EFSA, 2012, 2016)*

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

~~Data on nature of residues in livestock is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	*Cow /Goat /Sheep*	*[U-^{14}C]-phenyl*	*1*	*0.220*	*7*	*Milk*	*Twice daily*	*Reynolds, C. M. M.; Swalwell, L. M. (1999) M-192483-01-1 EFSA, 2012*
						Urine and faeces	*Daily*	
						Tissues	*At sacrifice[(a)]*	
Laying poultry	*Hens*	*[U-^{14}C]-phenyl*	*5*	*0.889*	*14*	*Eggs (yolk)*	*Twice daily*	*Moss, T.; Souza, R.A.D.; Reynolds, C. M. M. (1999) M-192269-01-1 EFSA, 2012*
						Eggs (white)	*Twice daily*	
						Excreta	*Daily*	
						Tissues	*At sacrifice[(a)]*	

(a): 22 hours after final dose.

Summary of animal metabolism studies reported in the EU

As stated in EFSA, 2012:
"Based on this second calculation, calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM. Consequently, provided that residue levels in maize silage are below 0.01 mg/kg, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary."

And in EFSA, 2016:
Livestock metabolism studies were not triggered.

Conclusion on metabolism in livestock

Sufficient data have been provided to acknowledge the metabolism of iodosulfuron-methyl in ruminant and poultry.

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

~~Conclusion on the nature of residues in commodities of animal origin is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Table 7.2-7: Summary on the nature of residues (iodulfuron-methyl-sodium) in commodities of animal origin

Endpoints	
Animals covered	-
	-
Time needed to reach a plateau concentration	-
	-
Animal residue definition for monitoring	*Not necessary (EFSA, 2012, 2016)*
Animal residue definition for risk assessment	*Not necessary (EFSA, 2012, 2016)*
Conversion factor	-
Metabolism in rat and ruminant similar	-
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

~~Summary of European data and new data supporting the intended uses is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application to support the proposed cGAP. Moreover, pending the outcome of the triazine amine toxicological profile final evaluation from the EU authorities (doi: 10.2903/j.efsa.2016.4453), a package of field trials on various formulations containing iodosulfuron has been performed to determine the magnitude of AE F059411 residues. The applications were made at different doses (from 1.5 to 10 g/ha) and at different growth stages (BBCH 32 to 39) in order to cover the various intended uses in the EU. These studies have to be considered only as additional information regarding the magnitude of triazine, AE F059411 and AE 0031838 and are pointed with a double asterisk and summarized in the table below.

The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of IMS+MSM+MPR OD 42 / JME-HER 12 OD 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
Cereal, grain (barley, rye, wheat)	*EFSA, 2016*	*N-EU*	*GAP on which EU a.s. assessment is based: 1 × 0.010-0.015 kg as/ha, BBCH 32-39, PHI not relevant, outdoor* *E: 14 × <0.01* *RA: 14 × <0.01*	*NA*				
	New trials 13-2127	*N-EU*	*0.003 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.01*		*E: 0.01* *RA: 0.01*			
	New trials 13-2129	*N-EU*	*0.009 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.01*		*E: 0.01* *RA: 0.01*			
	New trials 14-2011	*NEU*	*0.003 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.01*		*E: 0.01* *RA: 0.01*			

	*New trials 16-2029***	*N-EU*	*0.0075 kg/ha, BBCH 32, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.01*		*E: 0.01* *RA: 0.01*			
	*New trials 16-2030***	*N-EU*	*0.0037 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Barley 2 x <0.01, Wheat 3 × <0.01*		*E: 0.01* *RA: 0.01*			
	*New trials 16-2037***	*NEU*	*0.003-kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Barley 1 x <0.01, Wheat 2 × <0.01*		*E: 0.01* *RA: 0.01*			
	*New trials 16-2040***	*N-EU*	*0.010 kg/ha, BBCH 32, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.01*		*E: 0.01* *RA: 0.01*			
	*New trials 16-2041***	*N-EU*	*0.005 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Wheat 4 × <0.01*		*E: 0.01* *RA: 0.01*			
	*New trials 16-2043***	*N-EU*	*0.0010 kg/ha, BBCH 32, PHI not relevant, outdoor* *E and RA: Barley 1 x <0.01, Wheat 1 × <0.01*		*E: 0.01* *RA: 0.01*			
	EFSA, 2016	*S-EU for MRL setting*	*GAP on which EU a.s. assessment is based: 1 × 0.010-0.015 kg as/ha, BBCH 32-39, PHI not relevant, outdoor* *E: 18 × <0.01* *RA: 18 × <0.01*					
	Overall supporting data for cGAP	*N-EU & SEU*	*E : 58 × <0.01* *RA:58 × <0.01*	*E: 0.01* *RA: 0.01*	*E: 0.01* *RA: 0.01*	*0.01*	*0.01*	*Yes*
Cereal, straw (barley, rye, wheat)	*EFSA, 2016*	*N-EU*	*GAP on which EU a.s. assessment is based: 1 × 0.010-0.015 kg as/ha, BBCH 32-39, PHI not relevant, outdoor* *E: 14 × <0.05* *RA: 14 × <0.05*	*NA*				
	New trials 13-2127	*N-EU*	*0.003 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.05*		*E: 0.05* *RA: 0.05*			
	New trials 13-2129	*N-EU*	*0.009 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.05*		*E: 0.05* *RA: 0.05*			
	New trials 14-2011	*NEU*	*0.003 kg/ha, BBCH 39, PHI not relevant, outdoor* *E and RA: Wheat 2 × <0.05*		*E: 0.05* *RA: 0.05*			

	New trials 14-2017	*NEU*	*0.009 kg/ha, BBCH 39, PHI not relevant, outdoor E and RA: Wheat 2 × <0.05*		*E: 0.05 RA: 0.05*			
	*New trials 16-2029***	*N-EU*	*0.0075kg/ha, BBCH 32, PHI not relevant, outdoor E and RA: Wheat 2 × <0.05*		*E: 0.05 RA: 0.05*			
	*New trials 16-2030***	*N-EU*	*0.0037kg/ha, BBCH 39, PHI not relevant, outdoor E and RA: Barley 2 x <0.05, Wheat 3 × <0.05*		*E: 0.05 RA: 0.05*			
	*New trials 16-2037***	*NEU*	*0.003-kg/ha kg/ha, BBCH 39, PHI not relevant, outdoor E and RA: Barley 1 x <0.05, Wheat 2 × <0.05*		*E: 0.05 RA: 0.05*			
	*New trials 16-2040***	*N-EU*	*0.010 kg/ha, BBCH 32, PHI not relevant, outdoor E and RA: Wheat 2 × <0.05*		*E: 0.05 RA: 0.05*			
	*New trials 16-2041***	*N-EU*	*0.005 kg/ha, BBCH 39, PHI not relevant, outdoor E and RA: Wheat 4 × <0.05*		*E: 0.05 RA: 0.05*			
	*New trials 16-2043***	*N-EU*	*0.0010 kg/ha, BBCH 32, PHI: not relevant, outdoor E and RA: Barley 1 x <0.05, Wheat 1 × <0.05*		*E: 0.05 RA: 0.05*			
	EFSA, 2016	*S-EU*	*GAP on which EU a.s. assessment is based: 1 × 0.010 - 0.015 kg as/ha, BBCH 32-39, PHI not relevant, outdoor E: 18 × <0.05 RA: 18 × <0.05*					
	Overall supporting data for cGAP	*N-EU & SEU*	*E : 58 × <0.05 RA:58 × <0.05*	*E: 0.05 RA: 0.05*	*E: 0.05 RA: 0.05*	*0.05*	*0.05*	*Yes*

** Source of EU MRL: Commission Regulation (EU) No 289/2014, 21 March 2014*
EFSA, 2016: Three types of formulations have been used: OD (representative formulation), WG and EG. The WG and EG have been used in bridging studies. The residues at harvest in wheat grain and straw are below the LOQs, differences due to formulations have not been observed.
*** New trials: to be considered as additional data regarding the triazine amine AE F059411*

7.2.3.2 Conclusion on the magnitude of residues in plants

~~Conclusion on the magnitude of residues in plants is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Sufficient trials on cereals (wheat and barley) are available to support the proposed uses. Extrapolation from wheat to rye and triticale is possible (SANTE/2019/12752 - revision1 - 10 May 2023).

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

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.
The trials in study no. 14-2011 and 14-2017 are not independent (same location, same date). Only 14-2011 study regarding the Northern zone was consider.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The active substance iodosulfuron-methyl is authorised in EU for use on crops that might be fed to livestock, so dietary burden calculation was performed in EFSA reasoned opinion on the review of the existing maximum residue levels/import tolerances for iodosulfuron-methyl according to Article 12 of Regulation (EC) No 396/2005.

Nonetheless in this document, the additional calculation of the dietary burden was conducted based on requested uses of JME-HER 12 OD. The modelling was performed by Excel spreadsheet Animal model 2017.

The input values and results of the dietary burden calculations are summarised below. For the evaluation data included in EFSA Journal 2012;10(11):2974 were applied.

Table 7.2-9: Input values for the dietary burden calculation - iodosulfuron-methyl

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl				
Cereal grain	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Cereal bran (wheat, milled by-pdts)	0.01 x 8	Median residue grain x PF (EFSA, 2012)	0.01 x 8	Median residue grain x PF (EFSA, 2012)
Cereal straw	0.05	Highest residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)

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

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.002	0.002	0.05	0.05	Dairy cattle	Wheat	milled bypdts	No	
Cattle (dairy only)	0.002	0.002	0.05	0.05	Dairy cattle	Wheat	milled bypdts	No	
Sheep (all diets)	0.003	0.003	0.07	0.07	Lamb	Wheat	milled bypdts	No	
Sheep (ewe only)	0.002	0.002	0.07	0.07	Ram/Ewe	Wheat	milled bypdts	No	
Swine (all diets)	0.002	0.002	0.05	0.05	Swine (finishing)	Wheat	milled bypdts	No	
Poultry (all diets)	0.002	0.002	0.03	0.03	Poultry layer	Wheat	milled bypdts	No	
Poultry (layer only)	0.002	0.002	0.03	0.03	Poultry layer	Wheat	milled bypdts	No	
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"									
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".									

The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw for ruminants, swine and poultry. No further evaluation is required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Not relevant. The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw hence no livestock feeding studies are required.

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

7.2.5.1 Available data for all crops under consideration

~~Data on magnitude of residues in processed commodities for all crops under consideration is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

No residues in products of plant or animal origin subject to processing are expected, from the uses on cereals, to be higher than 0.01 mg/kg.
No studies were submitted and no studies are required.

7.2.5.2 Conclusion on processing studies

~~Conclusion on processing studies is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

No residues in products of plant or animal origin subject to processing are expected, from the uses on cereals, to be higher than 0.01 mg/kg.
No studies were submitted and no studies are required.

7.2.6 Magnitude of residues in representative succeeding crops

~~Data on magnitude of residues in representative succeeding crops is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data~~

~~are required.~~

The crops under consideration can be grown in rotation. However, based on the confined rotational crop 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 twice the normal application rate and that the primary use of this active substance is authorised on cereal crops, it can be concluded that iodosulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that iodosulfuron is applied in compliance with the GAPs of IMS+MSM+MPR OD 42.

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

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. In accordance with Reg. 284/2013 no further data are required.

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

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

7.2.8.1 Input values for the consumer risk assessment

The acute and chronic consumer risk assessment for iodosulfuron-methyl has been performed with MRL values included in Reg. (EU) 289/2014. No Conversion Factors have been applied.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition in plants: Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl				
Intended uses				
Wheat Triticale Rye	0.01	EU MRL*	0.01	EU MRL*
Further uses				
All other commodities of plant and products of animal origin	variable	EU MRL*	Not relevant. Acute risk assessment is performed only for intended uses.	

* Reg. (EC) No Reg. (EU) No 289/2014

7.2.8.1 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (https://www.efsa.europa.eu/).

This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

Table 7.2-12: Consumer risk assessment - iodosulfuron-methyl

ADI	0.03 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	6% (based on diet: NL toddler) with the highest contributors: 4% Milk: Cattle 0.4% Apples 0.2% Maize/corn
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	not relevant
ARfD	3.15 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Unprocessed commodities (children): 0.08% Milk: Cattle (based on diet: UK infant) 0.05% Potatoes (based on diet: UK infant) 0.05% Melons (based on diet: BE todlers) Unprocessed commodities (adults): 0.02% Milk: Cattle (based on diet: NL general population) 0.01% Head cabbages (based on diet: CZ females 1-17 years) 0.01% Watermelons (based on diet: IT adult) Processed commodities (children): 0.03% Sugar beets (root) / sugar (based on diet: NL child) 0.03% Potatoes / fried (based on diet: NL child) 0.03% Pumpkins / boiled (based on diet: NL child) Processed commodities (adults): 0.02% Pumpkins / boiled (based on diet: NL general population) 0.01% Sugar beets (root) / sugar (based on diet: FR adult) 0.01% Cauliflower / boiled (based on diet: NL general population)
NTMDI (% ADI) **	not relevant
NEDI (% ADI)**	not relevant
NESTI (% ARfD) **	not relevant

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

The potential chronic dietary exposure was compared to the ADI of 0.03 mg/kg bw/day and TMDI values were achieved. Input values for all commodities were derived from EU MRL, representing the worst-case scenario. The highest chronic exposure was calculated for NL toddler diet, representing 6% of the ADI.

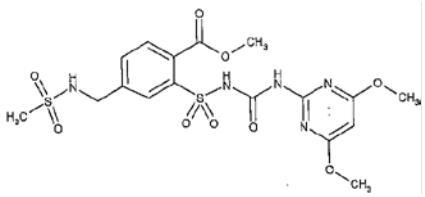
The potential acute dietary exposure was compared to the ARfD of 3.15 mg/kg bw and IESTI values were achieved. Input values, ~~only for intended uses~~ for all commodities were derived from EU MRL, representing the worst-case scenario. With regard to the acute exposure, no exceedances of the ARfD are identified and IESTI values are below 100%.

The proposed uses of iodosulfuron-methyl-sodium in the formulation JME-HER 12 OD does not represent unacceptable acute and chronic risks for the consumer.

7.3 Mesosulfuron-methyl

General data on mesosulfuron-methyl are summarized in the table below.

Table 7.3-1: General information on mesosulfuron-methyl

Active substance (ISO Common Name)	Mesosulfuron-methyl
IUPAC	methyl-2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-(methanesulfonamido)-p-toluate
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)	Selective to cereals. Inhibits plant amino acid synthesis - acetohydroxyacid synthase AHAS
Systemic	Yes
Company (ies)	Bayer CropScience*
Rapporteur Member State (RMS)	France (Renewal)
Approval status	Date of approval:01/04/2004 Date of renewal: 01/07/2017 Expiration of approval: 30/06/2032 Commission Implementing Regulation (EU) 2017/755 of 28 April 2017 renewing the approval of the active substance mesosulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494514919192&uri=CELEX:32017R0755
Restriction	see Regulation
Review Report	SANTE/11827/2016 Rev 2, 23 March 2017
Current MRL regulation	Reg. (EU) No 289/2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes. EFSA 2012
EFSA Journal: Conclusion on the peer review	EFSA Journal 2016;14(10):4584
EFSA Journal: conclusion on article 12	EFSA Journal 2012;10(11):2976
Current MRL applications on intended uses	NR

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

7.3.1 Stability of Residues (KCA 6.1)

~~Data on stability of residues is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application. Stability of residues has been evaluated during the Peer review (EFSA, 2016) showing that mesosulfuron-methyl is stable for 40 months, results are presented below.

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

Matrix	***Characteristics of the matrix***	***Acceptable Maximum Storage duration***	***Reference***
Data relied on in EU			
Plant products			
Wheat shoot	*High water content*	*40 months*	*Wrede, A.; (2000), M-198617-03-1 Peer Review (EFSA Journal 2016;14(10):4584)*
Wheat grain	*High starch content*	*40 months*	*Wrede, A.; (2003), M-216176-01-1 Peer Review (EFSA Journal 2016;14(10):4584)*
Wheat straw	*Other*	*40 months*	*Wrede, A.; (2003), M-198612-04-1 Peer Review (EFSA Journal 2016;14(10):4584)*
Animal Products			
Not applicable			*EFSA Journal 2016;14(10):4584*

Conclusion on stability of residues during storage

The maximum storage period of deep-frozen samples before analysis was of 340 for grain and straw, and 428 days for green material and was covered by the reviewed storage stability studies.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Stability of residues in sample extracts and stability of standard in solvents
Tests of stability of residues in matrix solutions and standard solvents have been conducted with

mesosulfuron-methyl.
As stated in the RAR, RMS France, 2016:
"*During the development of the method EMF 08/99-0 further renamed 00815 used for the analysis of the residue trials given in report C009932, relevant information on the stability of residues in the final or any intermediate extracts was derived from the fortification experiments performed during sample analysis. Every analytical batch contained at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples were handled and stored in parallel. If the recoveries in the fortified samples are within acceptable ranges, the stability of the sample extracts is considered as sufficiently proven.*"
and
"During the development of the method modification 00815/M001 (M-226888-01-1, KCA 4.2/16) used for the analysis of the residue trials given in reports RA-2677/03 and RA-2690/03, the stability of sulfonylureas (SU) in solvent (acetonitrile/aqueous triethylamine 0.02 mol/L (1/1, v/v); secondary standard solution: 0.005 mg/L of each SU) was tested. After nominal storage periods of 1, 2 and 4 months the aged standard solution was quantified against a freshly prepared standard solution. The aged standard solution was stored in a volumetric flask in a refrigerator at 4°C ± 3°C protected from light. All compounds tested are stable in solvent (acetonitrile/aqueous triethylamine 0.02 mol/L (1/1, v/v)) for at least two months. After a period of two months solutions containing the tested SU should be prepared freshly. After a period of four months, amidosulfuron, iodosulfuron-methyl and mesosulfuron-methyl declined up to 13%, compared to the mean of aged and freshly prepared standard solutions."

Data *(The referenced study corresponds to the method 01360/M001 (M-537921-01-1) which was validated during the mesosulfuron AIR process (RAR, RMS France/, 2016))*

Within the course of the analytical method validation 01360/M001 (ref. M-537921-01-1 in Part B5), the stability in final plant extracts was checked for wheat grain over a period of 15 days. The recoveries at day 0 (initial analysis) were compared to the recoveries analysed after storage of the final samples at 4°C ± 3°C in the dark over 15 days. To check the stability freshly prepared matrix standards were analyzed together with the aged recovery samples. For mesosulfuron-methyl in wheat grain an increase of 17% was observed. This result can be due to different matrix effects in fresh matrix standards compared to the older recovery samples. The detailed assessment of this study is presented in Appendix 2.

Conclusion on stability of residues during storage

The residues of mesosulfuron-methyl in standard solutions were found to be stable for at least two months. The analysis of cereal samples should be done as soon as possible after preparation.

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)

~~Data on nature of residue in primary crops is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	*Wheat*	*[2-^{14}C]-pyrimidinyl*	*F*	*0.01*	*1-2*	*0, 36, 49, 95*	*Active applied with non-labelled safener mefenpyr-diethyl*	*Braun, P. J.; Koehn, D. M.; Buerkle, L. W.; (2001) M-197766-02-1 EFSA, 2012*
		[U-^{14}C]-phenyl	*F*	*0.03*	*1-2*	*0, 42, 58, 104*		*Koehn, D. M.; Selzer, J.; Buerkle, L. W. (2001) M-198861-01-1 EFSA, 2012*

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

Summary of plant metabolism studies reported in the EU

As stated in EFSA, 2016:
"The metabolism of mesosulfuron–methyl was investigated upon foliar application at tillering stage (BBCH 29 (growth stages of mono- and dicotyledonous plants)) in cereals (wheat) using respectively 2-^{14}C-pyrimidyl and U-^{14}C-phenyl labellings. The total radioactive residues 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% of total radioactive residue (TRR) and 15% 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% to 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. […]
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."

Conclusion on metabolism in primary crops

Sufficient data have been provided to acknowledge the metabolism of mesosulfuron-methyl in cereal.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

~~Data on nature of residue in rotational crops is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Spinach	[2-^{14}C]-pyrimidinyl	Bare soil, F	0.015	32	162, 411	32DAT: spinach not harvested**	Frey, J. A.; Harrison, C. L.; Buerkle, L. W. (2000), M-197310-01-1 EFSA, 2012
Root and tuber vegetables	Carrot			0.015		139, 237, 487		
Cereals	Wheat			0.015		131, 238, 482		
Leafy vegetables	Spinach	U-^{14}C]-phenyl	Bare soil, F	0.015	32	162, 411	32DAT: spinach not harvested**	Frey, J. A.; Harrison, C. L.; Buerkle, L. W. (2000), M-197312-01-1 EFSA, 2012
Root and tuber vegetables	Carrot			0.015		139, 237, 487		
Cereals	Wheat			0.015		131, 238, 482		
Leafy vegetables	Spinach	[2-^{14}C]-pyrimidinyl	Bare soil, F	0.015	120	162, 411	32DAT: spinach not harvested**	Frey, J. A.; Harrison, C. L. (2000), M-197314-01-1 EFSA, 2012
Root and tuber vegetables	Carrot			0.015		139, 237, 487		
Cereals	Wheat			0.015		131, 238, 482		
Leafy vegetables	Spinach	U-^{14}C]-phenyl	Bare soil, F	0.015	120	162, 411	32DAT: spinach not harvested**	Frey, J. A.; Harrison, C. L. (2000), M-197315-01 EFSA, 2012
Root and tuber vegetables	Carrot			0.015		139, 237, 487		
Cereals	Wheat			0.015		131, 238, 482		
Leafy vegetables	Spinach	[2-^{14}C]-pyrimidinyl	Bare soil, F	0.015	365	162, 411	32DAT: spinach not harvested**	Frey, J. A.; Harrison, C. L. (2000), M-197311-01-1 EFSA, 2012
Root and tuber vegetables	Carrot			0.015		139, 237, 487		
Cereals	Wheat			0.015		131, 238, 482		
Leafy vegetables	Spinach	U-^{14}C]-phenyl	Bare soil, F	0.015	365	162, 411	32DAT: spinach not harvested**	Frey, J. A.; Harrison, C. L. (2000), M-197313-01-1 EFSA, 2012
Root and tuber vegetables	Carrot			0.015		139, 237, 487		

Cereals	*Wheat*			*0.015*		*131, 238, 482*		

Outdoor/field application (F) or glasshouse/protected/indoor application (G) Spinach showed severe growth damage due to the sensitivity of this plant to mesosulfuron-methyl.*

Summary of plant metabolism studies reported in the EU

As stated in EFSA, 2016:
"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 (1 N 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 d-PBI), 0.012 mg eq/kg (120 d-PBI) and 0.014 mg eq/kg (365 d-PBI) for both labelling forms. The radioactive residues in wheat straw at the 30 d-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). 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."

Conclusion on metabolism in rotational crops

Sufficient data have been provided to acknowledge the metabolism of mesosulfuron-methyl in rotational crops. The metabolism of mesosulfuron-methyl in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

~~Data on nature of residue in processed commodities is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

As stated in EFSA, 2012
"As quantifiable residues of mesosulfuron are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI (see also section 4), there is no need to investigate the effect of industrial and/or household processing. In addition, the chronic exposure does not exceed 10 % of the ADI."

And in EFSA, 2016:
"The investigation of effects of processing on the nature and magnitude of residues was not triggered by the representative uses". In Appendix A: "As residues in wheat grain are below the LOQ (<0.01 mg/kg) at the intended maximum application rate of 15 g a.s./ha, studies on the effects of processing on the nature of the residues are not required."

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

~~Conclusion on the nature of residues in commodities of plant origin is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

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	*Not relevant*
Residue pattern in processed commodities similar to pattern in raw commodities?	*Not applicable*
Plant residue definition for monitoring	*mesosulfuron-methyl (EFSA, 2016)*
Plant residue definition for risk assessment	*mesosulfuron-methyl (EFSA, 2016)*
Conversion factor from enforcement to RA	*1 (EFSA, 2016)*

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

~~Data on nature of residues in livestock is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Available data

No new data submitted in the framework of this application.

Table 7.3-6: Summary of animal metabolism studies

Group	***Species***	***Label position***	***No of animal***	***Application details***		***Sample details***		***Reference***
				Rate (mg/kg bw/d)	***Duration (days)***	***Commodity***	***Time of sampling***	
EU data								
Lactating ruminants	*Cow*	*[U-^{14}C]-phenyl[(a)]*	*1*	*0.417*	*5*	*Milk*	*Twice daily*	*Reynolds, C. M. M.; Swalwell, L. M. (1999) M-192023-01-1 EFSA, 2012*
						Excreta	*Daily*	
						Tissues	*At sacrifice[(c)]*	
Laying poultry	*Hens*	*[U-^{14}C]-phenyl*	*6*	*0.758*	*14*	*Eggs (yolk)*	*Twice daily*	*Reynolds, C. M. M.; Swalwell, L. M. (1999) M-192019-01-1 EFSA, 2012*
						Eggs (white)	*Twice daily*	
						Excreta	*Daily*	
						Tissues	*At sacrifice[(c)]*	

(a): typo in EFSA, 2012 (where the label is erroneously attributed to the ^{14}C-pyrimidinyl moiety). (b): Based on a mean daily dose of 1.44 mg per hen (as stated in the DAR) and 1.9 kg, the average weight of a hen (the weight of the hens in the study was not given in the DAR). (c): 22 hours after final dose.

Summary of animal metabolism studies reported in the EU

As stated in EFSA, 2016:
"Although livestock metabolism studies are not triggered according to the representative uses, poultry and ruminants 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 muscle because of the low recovered residue levels (0.012 mg eq/kg 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. It is however highlighted that in case of future uses with feed items, the need for additional livestock metabolism data tracking the fate of the pyrimidyl ring moiety of the parent molecule should be reconsidered."

Conclusion on metabolism in livestock

Sufficient data have been provided to acknowledge the metabolism of mesosulfuron-methyl in ruminant and poultry.

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

~~Conclusion on the nature of residues in commodities of animal origin is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

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

Endpoints	
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)*
Animal residue definition for risk assessment	*Mesosulfuron-methyl (EFSA, 2016)*
Conversion factor	*1*
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

~~Summary of European data and new data supporting the intended uses is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

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

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of IMS+MSM+MPR OD 42 /* JME-HER 12 OD *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***
Wheat and rye grain[(a)]	*EFSA Journal 2012;10(11):2976*	*N-EU*	*GAP on which MRL/EU a.s. assessment is based: 20 g as/ha, BBCH 13 to 32, PHI 90d, outdoor, formulation type WG E: 18 × <0.01 RA: 18 × <0.01*	*E: 0.01 RA: 0.01*	*E: 0.01 RA: 0.01*		*0.01**	
Cereal grain Wheat →extrapolated to rye	*Appendix A of EFSA Journal 2016;14(10):4584*	*N-EU*	*Trials GAP[(d)]: 15 g/a.s./ha, up to BBCH 32, outdoor, formulation types WG and OD E and RA: Wheat: 15 × <0.01 Rye: 1 × <0.01*	*0.01*	*0.01*		*0.01*[(c)]*	
Wheat grain	*New trials*	*N-EU*	*Trials GAP: 15 g a.s./ha, BBCH 39, outdoor, formulation type*	*-*	*E: 0.01*			

Commodity	***Source***	***Residue zone (N-EU, S-EU, EU, outside EU)***	***Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition***	***STMR (mg/kg)***	***HR (mg/kg)***	***Unrounded OECD calculator MRL (mg/kg)***	***Current EU MRL (mg/kg) ****	***MRL compliance***
	13-2127		*WG E and RA:2 × <0.01*		*RA: 0.01*			
Wheat grain	*New trials 13-2129*	*N-EU*	*Trials GAP: 9 g a.s./ha, BBCH 39, outdoor, formulation type WG E and RA:2 × <0.01*	*-*	*E: 0.01 RA: 0.01*			
Wheat grain	*New trials 14-2011*	*N-EU*	*Trials GAP: 15 g a.s./ha, BBCH 39-41, outdoor, formulation type WG E and RA: 2 × <0.01*	*-*	*E: 0.01 RA: 0.01*			
Wheat and rye grain[(b)]	*EFSA Journal 2012;10(11):2976*	*S-EU*	*GAP on which MRL/EU a.s. assessment is based: 20 g as/ha, BBCH 13 to 32, PHI 90d, outdoor, formulation type WG E: 4 × <0.01 RA: 4 × <0.01*	*E: 0.01 RA: 0.01*	*E: 0.01 RA: 0.01*		*0.01**	
Cereal grain Wheat →extrapolated to rye	*Appendix A of EFSA Journal 2016;14(10):4584*	*S-EU*	*Trials GAP(d): 15 g/a.s./ha, up to BBCH 32, outdoor, formulation types WG and OD E and RA: Wheat:12 × <0.01 Triticale: 1 × <0.01*	*0.01*	*0.01*		*0.01*[(c)]*	
Cereal grain Wheat →extrapolated to rye	*Overall supporting data for cGAP*	*N-EU & S-EU*	*E and RA: Wheat:58 × <0.01 Triticale:1 × <0.01*	*0.01*	*0.01*		*0.01*[(c)]*	*Yes*
Wheat and rye straw[(a)]	*EFSA Journal 2012;10(11):2976*	*N-EU*	*GAP on which MRL/EU a.s. assessment is based: 20 g as/ha, BBCH 13 to 32, PHI 90d, outdoor, formulation type WG E: 18 × <0.05 RA: 18 × <0.05*	*E: 0.05 RA: 0.05*	*E: 0.05 RA: 0.05*		*0.05**	

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***
Cereal straw	*Appendix A of EFSA Journal 2016;14(10):4584*	*N-EU*	*Trials GAP[(d)]: 15 g/a.s./ha, up to BBCH 32, outdoor, formulation types WG and OD E and RA: Wheat: 15 × <0.05 Rye:1 × <0.05*	*0.05*	*0.05*		*No need to derived a MRL*	
Wheat straw	*New trials 13-2127*	*N-EU*	*Trials GAP: 15 g a.s./ha, BBCH 39, outdoor, formulation type WG E and RA: 2 × <0.05*	*-*	*E: 0.05 RA: 0.05*			
Wheat straw	*New trials 13-2129*	*N-EU*	*Trials GAP: 9 g a.s./ha, BBCH 39, outdoor, formulation type WG E and RA: 2 × <0.05*	*-*	*E: 0.05 RA: 0.05*			
Wheat straw	*New trials 14-2011*	*N-EU*	*Trials GAP: 15 g a.s./ha, BBCH 39-41, outdoor, formulation type WG E and RA: 2 × <0.05*		*E: 0.05 RA: 0.05*			
Wheat straw	*New trials 14-2017*	*N-EU*	*Trials GAP: 9 g a.s./ha, BBCH 39, outdoor, formulation type WG E and RA: 2 × <0.05*		*E: 0.05 RA: 0.05*			
Wheat and rye straw[(b)]	*EFSA Journal 2012;10(11):2976*	*S-EU*	*GAP on which MRL/EU a.s. assessment is based: 20 g a.s./ha, BBCH 13 to 32, PHI 90d, outdoor, formulation type WG E: 4 × <0.05 RA: 4 × <0.05*	*E: 0.05 RA: 0.05*	*E: 0.05 RA: 0.05*		*0.05**	
Cereal straw	*Overall supporting data for cGAP*	*N-EU & S-EU*	*Wheat: 46 × <0.05; Rye:1 × <0.05*	*0.05*	*0.09*		*No need to derived a MRL*	

* *Source of EU MRL: Article 12 of Regulation (EC) No 396/2005 and Commission Regulation (EU) No 289/2014*

(a) Combined dataset on wheat, rye and triticale supporting the critical NEU GAP. 15 trials performed at more critical GAP (BBCH 39 instead of 32) but acceptable as <LOQ.
(b) Combined dataset on wheat, rye and triticale supporting the critical SEU GAP. All trials performed at more critical GAP (BBCH 39 instead of 32) but acceptable as residues <LOQ.
(c) derived from the merged data set
(d) Two types of formulations have been used: an OD (representative formulation) and a WG. No differences in terms of residues are expected applying the WG or the OD formulations.

7.3.3.2 Conclusion on the magnitude of residues in plants

~~Conclusion on the magnitude of residues in plants is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

Sufficient trials on cereals (wheat) are available to support the proposed uses. Extrapolation from wheat to rye and triticale is possible (SANTE/2019/12752 - revision1 - 10 May 2023).

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

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.
The trials in study no. 14-2011 and 14-2017 are not independent (same location, same date). Only 14-2011 study regarding the Northern zone was consider.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The active substance mesosulfuron-methyl is authorised in EU for use on crops that might be fed to livestock, so dietary burden calculation was performed in EFSA reasoned opinion on the review of the existing maximum residue levels/import tolerances for mesosulfuron-methyl according to Article 12 of Regulation (EC) No 396/2005.

Nonetheless in this document, the additional calculation of the dietary burden was conducted based on requested uses of JME-HER 12 OD. The modelling was performed by Excel spreadsheet Animal model 2017.

The input values and results of the dietary burden calculations are summarised below. For the evaluation data included in EFSA Journal 2012;10(11):2976 were applied.

Table 7.3-9: Input values for the dietary burden calculation - mesosulfuron-methyl

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: mesosulfuron-methyl				
Cereal grain and bran	0.01	Median residue[(a)] (EFSA, 2012)	0.01	Median residue[(a)] (EFSA, 2012)
Cereal straw	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)

(a): Considering that mesosulfuron is applied at an early growth stage and that residues were all found to be below the LOQ, residues are not expected to concentrate in the processed fractions; a default processing factor was therefore not used.

Table 7.3-10: Results of the dietary burden calculation- mesosulfuron -methyl

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.002	0.002	0.05	0.05	Dairy cattle	Wheat	milled bypdts	No	
Cattle (dairy only)	0.002	0.002	0.05	0.05	Dairy cattle	Wheat	milled bypdts	No	
Sheep (all diets)	0.003	0.003	0.07	0.07	Lamb	Wheat	milled bypdts	No	
Sheep (ewe only)	0.002	0.002	0.07	0.07	Ram/Ewe	Wheat	milled bypdts	No	
Swine (all diets)	0.001	0.001	0.05	0.05	Swine (finishing)	Wheat	milled bypdts	No	
Poultry (all diets)	0.002	0.002	0.03	0.03	Poultry layer	Wheat	milled bypdts	No	
Poultry (layer only)	0.002	0.002	0.03	0.03	Poultry layer	Wheat	milled bypdts	No	
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"									
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".									

The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw for ruminants, swine and poultry. No further evaluation is required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Not relevant. The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw hence no livestock feeding studies are required.

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

~~Data on magnitude of residues in processed commodities for all crops under consideration is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

As residues in wheat grain are below the LOQ (<0.01 mg/kg) at the intended maximum application rate of 15 g a.s./ha, studies on the effects of processing on the nature of the residues are not required.

7.3.5.2 Conclusion on processing studies

~~Conclusion on processing studies is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

As residues in wheat grain are below the LOQ (<0.01 mg/kg) at the intended maximum application rate of 15 g a.s./ha, studies on the effects of processing on the nature of the residues are not required.

7.3.6 Magnitude of residues in representative succeeding crops

~~Data on magnitude of residues in representative succeeding crops is included in Renewal RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.~~

The crops under consideration can be grown in rotation. However, based on the confined rotational crop 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 the normal application rate and that the primary use of this active substance is authorised on cereal crops, it can be concluded that mesosulfuron-methyl residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that mesosulfuron-methyl is applied in compliance with the GAPs of IMS+MSM+MPR OD 42 (2+10+30) / JME-HER 12 OD.

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

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. In accordance with Reg. 284/2013 no further data are required.

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

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

7.3.8.1 Input values for the consumer risk assessment

The acute and chronic consumer risk assessment for mesosulfuron-methyl has been performed with MRL values included in Reg. (EU) 289/2014. No Conversion Factors have been applied.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition in plants: mesosulfuron-methyl				
Intended uses				
Wheat Triticale Rye	0.01	EU MRL*	Not relevant. No ARfD derived, not necessary.	
Further uses				
All other commodities of plant and products animal origin	variable	EU MRL*	Not relevant. No ARfD derived, not necessary.	

* Reg. (EC) No Reg. (EU) No 289/2014

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (https://www.efsa.europa.eu/). This exposure assessment model contains the relevant European food consumption data for different

subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

Table 7.3-12: Consumer risk assessment - mesosulfuron-methyl

ADI	1 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	0.19% (based on diet: NL toddler) with the highest contributors: 0.12% Milk: Cattle 0.01% Apples 0.01% Maize/corn
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	not relevant
ARfD	no ARfD derived, not necessary
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	not relevant
NTMDI (% ADI) **	not relevant
NEDI (% ADI)**	not relevant
NESTI (% ARfD) **	not relevant

The potential chronic dietary exposure was compared to the ADI of 1.0 mg/kg bw/day and TMDI values were achieved. Input values for all commodities were derived from EU MR, representing the worst-case scenario. The highest chronic exposure was calculated for NL toddler diet, representing 0.19% of the ADI. As ARfD was not deemed necessary, acute risk assessment is not relevant.

The proposed uses of mesosulfuron-methyl in the formulation JME-HER 12 OD does not represent unacceptable acute and chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of two active substances, but an acute reference dose (ARfD) has been allocated only for one active substance. Therefore, combined acute exposure cannot be conducted.

7.4.1 Acute consumer risk assessment from combined exposure

Not relevant.

7.4.2 Chronic consumer risk assessment from combined exposure

Not relevant.

7.5 References

EFSA (European Food Safety Authority), 2016, *Peer review of the pesticide risk assessment of the active substance iodosulfuron-methyl-sodium (approved as iodosulfuron)*, EFSA Journal 2016;14(4):4453

EFSA (European Food Safety Authority), 2012, *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

EFSA (European Food Safety Authority), 2016, *Peer review of the pesticide risk assessment of the active substance mesosulfuron (variant evaluated mesosulfuron-methyl)*, EFSA Journal 2016;14(10):4584

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

Appendix to EFSA (European Food Safety Authority), 2016 Conclusion on the peer review of the pesticide risk assessment *of the active substance mesosulfuron EFSA Journal 2016;14(10):4584, 97 pp. doi:10.2903/j.efsa.2016.4584*

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

Appendix 1 Lists of data considered in support of the evaluation

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
-	-	-	-	-	-

List of unprotected data referred to by the applicant and relied on, but already evaluated

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.1 / 01	*Kaussmann, M.*	*2019*	*Storage stability of foramsulfuron, iodosulfuron-methyl and their metabolites AE F153745, AE F092944, AE F059411 and AE 0031838 in wheat (grain, green material, straw) for 24 months - Interim report* *Report No.: P642176501, Edition Number: M-635482-02-1* *Bayer AG, Crop Science Division, Monheim, Germany* *... amended: 2019-04-23* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*

KCA 6.1 / 02 ***... also filed:*** ***KCP 5.2.1 / 01***	*Stuke, S.*	*2015*	*Modification 001 of analytical method 01360 for the determination of amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl, and foramsulfuron in samples from plant origin by HPLC-MS/MS* *Report No.: MR-15/090, Edition Number: M-537921-01-1* *Bayer CropScience AG, Monheim, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 01 ***... also filed:*** ***KCA 6.3.1.2 / 01*** ***KCP 5.1.2 / 01***	*Stuke, S.; Kerkering, S.*	*2018*	*Amendment no. 2: Determination of the residues of BYH 18636, iodosulfuron-methyl-sodium, mefenpyr-diethyl and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 12.6 and thiencarbazone-methyl WG 70 in the field in Germany, Spain and Portugal* *Report No.: 13-2127, Edition Number: M-503498-03-1* *Bayer AG, Crop Science Division, Monheim, Germany* *... amended: 2018-08-31* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 02 ***... also filed:*** ***KCA 6.3.1.2 / 02*** ***KCP 5.1.2 / 02***	*Stuke, S.; Kerkering, S.*	*2018*	*Amendment no. 2: Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methylsodium and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 15 and thiencarbazone-methyl WG 70 in the field in Belgium, the Netherlands and Italy* *Report No.: 13-2129, Edition Number: M-506719-03-1* *Bayer AG, Crop Science Division, Monheim, Germany* *... amended: 2018-08-31* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 03 ***... also filed:*** ***KCA 6.3.1.2 / 03***	*Braune, M.; van Berkum, S.*	*2017*	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 21.15 in Germany, the United Kingdom, southern France and Italy* *Report No.: 14-2011, Edition Number: M-594771-01-1* *Bayer AG, Crop Science Division, Monheim, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*

KCA 6.3.1.1 / 04 ***... also filed:*** ***KCA 6.3.1.2 / 04***	*Braune, M.; van Berkum, S.*	*2018*	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 26.25 in Germany, the United Kingdom, southern France and Italy* *Report No.: 14-2017, Edition Number: M-611796-01-1* *Bayer AG, Crop Science Division, Monheim, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 05	*Ziske, J.; Gabriel, E.; Andre, M.*	*2017*	*Determination of the residues of iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & MPR OD 037.5 in Germany and Denmark* *Report No.: 16-2029, Edition Number: M-610268-01-1* *SGS Institut Fresenius GmbH, Taunusstein, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 06 ***... also filed:*** ***KCP 5.1.2 / 03***	*Mahlo, C.; Gabriel, E.; Vagt, I.; Meyer, M.*	*2017*	*Determination of the residues of amidosulfuron and iodosulfuron-methyl-sodium in/on wheat and barley after spray application of AMS & IMS & MPR OD 375 in Germany, Denmark, Poland and the United Kingdom* *Report No.: 16-2030, Edition Number: M-612290-01-1* *SGS Institut Fresenius GmbH, Taunusstein, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 07	*Mahlo, C.; Vagt, I.; Meyer, M.*	*2017*	*Determination of the residues of amidosulfuron and iodosulfuron-methyl-sodium in/on wheat and barley after spray application of AMS & IMS & MPR WG 26.25 in Germany, Poland and the United Kingdom* *Report No.: 16-2037, Edition Number: M-612291-01-1* *SGS Institut Fresenius GmbH, Taunusstein, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 08	*Meyer, M.; Gabriel, E.*	*2017*	*Determination of the residues of fenoxaprop-P-ethyl and iodosulfuron-methyl-sodium in/on winter wheat after spray application of FPP & IMS & MPR EC 96 in Germany and Denmark* *Report No.: M-610265-01-1* *SGS Institut Fresenius GmbH, Taunusstein, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*

KCA 6.3.1.1 / 09	*Mahlo, C.; Gabriel, E.; Meyer, M.*	*2017*	*Determination of the residues of amidosulfuron-sodium, iodosulfuron-methyl-sodium and mesosulfuron-methyl-sodium in/on wheat after spray application of AMS & IMS & MSM & MPR WG 18 in Germany, the United Kingdom and Hungary* *Report No.: 16-2041, Edition Number: M-600589-02-1* *SGS Institut Fresenius GmbH, Taunusstein, Germany* *... amended: 2017-11-02* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.1 / 10	*Meyer, M.; Gabriel, E.*	*2017*	*Determination of the residues of iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on spring wheat and spring barley, after spray application of IMS & MSM & MPR OD 307.5 in Germany and the United Kingdom* *Report No.: 16-2043, Edition Number: M-610266-01-1* *SGS Institut Fresenius GmbH, Taunusstein, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.2 / 01 *... also filed:* *KCA 6.3.1.1 / 01* *KCP 5.1.2 / 01*	*Stuke, S.; Kerkering, S.*	*2018*	*Amendment no. 2: Determination of the residues of BYH 18636, iodosulfuron-methyl-sodium, mefenpyr-diethyl and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 12.6 and thiencarbazone-methyl WG 70 in the field in Germany, Spain and Portugal* *Report No.: 13-2127, Edition Number: M-503498-03-1* *Bayer AG, Crop Science Division, Monheim, Germany* *... amended: 2018-08-31* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.2 / 02 *... also filed:* *KCA 6.3.1.1 / 02* *KCP 5.1.2 / 02*	*Stuke, S.; Kerkering, S.*	*2018*	*Amendment no. 2: Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methylsodium and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 15 and thiencarbazone-methyl WG 70 in the field in Belgium, the Netherlands and Italy* *Report No.: 13-2129, Edition Number: M-506719-03-1* *Bayer AG, Crop Science Division, Monheim, Germany* *... amended: 2018-08-31* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*

KCA 6.3.1.2 / 03 *... also filed:* *KCA 6.3.1.1 / 03*	*Braune, M.;* *van Berkum, S.*	*2017*	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 21.15 in Germany, the United Kingdom, southern France and Italy* *Report No.: 14-2011, Edition Number: M-594771-01-1* *Bayer AG, Crop Science Division, Monheim, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*
KCA 6.3.1.2 / 04 *... also filed:* *KCA 6.3.1.1 / 04*	*Braune, M.;* *van Berkum, S.*	*2018*	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 26.25 in Germany, the United Kingdom, southern France and Italy* *Report No.: 14-2017, Edition Number: M-611796-01-1* *Bayer AG, Crop Science Division, Monheim, Germany* *GLP/GEP: Yes* *unpublished*	*No*	*Bayer*

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

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

Iodosulfuron-Methyl-Sodium

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	*Heinemann, O.*	*2004*	*Modification M001 to method 00815 for the determination of residues of amidosulfuron, iodosulfuron-methyl-sodium including metabolite metsulfuron-methyl, foramsulfuron and mesosulfuron-methyl in/on flax and wheat matrices by HPLC-MS/MS* *Bayer CropScience,* *Report No.: 00815/M001,* *Report includes Trial Nos.: P602033000* *Edition Number: M-226888-01-1* *Date: 2004-01-30* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*

KCA 6.2.1	*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,* *Edition Number: M-182772-01-1* *EPA MRID No.: 45108921* *Date: 1998-11-16* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*
KCA 6.2.1	*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 CropScience*
KCA 6.2.2	*Moss, T.; D'Souza, R. A.; Reynolds, C. M. M.*	*1999*	*Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues Code: (14C)-AE F115008* *AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom* *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*	*N*	*Bayer CropScience*
KCA 6.2.3	*Reynolds, C. M. M.; Swalwell, L. M.*	*1999*	*Ruminant - Metabolism, distribution and nature of residues in milk and edible tissues (14C) AE F115008 Code: AE F115008* *AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom* *Bayer CropScience,* *Report No.: C005678,* *Report includes Trial Nos.: TOX95290*	*N*	*Bayer CropScience*

			Edition Number: M-192483-01-1 *EPA MRID No.: 45108924* *Date: 1999-12-15* *GLP/GEP: yes, unpublished*		
KCA 6.3.1	*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) 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*	*N*	*Bayer CropScience*
KCA 6.3.1	*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 CropScience*
KCA 6.3.1	*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*	*N*	*Bayer CropScience*

			GLP/GEP: yes, unpublished		
KCA 6.3.1	*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,* *Report No.: A59541,* *Edition Number: M-143212-01-1* *Date: 1998-05-18* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*
KCA 6.3.1	*Bourgade, C.*	*2014*	*Residue trial tables - Iodosulfuron-methyl-sodium - Annex I Renewal* *Bayer CropScience* *Bayer CropScience,* *Report No.: M-471100-01-1,* *Edition Number: M-471100-01-1, updated: M-471100-02-1* *Date: 2014-06-26, updated July 2014* *GLP/GEP: n.a., unpublished*	*N*	*Bayer CropScience*
KCA 6.3.1	*Davies, P.*	*2002*	*Residues in wheat European Union (Southern zone) 2001 Biopower® Iodosulfuron-methyl-sodium (5 %) Mefenpyr-diethyl (15 %) Code: AE F115008 02 WG20 B301* *Aventis CropScience GmbH, Frankfurt am Main, Germany* *Bayer CropScience,* *Report No.: C020875,* *Edition Number: M-210317-01-1* *Date: 2002-07-09* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*
KCA 6.3.1	*Freitag, T.*	*2004a*	*Determination of residues of iodosulfuron-methyl-sodium and mefenpyr-diethyl in/on wheat following spray application of AE F115008 02 1L35 A2 400 OD in the field in Italy, Spain and Southern France* *Bayer CropScience,* *Report No.: RA-2616/03,* *Report includes Trial Nos.:* *0226-03* *0489-03*	*N*	*Bayer CropScience*

			0490-03 *0491-03* *R20030226/6* *R20030489/7* *R20030490/0* *R20030491/9* *Edition Number: M-231305-02-1* *Date: 2004-05-10* *GLP/GEP: yes, unpublished*		
KCA 6.3.1	*Freitag, T.*	*2004b*	*Determination of residues of iodosulfuron-methyl-sodium and mefenpyr-diethyl in/on wheat following spray application of AE F115008 02 OD35 A1 400 OD and AE F115008 02 1L35 A2 400 OD in the field in Sweden, Germany, Great Britain and Northern France* *Bayer CropScience,* *Report No.: RA-2615/03,* *Report includes Trial Nos.:* *0225-03* *0492-03* *0493-03* *0494-03* *R20030225/8* *R20030492/7* *R20030493/5* *R20030494/3* *Edition Number: M-231310-02-1* *Date: 2004-05-10* *...Amended: 2007-01-16* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*
KCA 6.3.1	*Freitag, T.*	*2004c*	*Determination of residues of iodosulfuron-methyl-sodium and mefenpyr-diethyl in/on wheat following spray application of AE F115008 02 1L35 A2 (400 OD) in the field in Great Britain and Sweden* *Bayer CropScience,* *Report No.: RA-2751/03,* *Report includes Trial Nos.:* *R20031136/2* *R20031137/0*	*N*	*Bayer CropScience*

			Edition Number: M-230725-02-1 *Date: 2004-04-23* *...Amended: 2007-01-16* *GLP/GEP: yes, unpublished*		
KCA 6.6.2	*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 CropScience*
KCA 6.6.2	*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 CropScience*
KCA 6.6.2	*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 CropScience*
KCA 6.6.2	*Meyer, B. N.; Tull, P. J.*	*1999*	*Uptake of [14C]-AE F115008 residues from soil by rotational wheat, soybeans and sugarbeets under confined conditions*	*N*	*Bayer CropScience*

			AgrEvo USA Company, Environmental Chemistry, Pikeville, NC, USA *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 6.7.2	*Wrede, A.*	*1998d*	*Determination of the maximum residue level (MRL) for AE F115008 in cereal grain (statement) Code: AE F115008* *Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany* *Bayer CropScience,* *Report No.: C001479,* *Edition Number: M-182735-01-1* *Date: 1998-11-10* *GLP/GEP: no, unpublished* *...also filed: KCA 6.8 /01*	*N*	*Bayer CropScience*
KCA 6.8	*Wrede, A.*	*1998d*	*Determination of the maximum residue level (MRL) for AE F115008 in cereal grain (statement) Code: AE F115008* *Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany* *Bayer CropScience,* *Report No.: C001479,* *Edition Number: M-182735-01-1* *Date: 1998-11-10* *GLP/GEP: no, unpublished* *...also filed: KCA 6.7.2 /01*	*N*	*Bayer CropScience*
KCA 6.9	*Wrede, A.*	*1998e*	*TMDI estimation of dietary intake of AE F115008 from residues in cereals (statement) Code: AE F115008* *Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany* *Bayer CropScience,* *Report No.: C001482,* *Edition Number: M-182742-01-1* *Date: 1998-11-11* *GLP/GEP: no, unpublished*	*N*	*Bayer CropScience*

Mesosulfuron-Methyl

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	*Wrede, A.*	*2003*	*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-198612-04-1* *EPA MRID No.: 46229003* *Date: 2000-08-29* *...Amended: 2003-01-27* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*
KCA 6.1	*Wrede, A.*	*2003*	*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-198617-04-1* *EPA MRID No.: 46229002* *Date: 2000-08-29* *...Amended: 2003-01-27* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*
KCA 6.3.1	*Davies, P.*	*2000*	*Decline of residues in wheat European Union Northern Zone and Southern France 1999 Iodosulfuron-methyl-sodium + mesosulfuron-methyl + mefenpyr-diethyl water dispersible granule 1 % + 3 % + 9 %*	*N*	*Bayer CropScience*

			Code: AE F130060 02 WG13 A202 *Aventis CropScience GmbH, Frankfurt am Main, Germany* *Bayer CropScience,* *Report No.: C009932,* *Edition Number: M-199542-01-1* *Date: 2000-12-15* *GLP/GEP: yes, unpublished*		
KCA 6.3.1	*Freitag, T.*	*2004*	*Determination of residues of iodosulfuron-methyl-sodium, mesosulfuron-methyl-sodium and mefenpyr-diethyl in / on wheat following spray application of AE F115008 06 OD04 A1 (042 OD) in the field in Germany, Sweden, Great Britain, and Norther* *Bayer CropScience,* *Report No.: RA-2677/03,* *Edition Number: M-227133-02-1* *Date: 2004-01-30* *...Amended: 2007-01-16* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*
KCA 6.3.1	*Freitag, T.*	*2004*	*Determination of residues of iodosulfuron-methyl-sodium, mesosulfuron-methyl-sodium and mefenpyr-diethyl in / on wheat following spray application of AE F115008 06 OD04 A1 (042 OD) in the field in Italy and Southern France* *Bayer CropScience,* *Report No.: RA-2690/03,* *Edition Number: M-227096-02-1* *Date: 2004-01-30* *...Amended: 2007-01-16* *GLP/GEP: yes, unpublished*	*N*	*Bayer CropScience*

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

Not relevant. No new studies submitted.

A 2.1 Iodosulfuron-methyl-sodium

A 2.1.1 7.2.1 Stability of residues

A 2.1.1.1 7.2.1.1 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 report P642176501

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.1/01***
Title:	*Storage stability of foramsulfuron, iodosulfuron-methyl and their metabolites AE F153745, AE F092944, AE F059411 and AE 0031838 in wheat (grain, green material, straw) for 24 months - Final report*
Report:	*Kaussmann, M.; 2019; P642176501; M-635482-02-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16* *US EPA OCSPP 860.1380, Storage Stability Data*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The study was conducted to determine the stability of residues of foramsulfuron, iodosulfuron-methyl and their metabolites AE F153745, AE F092944, AE F059411 and AE 0031838 in fortified control samples of material of plant origin (wheat grain, green material and straw) for about 24 months under frozen storage conditions (≤-18°C). In the following summary only results for iodosulfuron-methyl and its metabolites (AE F059411 and AE 0031838) are shown.

Control samples of the respective plant matrices were fortified with iodosulfuron-methyl, AE F059411 and AE 0031838. The intended fortification level as scheduled within the study plan was 0.10 mg/kg for each analyte.

The fortification level of AE F059411 and AE 0031838 are expressed as parent equivalents. The fortified samples were stored in centrifuge tubes at ≤-18°C until analysis.

The spiking solutions of iodosulfuron-methyl were prepared in a mixture of acetonitrile/0.02 N triethylamin (4:1; v:v), whereas the spiking solutions of its metabolites (AE F059411 and AE 0031838) were prepared in a mixture of acetonitrile:water (1:1; v:v).

The residues of iodosulfuron-methyl were determined in/on wheat matrices according to the method 01376/M002 and quantified using external calibration with matrix-matched standards.

The residues of AE F059411 and AE 0031838 were determined in/on wheat according to the method 01514 and quantified using external calibration with matrix-matched standards.

In the method 01376/M002 residues of iodosulfuron-methyl were extracted twice from a 5-g specimen with a 100 mL mixture of acetonitrile/ 0.02 M trimethylamine in water (80:20, v:v). Residues of iodosulfuron-methyl were determined without further clean-up by reversed phase HPLC-MS/MS.

In the method 01514 residues of iodosulfuron-methyl metabolites were extracted twice from 5-g specimen with a 100 mL mixture of acetonitrile and water (50:50, v:v).. Residues of AE 0031838 were determined without further clean-up by HILIC HPLC-MS/MS. Residues of AE F059411 were determined with reversed phase HPLC-MS/MS after a clean-up of the raw extract with solid-liquid partition on a diatomaceous earth cartridge (SLE; ChemElut).

In both methods, all compounds were detected in positive electrospray ionization mode, quantified using matrix-matched calibration standards and expressed as parent equivalents.

The Limits of Quantification (LOQ) for all compounds was 0.5 µL/L corresponding to 0.01 mg/kg in plant material (expressed as parent equivalents). During each set of analysis, a calibration curve (1/x weighted linear regression) was established with at least five concentration levels and used for the quantitation of each analyte in each sample material. For each calibration curve, the correlation coefficient R was above 0.99.

For each sample material, five spiked samples and one control sample were analyzed on day 0 (zero time analysis). In addition, three recoveries at the respective LOQ level and three recoveries at the respective 10-fold LOQ level were determined to validate the use of the method for analysis of the respective sample materials.

The remaining samples were stored in a deep-freezer at ≤-18°C. The temperature in the deep-freezer was recorded during the entire storage period. At each storage period except day 0, three fortified and three control samples of each tested plant material were removed from the deep-freezer and allowed to reach room temperature. Subsequently, two of the control samples of each sample material were fortified with the analytes to determine the concurrent recoveries (fortification levels were at the same magnitude as the spiked storage samples). All samples were extracted and analyzed concurrently.

Results and discussions

The performance of the analytical method was tested during the conduct of the whole study. Concurrent recoveries were deemed acceptable (between 70 and 110%) as shown in the table below.
For both untreated and treated samples, a sufficient number of samples has been tested for each storage period. In the control samples, the apparent residues were below 30% of the LOQ. The results of the spiked stored samples are summarised in the table below.
Iodosulfuron-methyl and its metabolites AE F059411 and AE 0031838 are stable in all tested matrices for at least 24 months under deep-freezer storage conditions (≤-18°C) except for AE 0031838 in wheat, green material (68% recovery after 24 months) for which it is recommended to analyse the residues within 587 days.

Table A 1: Summary of concurrent recoveries of iodosulfuron-methyl and its metabolites (AE F059411 and AE 0031838) in different matrices

Matrix	*Spike level (mg/kg)*	*Storage Interval (days)*	*Sample size (n)*	*Individual procedural recoveries (%)*	*Mean (%)*
Iodosulfuron-methyl					
Wheat (grain)	*0.10*	*29*	*2*	*92, 91*	*92*
		90	*2*	*102, 98*	*100*
		182	*2*	*100, 101*	*101*
		456	*2*	*98, 98*	*98*
		587	*2*	*100, 98*	*99*
		721	*2*	*103, 108*	*106*
Wheat (green material)	*0.10*	*29*	*2*	*89, 91*	*90*
		90	*2*	*100, 97*	*99*
		182	*2*	*98, 95*	*97*
		456	*2*	*97, 95*	*96*
		587	*2*	*104, 103*	*104*
		721	*2*	*101, 101*	*101*
Wheat (straw)	*0.10*	*29*	*2*	*101, 98*	*100*
		90	*2*	*104, 103*	*104*
		182	*2*	*105, 105*	*105*
		456	*2*	*99, 91*	*95*
		587	*2*	*107, 107*	*107*
		721	*2*	*100, 103*	*102*
AE F059411					
Wheat (grain)	*0.10*	*29*	*2*	*89, 94*	*92*
		90	*2*	*90, 96*	*93*
		182	*2*	*92, 91*	*92*
		456	*2*	*97, 100*	*99*
		587	*2*	*107, 105*	*106*
		721	*2*	*101, 107*	*104*
Wheat (green material)	*0.10*	*29*	*2*	*87, 89*	*88*
		90	*2*	*89, 93*	*91*
		182	*2*	*90, 90*	*90*
		456	*2*	*89, 97*	*93*
		587	*2*	*96, 101*	*99*
		721	*2*	*95, 92*	*94*
Wheat (straw)	*0.10*	*29*	*2*	*87, 87*	*87*

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean (%)
		90	2	74, 76	75
		182	2	81, 84	83
		456	2	84, 85	85
		587	2	86, 92	89
		721	2	90, 109	100
AE 0031838					
Wheat (grain)	0.10	29	2	96, 96	96
		90	2	101, 96	99
		182	2	106, 98	102
		456	2	79, 88	84
		587	2	101, 98	100
		721	2	99, 97	98
Wheat (green material)	0.10	29	2	102, 105	104
		90	2	94, 91	93
		182	2	88, 91	90
		456	2	90, 90	90
		587	2	86, 87	87
		721	2	97, 92	95
Wheat (straw)	0.10	29	2	90, 87	89
		90	2	97, 93	95
		182	2	81, 82	82
		456	2	107, 95	101
		587	2	106, 107	107
		721	2	98, 100	99

Table A 2: Stability of residues of iodosulfuron-methyl and its metabolite (AE F 059411, AE 0031838) in different matrices following storage at -18°C

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD (%)
Iodosulfuron-methyl sodium					
Wheat (grain)	0.10	0	5	104, 105, 99, 107, 103	104 ± 2.9
		29	3	95, 93, 96	95 ± 1.6
		90	3	96, 97, 93	95 ± 2.2
		182	3	105, 103, 102	103 ± 1.5
		456	3	104, 103, 106	104 ± 1.5

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD (%)
		587	3	110, 107, 109	109 ± 1.4
		721	3	111, 110, 114	112 ± 1.9
Wheat (green material)	0.10	0	5	104, 104, 103, 101, 104	103 ± 1.3
		29	3	90, 90, 92	91 ± 1.3
		90	3	97, 102, 107	102 ± 4.9
		182	3	102, 110, 101	104 ± 4.7
		456	3	103, 105, 105	104 ± 1.1
		587	3	93, 96, 96	95 ± 1.8
		721	3	94, 98, 98	97 ± 2.4
Wheat (straw)	0.10	0	5	97, 97, 97, 94, 94	96 ± 1.7
		29	3	98, 99, 98	98 ± 0.6
		90	3	103, 109, 108	107 ± 3.0
		182	3	110, 111, 107	109 ± 1.9
		456	3	103, 102, 107	104 ± 2.5
		587	3	107, 106, 103	105 ± 2.0
		721	3	105, 104, 104	104 ± 0.6
AE F 059411					
Wheat (grain)	0.10	0	5	93, 94, 97, 96, 94	95 ± 1.7
		29	3	92, 93, 90	92 ± 1.7
		90	3	95, 98, 96	96 ± 1.6
		182	3	95, 95, 95	95 ± 0.0
		456	3	102, 108, 107	106 ± 3.0
		587	3	107, 111, 108	109 ± 1.9
		721	3	105, 114, 114	111 ± 4.7
Wheat (green material)	0.10	0	5	96, 98, 94, 95, 97	96 ± 1.7
		29	3	88, 94, 89	90 ± 3.6
		90	3	89, 93, 90	91 ± 2.3
		182	3	93, 95, 96	95 ± 1.6
		456	3	96, 100, 99	98 ± 2.1
		587	3	98, 100, 102	100 ± 2.0
		721	3	95, 100, 103	99 ± 4.1
Wheat (straw)	0.10	0	5	87, 93, 87, 87, 86	88 ± 3.2
		29	3	88, 88, 90	89 ± 1.3
		90	3	79, 92, 77	83 ± 9.9
		182	3	86, 89, 84	86 ± 2.9

Matrix	***Spike level (mg/kg)***	***Storage Interval (days)***	***Sample size (n)***	***Individual procedural recoveries (%)***	***Mean ± RSD (%)***
		456	*3*	*87, 88, 90*	*88 ± 1.7*
		587	*3*	*94, 89, 70*	*84 ± 15*
		721	*3*	*94, 91, 107*	*97 ± 8.7*
AE 0031838					
Wheat (grain)	*0.10*	*0*	*5*	*74, 83, 72, 73, 72*	*75 ± 6.2*
		29	*3*	*93, 94, 97*	*95 ± 2.2*
		90	*3*	*92, 93, 93*	*93 ± 0.6*
		182	*3*	*91, 101, 97*	*96 ± 5.2*
		456	*3*	*83, 90, 86*	*86 ± 4.1*
		587	*3*	*105, 99, 105*	*103 ± 3.4*
		721	*3*	*106, 100, 106*	*104 ± 3.3*
Wheat (green material)	*0.10*	*0*	*5*	*100, 95, 95, 92, 93*	*95 ± 3.2*
		29	*3*	*82, 78, 78*	*79 ± 2.9*
		90	*3*	*96, 96, 97*	*96 ± 0.6*
		182	*3*	*81, 97, 88*	*89 ± 9.0*
		456	*3*	*80, 77, 71*	*76 ± 6.0*
		587	*3*	*79, 79, 77*	*78 ± 1.5*
		721	*3*	*67, 71, 67*	*68 ± 3.4*
Wheat (straw)	*0.10*	*0*	*5*	*79, 81, 77, 74, 80*	*78 ± 3.5*
		29	*3*	*80, 87, 91*	*86 ± 6.5*
		90	*3*	*91, 90, 89*	*90 ± 1.1*
		182	*3*	*80, 81, 79*	*80 ± 1.3*
		456	*3*	*99, 96, 97*	*97 ± 1.6*
		587	*3*	*93, 88, 91*	*91 ± 2.8*
		721	*3*	*96, 94, 98*	*96 ± 2.1*

Conclusion

The study results demonstrate that the residues of iodosulfuron-methyl and its metabolites are stable in wheat grain, green material and straw for at least 24 months (721 days) under deep-freezer storage conditions (≤-18°C) except for AE 0031838 in wheat, green material (68% recovery after 24 months) for which it is recommended to analyse the residues within 587 days.

A 2.1.1.1.2 Storage stability of residues in animal products

No new data submitted in the framework of this application.

A 2.1.1.2 7.2.1.2 Stability of residues in sample extracts

A 2.1.1.2.1 Storage stability of residues in plant sample extracts

No new data submitted in the framework of this application.

A 2.1.1.2.2 Storage stability of residues in animal sample extracts

No new data submitted in the framework of this application.

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

A 2.1.2.1 Nature of residue in primary crops

No new data submitted in the framework of this application.

A 2.1.2.2 Nature of residue in rotational crops

A 2.1.2.3 Nature of residues in processed commodities

No new data submitted in the framework of this application.

A 2.1.2.4 Nature of residues in livestock

No new data submitted in the framework of this application.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Cereals

Table A 3: Comparison of intended and critical EU GAPs

Type of GAP	***Number of applications***	***Application rate per treatment (kg as/ha)***	***Interval between application***	***Growth stage at last application (BBCH)***	***PHI (days)***
*Representative uses (EFSA, 2016)**	*1*	*0.010*	*39*	*39*	*-*
cGAP EU (Art. 12, EFSA, 2012)	*1*	*0.010*	*-*	*37*	*-*
Intended cGAP** for 102000008429 in Central Zone (33)	*1*	*0.0024*	*-*	*39*	*-*

** Residue trials conducted at 10-15 g ai/ha and GS 32-39*
*** Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0*

A 2.1.3.1.1 Study 13-2127

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/01***
Title:	*Amendment no. 2: Determination of the residues of BYH 18636 , iodosulfuron-methyl-sodium, mefenpyr-diethyl and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 12.6 and thiencarbazone-methyl WG 70 in the field in Germany, Spain and Portugal*
Report:	*Stuke, S.; Kerkering, S.; 2018; 13-2127; M-503498-03-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*Yes, see Appendix 5*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 4: Summary of the 13-2127 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as iodosulfuron-methyl-sodium)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)	PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium		
13-2127-01 Germany 49377 Langförden OT Repke Europe, North F 2013	Wheat, winter Julius	1) 09.10.2012 2) 21.06.2013 - 04.07.2013 3) 12.08.2013 - 02.09.2013	3.0	400	0.75	31.05.2013/0	39	green material grain straw	39 54 59 89 89	0.055 <0.05 <0.05 <0.01 <0.05	0 7 14 86 86	(g) 13-2127 (h) WG (iodosulfuron-methyl-sodium 0.6 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 1 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 136 days Analyte 1 green material: 216 days Analyte 1 grain: 135 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % mesosulfuron-methyl 3 % mefenpyr-diethyl 9 %

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)	PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium		
13-2127-02 Germany 51399 Burscheid Europe, North F 2013	Wheat, winter Winnetou	1) 29.10.2012 2) 17.06.2013 - 24.06.2013 3) 10.08.2013 - 31.08.2013	3.0	300	1.00	03.06.2013/0	39	green material grain straw	39 51 61 89 89	0.054 <0.05 <0.05 <0.01 <0.05	0 7 14 82 82	(g) 13-2127 (h) WG (iodosulfuron-methyl-sodium 0.6 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 1 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 137 days Analyte 1 green material: 213 days Analyte 1 grain: 136 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % mesosulfuron-methyl 3 % mefenpyr-diethyl 9 %

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.1.2 Study 13-2129

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/02***
Title:	*Amendment no. 2: Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methylsodium and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 15 and thiencarbazone-methyl WG 70 in the field in Belgium, the Netherlands and Italy*
Report:	*Stuke, S.; Kerkering, S.; 2018; 13-2129; M-506719-03-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 5: Summary of the study 13-2129 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as iodosulfuron-methyl-sodium)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium		
	(a)	(b)				(c)	(d)		(d)		(e)	(f)
13-2129-01 Belgium 6210 Villers-Perwin Europe, North F 2013	Wheat, winter Matrix	1) 20.10.2012 2) 18.06.2013 - 03.07.2013 3) 05.08.2013 - 12.08.2013	9.0	250	3.6	03.06.2013/0	39	green material grain straw	39 45 65 89 89	0.17 <0.05 <0.05 <0.01 <0.05	0 7 17 66 66	(g) 13-2129 (h) WG (iodosulfuron-methyl-sodium 3 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 1 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 153 days Analyte 1 green material: 217 days Analyte 1 grain: 152 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % mesosulfuron-methyl 3 % mefenpyr-diethyl 9 %

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium		
	(a)	(b)				(c)	(d)		(d)		(e)	(f)
13-2129-02 Netherlands 1774 PE Slootdorp Europe, North F 2013	Wheat, winter Winter Malt	1) 01.11.2012 2) 15.07.2013 - 01.08.2013 3) 26.08.2013 - 09.09.2013	9.0	400	2.3	17.06.2013/0	39	green material grain straw	39 55 55 89 89	0.20 <0.05 <0.05 <0.01 <0.05	0 7 14 74 74	(g) 13-2129 (h) WG (iodosulfuron-methyl-sodium 3 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte1 straw, green material: 0.05 mg/kg Analyte 1 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 131 days Analyte 1 green material: 203 days Analyte 1 grain: 130 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % mesosulfuron-methyl 3 % mefenpyr-diethyl 9 %

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.1.3 Study 14-2011

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD. The trials in study no. 14-2011 and 14-2017 were not deemed as independent (same location, same date). Only 14-2011 study regarding the Northern zone was consider.

Reference:	***KCA 6.3.1.1/03***
Title:	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 21.15 in Germany, the United Kingdom, southern France and Italy*
Report:	*Braune, M.; van Berkum, S.; 2017; 14-2011; M-594771-01-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market* *OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)* *US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial*
Deviations:	*none*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 6: Summary of the 14-2011 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as iodosulfuron-methyl-sodium)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 AE F114844 as iodosulfuron-methyl-sodium		
	(a)	(b)				(c)	(d)		(d)		(e)	(f)
14-2011-01 Germany 51399 Burscheid Europe, North F 2014	Wheat, winter Tobak	1) 30.09.2013 2) 26.05.2014 - 02.06.2014 3) 15.07.2014 - 15.08.2014	3.0	300	0.99	05.05.2014/0	39	green material grain straw	39 45 49 89 89	0.070 <0.05 <0.05 <0.01 <0.05	0 7 14 84 84	(g) 14-2011 (h) WG (iodosulfuron-methyl-sodium 0.9 % ,mefenpyr-diethyl 13.5 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 2.25 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain, straw: 00815/M001 (k) LOQ: Analyte green material, straw: 0.05 mg/kg Analyte grain: 0.01 mg/kg (l) Method Validation Data: method 00815/M001 (m) Storage: Analyte 1 green material: 427 days Analyte 1 grain: 339 days Analyte 1 straw: 337 days Appl 1 +Biopower 1.0 L/ha

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 AE F114844 as iodosulfuron-methyl-sodium		
	(a)	(b)				(c)	(d)		(d)		(e)	(f)
14-2011-02 United Kingdom SG8 8SS Great Chishill, Royston Europe, North F 2014	Wheat, winter Solstice	1) 11.10.2013 2) 01.06.2014 - 16.06.2014 3) 25.07.2014 - 14.08.2014	3.0	200	1.5	19.05.2014/0	41	green material grain straw	41 51 65 89 89	0.070 <0.05 <0.05 <0.01 <0.05	0 8 16 72 72	(g) 14-2011 (h) WG (iodosulfuron-methyl-sodium 0.9 % ,mefenpyr-diethyl 13.5 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 2.25 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain, straw: 00815/M001 (k) LOQ: Analyte green material, straw: 0.05 mg/kg Analyte grain: 0.01 mg/kg (l) Method Validation Data: method 00815/M001 (m) Storage: Analyte 1 green material: 413 days Analyte 1 grain: 337 days Analyte 1 straw: 335 days Appl 1 +Biopower 1.0 L/ha

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.1.4 Study 14-2017

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD. The trials in study no. 14-2011 and 14-2017 were not deemed as independent (same location, same date). Only 14-2011 study regarding the Northern zone was consider.

Reference:	***KCA 6.3.1.1/04***
Title:	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 26.25 in Germany, the United Kingdom, southern France and Italy*
Report:	*Braune, M.; van Berkum, S.; 2018; 14-2017; M-611796-01-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market* *OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)* *US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 7: Summary of the study 14-2017 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as iodosulfuron-methyl-sodium)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 AE F114844		
	(a)	(b)				(c)	(d)		(d)		(e)	(f)
14-2017-01 Germany 51399 Burscheid Europe, North F 2014	Wheat, winter Tobak	1) 30.09.2013 2) 26.05.2014 - 02.06.2014 3) 15.07.2014 - 15.08.2014	9.0	300	3.0	05.05.2014/0	39	green material grain straw	39 45 49 89 89	0.17 <0.05 <0.05 <0.01 <0.05	0 7 14 84 84	(g) 14-2017 (h) WG (iodosulfuron-methyl-sodium 4.5 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 3.75 % ,mefenpyr-diethyl 13.5 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain, straw: 00815/M001 (k) LOQ: Analyte green material, straw: 0.05 mg/kg Analyte grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 338 days Analyte 1 green material: 428 days Analyte 1 grain: 340 days Appl 1 +Biopower 1.0 L/ha

Trial No. / Location / EU zone / Year (a)	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment: g a.s./ha	Application rate per treatment: Water (L/ha)	Application rate per treatment: g a.s./hL	Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg) Analyte 1 AE F114844	PHI (days) (e)	Details on trial (f)
14-2017-02 United Kingdom SG8 8SS Great Chishill, Royston Europe, North F 2014	Wheat, winter Solstice	1) 11.10.2013 2) 01.06.2014 - 16.06.2014 3) 25.07.2014 - 14.08.2014	9.0	200	4.5	19.05.2014/0	41	green material grain straw	41 51 65 89 89	0.17 <0.05 <0.05 <0.01 <0.05	0 8 16 72 72	(g) 14-2017 (h) WG (iodosulfuron-methyl-sodium 4.5 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 3.75 % ,mefenpyr-diethyl 13.5 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain, straw: 00815/M001 (k) LOQ: Analyte green material, straw: 0.05 mg/kg Analyte grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 336 days Analyte 1 green material: 414 days Analyte 1 grain: 338 days Appl 1 +Biopower 1.0 L/ha

(a)	According to CODEX Classification / Guide	(e)	Days after last application (Label pre-harvest interval, PHI, underline)	(h)	Formulation type	(l)	Method validation
(b)	Only if relevant	(f)	Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included	(i)	Application method	(m)	Storage (max)
(c)	Year must be indicated			(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code	(g)	Study reference	(k)	LOQ		P based on production date
G	greenhouse F field	*	prior to last treatment	**	residue in control	#	no data available

A 2.1.3.1.5 Study 16-2029

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/05***
Title:	*Determination of the residues of iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & MPR OD 037.5 in Germany and Denmark*
Report:	*Ziske, J.; Gabriel, E.; Andre, M.; 2017; 16-2029; M-610268-01-1*
Authority registration No:	
Guideline(s):	*REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*supplementary data*
Duplication (if vertebrate study):	

Table A 8: Summary of the 16-2029 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as AE F114844), Analyte 2: AE 0031838 (determined as AE 0031838, calculated as AE F114844), Analyte 3: BCS-AA40997 or AE F059411 (determined as BCS-AA40997 = AE F059411, calculated as AE F114844)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1	Analyte 2	Analyte 3		
	(a)	(b)				(c)	(d)		(d)	iodosulfuron-methyl-sodium	AE 0031838	BCS-AA40997	(e)	(f)
16-2029-01 Germany 49328 Melle Europe, North F 2016	Wheat, winter Julius	1) 15.10.2015 2) 08.06.2016 - 17.06.2016 3) 26.07.2016	7.5	200	3.8	06.05.2016/0	32	green material grain straw	32 75 89 89	0.27 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 48 81 81	(g) 16-2029 (h) OD (iodosulfuron-methyl-sodium 7.5 g/L ,mesosulfuron-methyl 7.5 g/L ,mefenpyr-diethyl 22.5 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2, 3 straw, green material, grain: 01514 Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 238 days Analyte 2, 3 straw: 356 days Analyte 1 green material: 308 days Analyte 2, 3 green material: 460 days Analyte 1 grain: 227 days Analyte 2, 3 grain: 345 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)			PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
16-2029-02 Denmark 6400 Sønderborg Europe, North F 2016	Wheat, winter Dakanto	1) 22.09.2015 2) 05.06.2016 - 08.06.2016 3) 25.07.2016	7.5	200	3.8	12.05.2016/0	32	green material grain straw	32 75 89 89	0.26 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 48 74 74	(g) 16-2029 (h) OD (iodosulfuron-methyl-sodium 7.5 g/L ,mesosulfuron-methyl 7.5 g/L ,mefenpyr-diethyl 22.5 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2, 3 straw, green material, grain: 01514 Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 239 days Analyte 2, 3 straw: 357 days Analyte 1 green material: 302 days Analyte 2, 3 green material: 454 days Analyte 1 grain: 228 days Analyte 2, 3 grain: 346 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.1.6 Study 16-2030

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/06***
Title:	*Determination of the residues of amidosulfuron and iodosulfuron-methyl-sodium in/on wheat and barley after spray application of AMS & IMS & MPR OD 375 in Germany, Denmark, Poland and the United Kingdom*
Report:	*Mahlo, C.; Gabriel, E.; Vagt, I.; Meyer, M.; 2017; 16-2030; M-612290-01-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*Yes (see report)*
GLP/GEP:	*yes*
Acceptability:	*supplementary data*
Duplication (if vertebrate study):	

Table A 9: Summary of the 16-2030 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range of 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as AE F114844), Analyte 2: AE 0031838 (determined as AE 0031838, calculated as AE F114844), Analyte 3: BCS-AA40997 or AE F059411 (determined as BCS-AA40997 = AE F059411, calculated as AE F114844)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2030-01 Germany 24857 Fahrdorf Europe, North F 2016	Barley Zomerit	1) 15.09.2015 2) 25.05.2016 - 27.05.2016 3) 14.07.2016	3.7	200	1.9	13.05.2016/0	39	green material grain straw	39 75 89 89	<0.05 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 26 62 62	(g) 16-2030 (h) OD (amidosulfuron 100 g/L ,iodosulfuron-methyl-sodium 25 g/L ,mefenpyr-diethyl 250 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 176 days Analyte 2, 3 straw: 382 days Analyte 1 green material: 237 days Analyte 2, 3 green material: 455 days Analyte 1 grain: 176 days Analyte 2, 3 grain: 371 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2030-02 Germany 16845 Breddin Europe, North F 2016	Wheat Julius	1) 16.10.2015 2) 02.06.2016 - 08.06.2016 3) 20.07.2016	3.7	300	1.2	18.05.2016/0	39	green material grain straw	39 75 89 89	0.060 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 36 63 63	(g) 16-2030 (h) OD (amidosulfuron 100 g/L ,iodosulfuron-methyl-sodium 25 g/L ,mefenpyr-diethyl 250 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 173 days Analyte 2, 3 straw: 362 days Analyte 1 green material: 233 days Analyte 2, 3 green material: 442 days Analyte 1 grain: 174 days Analyte 2, 3 grain: 351 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2030-03 Denmark 6270 Tønder Europe, North F 2016	Barley Evergreen	1) 05.04.2016 2) 14.06.2016 - 16.06.2016 3) 15.08.2016	3.7	200	1.9	03.06.2016/0	39	green material grain straw	39 75 89 89	0.11 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 25 73 73	(g) 16-2030 (h) OD (amidosulfuron 100 g/L ,iodosulfuron-methyl-sodium 25 g/L ,mefenpyr-diethyl 250 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 144 days Analyte 2, 3 straw: 350 days Analyte 1 green material: 216 days Analyte 2, 3 green material: 434 days Analyte 1 grain: 144 days Analyte 2, 3 grain: 339 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2030-04 Poland 06-420 Konarzewo-Slawki Europe, North F 2016	Wheat Genius	1) 04.04.2016 2) 07.06.2016 - 19.06.2016 3) 08.08.2016 - 10.08.2016	3.7	300	1.2	06.06.2016/0	39	green material grain straw	39 75 89 89	0.060 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 22 63 63	(g) 16-2030 (h) OD (amidosulfuron 100 g/L ,iodosulfuron-methyl-sodium 25 g/L ,mefenpyr-diethyl 250 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 154 days Analyte 2, 3 straw: 343 days Analyte 1 green material: 214 days Analyte 2, 3 green material: 423 days Analyte 1 grain: 155 days Analyte 2, 3 grain: 332 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2030-05 United Kingdom Great Bently, Colchester, CO7 8RP Europe, North F 2016	Wheat Galant	1) 02.11.2015 2) 03.06.2016 - 18.06.2016 3) 10.08.2016 - 28.08.2016	3.7	200	1.9	17.05.2016/0	39	green material grain straw	39 75 89 89	<0.05 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 49 105 105	(g) 16-2030 (h) OD (amidosulfuron 100 g/L ,iodosulfuron-methyl-sodium 25 g/L ,mefenpyr-diethyl 250 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 132 days Analyte 2, 3 straw: 321 days Analyte 1 green material: 234 days Analyte 2, 3 green material: 443 days Analyte 1 grain: 133 days Analyte 2, 3 grain: 310 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field
(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment
(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.1.7 Study 16-2037

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/07***
Title:	*Determination of the residues of amidosulfuron and iodosulfuron-methyl-sodium in/on wheat and barley after spray application of AMS & IMS & MPR WG 26.25 in Germany, Poland and the United Kingdom*
Report:	*Mahlo, C.; Vagt, I.; Meyer, M.; 2017; 16-2037; M-612291-01-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*Yes (see report)*
GLP/GEP:	*yes*
Acceptability:	*supplementary data*
Duplication (if vertebrate study):	

Table A 10: Summary of the 16-2037 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as AE F114844), Analyte 2: AE 0031838 (determined as AE 0031838, calculated as AE F114844), Analyte 3: BCS-AA40997 or AE F059411 (determined as BCS-AA40997 = AE F059411, calculated as AE F114844)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2037-01 Germany 77694 Kehl-Bodersweier Europe, North F 2016	Barley Wootan	1) 25.09.2015 2) 07.05.2016 - 16.05.2016 3) 23.06.2016 - 29.06.2016	3.0	300	0.82	21.04.2016/0	39	green material grain straw	39 75 89 89	<0.05 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 36 63 63	(g) 16-2037 (h) WG (amidosulfuron-sodium 13.24 % ,iodosulfuron-methyl-sodium 1.25 % ,mefenpyr-diethyl 12.5 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1, 2 ,3 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg Analyte 2,3 green material, straw: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 242 days Analyte 2, 3 straw: 403 days Analyte 1 green material: 302 days Analyte 2, 3 green material: 468 days Analyte 1 grain: 238 days Analyte 2, 3 grain: 392 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2037-02 Poland 05-850 Piotrkówek Mali Europe, North F 2016	Wheat Tybalt	1) 15.03.2016 2) 05.06.2016 - 17.06.2016 3) 16.08.2016 - 18.08.2016	3.0	300	0.82	06.06.2016/0	39	green material grain straw	39 75 89 89	<0.05 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 24 71 71	(g) 16-2037 (h) WG (amidosulfuron-sodium 13.24 % ,iodosulfuron-methyl-sodium 1.25 % ,mefenpyr-diethyl 12.5 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1, 2 ,3 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg Analyte 2,3 green material, straw: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 188 days Analyte 2, 3 straw: 343 days Analyte 1 green material: 256 days Analyte 2, 3 green material: 427 days Analyte 1 grain: 184 days Analyte 2, 3 grain: 328 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)			PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
16-2037-03 United Kingdom CM22 6JD Ugley Green Europe, North F 2016	Wheat Galant	1) 02.11.2015 2) 01.06.2016 - 20.06.2016 3) 15.08.2016 - 30.08.2016	3.0	200	1.2	17.05.2016/0	39	green material grain straw	39 75 89 89	<0.05 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 48 105 105	(g) 16-2037 (h) WG (amidosulfuron-sodium 13.24 % ,iodosulfuron-methyl-sodium 1.25 % ,mefenpyr-diethyl 12.5 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1, 2 ,3 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg Analyte 2,3 green material, straw: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 174 days Analyte 2, 3 straw: 329 days Analyte 1 green material: 276 days Analyte 2, 3 green material: 416 days Analyte 1 grain: 170 days Analyte 2, 3 grain: 314 days

(a) According to CODEX Classification / Guide (e) Days after last application (Label pre-harvest interval, PHI, underline) (h) Formulation type (l) Method validation

(b)	*Only if relevant*	*(f)*	*Remarks may include: Climatic conditions; Reference to analytical method and*	*(i)*	*Application method*	*(m)*	*Storage (max)*
(c)	*Year must be indicated*		*information which metabolites are included*	*(j)*	*Method information*		*! based on date of analysis*
(d)	*Either growth stage description or BBCH Code*	*(q)*	*Study reference*	*(k)*	*LOQ*		*P based on production date*
G	*greenhouse* *F field*	*	*prior to last treatment*	**	*residue in control*	#	*no data available*

A 2.1.3.1.8 Study 16-2040

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/08***
Title:	*Determination of the residues of fenoxaprop-P-ethyl and iodosulfuron-methyl-sodium in/on winter wheat after spray application of FPP & IMS & MPR EC 96 in Germany and Denmark*
Report:	*Meyer, M.; Gabriel, E.; 2017; M-610265-01-1*
Authority registration No:	
Guideline(s):	*REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*supplementary data*
Duplication (if vertebrate study):	

Table A 11: Summary of the 16-2040 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as AE F114844), Analyte 2: AE 0031838 (determined as AE 0031838, calculated as AE F114844), Analyte 3: BCS-AA40997 or AE F059411 (determined as BCS-AA40997 = AE F059411, calculated as AE F114844)

Trial No. / Location / EU zone / Year (a)	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)			PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 AE F059411		
16-2040-01 Germany 49685 Emstek Europe, North F 2016	Wheat, winter Elixer	1) 26.10.2015 2) 08.06.2016 - 15.06.2016 3) 25.07.2016 - 27.07.2016	10	200	5.0	02.05.2016/ 0	32	green material grain straw	32 75 89 89	0.32 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 49 86 86	(g) 16-2040 (h) EC (fenoxaprop-P-ethyl 64 g/L iodosulfuron-methyl-sodium 8 g/L ,mefenpyr-diethyl 24 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2, 3 straw, green material, grain: 01514 Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 202 days Analyte 2, 3 straw: 363 days Analyte 1 green material: 287 days Analyte 2, 3 green material: 462 days Analyte 1 grain: 198 days Analyte 2, 3 grain: 348 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 AE F059411		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2040-02 Denmark 6640 Gelballe Europe, North F 2016	Wheat, winter Jensen	1) 25.09.2015 2) 02.06.2016 - 04.06.2016 3) 27.07.2016	10	200	5.0	10.05.2016/ 0	32	green material grain straw	32 75 89 89	0.39 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 49 78 78	(g) 16-2040 (h) EC (fenoxaprop-P-ethyl 64 g/L iodosulfuron-methyl-sodium 8 g/L ,mefenpyr-diethyl 24 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2, 3 straw, green material, grain: 01514 Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 202 days Analyte 2, 3 straw: 363 days Analyte 1 green material: 279 days Analyte 2, 3 green material: 454 days Analyte 1 grain: 198 days Analyte 2, 3 grain: 348 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field
(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment
(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.1.9 Study 16-2041

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/09***
Title:	*Determination of the residues of amidosulfuron-sodium, iodosulfuron-methyl-sodium and mesosulfuron-methyl-sodium in/on wheat after spray application of AMS & IMS & MSM & MPR WG 18 in Germany, the United Kingdom and Hungary*
Report:	*Mahlo, C.; Gabriel, E.; Meyer, M.; 2017; 16-2041; M-600589-02-1*
Authority registration No:	
Guideline(s):	*REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*supplementary data*
Duplication (if vertebrate study):	

Table A 12: Summary of the 16-2041 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as AE F114844), Analyte 2: AE 0031838 (determined as AE 0031838, calculated as AE F114844), Analyte 3: BCS-AA40997 or AE F059411 (determined as BCS-AA40997 = AE F059411, calculated as AE F114844)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)			PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
16-2041-01 Germany 25870 Oldeswort Europe, North F 2016	Wheat, winter Primus	1) 02.10.2015 2) 10.06.2016 - 12.06.2016 3) 07.08.2016	5.0	200	2.5	24.05.2016/0	39	green material grain straw	39 75 89 89	0.080 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 34 75 75	(g) 16-2041 (h) WG (amidosulfuron-sodium 5.3 % ,iodosulfuron-methyl-sodium 1 % ,mesosulfuron-methyl-sodium 3.13 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1 green material, straw: 0.05 mg/kg Analyte 2, 3 green material, straw: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 201 days Analyte 2, 3 straw: 344 days Analyte 1 green material: 275 days Analyte 2, 3 green material: 405 days Analyte 1 grain: 201 days Analyte 2, 3 grain: 333 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2041-02 Germany 79189 Bad Krozingen Europe, North F 2016	Wheat, winter Desamo	1) 30.10.2015 2) 30.05.2016 - 08.06.2016 3) 16.07.2016 - 21.07.2016	5.0	300	1.7	15.05.2016/0	39	green material grain straw	39 75 89 89	0.052 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 33 64 64	(g) 16-2041 (h) WG (amidosulfuron-sodium 5.3 % ,iodosulfuron-methyl-sodium 1 % ,mesosulfuron-methyl-sodium 3.13 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)			PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
														straw: 01514 (k) LOQ: Analyte 1 green material, straw: 0.05 mg/kg Analyte 2, 3 green material, straw: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 221 days Analyte 2, 3 straw: 364 days Analyte 1 green material: 284 days Analyte 2, 3 green material: 414 days Analyte 1 grain: 221 days Analyte 2, 3 grain: 353 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2041-03 United Kingdom Thetford IP24 2RL Europe, North F 2016	*Wheat, winter KW Tower*	*1) 18.11.2015 2) 29.05.2016 - 10.06.2016 3) 10.08.2016 - 31.08.2016*	*5.3*	*212*	*2.5*	*19.05.2016/0*	*39*	*green material grain straw*	*39 75 89 89*	*0.083 <0.05 <0.01 <0.05*	*<0.01 <0.01 <0.01 <0.01*	*<0.01 <0.01 <0.01 <0.01*	*0 46 103 103*	*(g) 16-2041 (h) WG (amidosulfuron-sodium 5.3 % ,iodosulfuron-methyl-sodium 1 % ,mesosulfuron-methyl-sodium 3.13 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain*

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)			PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 BCS-AA40997		
														and straw: 01514 *(k) LOQ:* *Analyte 1 green material, straw: 0.05 mg/kg* *Analyte 2, 3 green material, straw: 0.01 mg/kg* *Analyte 1, 2, 3 grain: 0.01 mg/kg* *(l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129* *(m) Storage:* *Analyte 1 straw: 178 days* *Analyte 2, 3 straw: 321 days* *Analyte 1 green material: 280 days* *Analyte 2, 3 green material: 410 days* *Analyte 1 grain: 178 days* *Analyte 2, 3 grain: 310 days*

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1	Analyte 2	Analyte 3		
	(a)	(b)				(c)	(d)		(d)	iodosulfuron-methyl-sodium	AE 0031838	BCS-AA40997	(e)	(f)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1	Analyte 2	Analyte 3		
	(a)	(b)				(c)	(d)		(d)	iodosulfuron-methyl-sodium	AE 0031838	BCS-AA40997	(e)	(f)

16-2041-04 Hungary 4461 Nyirtelek Europe, North F 2016	Wheat, winter Hyxtra	1) 16.10.2015 2) 19.06.2016 - 25.06.2016 3) 05.07.2016 - 06.07.2016	5.0	250	2.0	06.05.2016/0	39	green material grain straw	39 75 89 89	0.12 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 32 61 61	(g) 16-2041 (h) WG (amidosulfuron-sodium 5.3 % ,iodosulfuron-methyl-sodium 1 % ,mesosulfuron-methyl-sodium 3.13 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: Analyte 1 green material, grain and straw: 00815/M001 Analyte 2, 3 green material, grain and straw: 01514 (k) LOQ: Analyte 1 green material, straw: 0.05 mg/kg Analyte 2, 3 green material, straw: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 233 days Analyte 2, 3 straw: 376 days Analyte 1 green material: 293 days Analyte 2, 3 green material: 423 days Analyte 1 grain: 233 days Analyte 2, 3 grain: 365 days

(a)	*According to CODEX Classification / Guide*	*(e)*	*Days after last application (Label pre-harvest interval, PHI, underline)*	*(h)*	*Formulation type*	*(l)*	*Method validation*
(b)	*Only if relevant*	*(f)*	*Remarks may include: Climatic conditions; Reference to analytical method and*	*(i)*	*Application method*	*(m)*	*Storage (max)*
(c)	Year must be indicated		information which metabolites are included	(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code	(g)	Study reference	(k)	LOQ		P based on production date
G	greenhouse F field	*	prior to last treatment	**	residue in control	#	no data available

A 2.1.3.1.10 Study 16-2043

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.1/10***
Title:	*Determination of the residues of iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on spring wheat and spring barley, after spray application of IMS & MSM & MPR OD 307.5 in Germany and the United Kingdom*
Report:	*Meyer, M.; Gabriel, E.; 2017; 16-2043; M-610266-01-1*
Authority registration No:	
Guideline(s):	*REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*supplementary data*
Duplication (if vertebrate study):	

Table A 13: Summary of the 16-2043 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: iodosulfuron-methyl-sodium (determined as AE F114844, calculated as AE F114844), Analyte 2: AE 0031838 (determined as AE 0031838, calculated as AE F114844), Analyte 3: BCS-AA40997 or AE F059411 (determined as BCS-AA40997 = AE F059411, calculated as AE F114844)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 AE F114844		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2043-01 Germany 16831 Rheinsberg Europe, North F 2016	Barley, spring Simba	1) 25.03.2016 2) 10.06.2016 - 10.06.2016 3) 19.07.2016	10	300	3.3	18.05.2016/0	32	green material grain straw	32 75 89 89	0.33 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 40 62 62	(g) 16-2043 (h) OD (iodosulfuron-methyl-sodium 50 g/L ,mesosulfuron-methyl 7.5 g/L ,mefenpyr-diethyl 250 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2, 3 straw, green material, grain: 01514 Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 216 days Analyte 2, 3 straw: 377 days Analyte 1 green material: 275 days Analyte 2, 3 green material: 419 days Analyte 1 grain: 212 days Analyte 2, 3 grain: 366 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 iodosulfuron-methyl-sodium	Analyte 2 AE 0031838	Analyte 3 AE F114844		
	(a)	(b)				(c)	(d)		(d)				(e)	(f)
16-2043-02 United Kingdom Banbury, OX15 &EP Europe, North F 2016	Wheat, spring Granary	1) 26.02.2016 2) 02.07.2016 - 06.07.2016 3) 09.08.2016 - 20.08.2016	10	300	3.3	11.06.2016/0	32	green material grain straw	3 75 89 89	0.28 <0.05 <0.01 <0.05	<0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01	0 33 67 67	(g) 16-2043 (h) OD (iodosulfuron-methyl-sodium 50 g/L ,mesosulfuron-methyl 7.5 g/L ,mefenpyr-diethyl 250 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2, 3 straw, green material, grain: 01514 Analyte 1 straw, green material, grain: 00815/M001 (k) LOQ: Analyte 1 straw, green material: 0.05 mg/kg Analyte 2, 3 straw, green material: 0.01 mg/kg Analyte 1, 2, 3 grain: 0.01 mg/kg (l) Method Validation Data: 00815/M001, 01514, 13-2127, 13-2129, 16-2030 (m) Storage: Analyte 1 straw: 187 days Analyte 2, 3 straw: 342 days Analyte 1 green material: 251 days Analyte 2, 3 green material: 387 days Analyte 1 grain: 183 days Analyte 2, 3 grain: 327 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

A 2.1.5.2 Processing studies on a core set of representative processes

No new data submitted in the framework of this application.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application.

A 2.1.7 Other/Special Studies

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

A 2.2.1.1.2 Storage stability of residues in animal products

No new data submitted in the framework of this application.

A 2.2.1.2 Stability of residues in sample extracts

A 2.2.1.2.1 Storage stability of residues in plant sample extracts

A 2.2.1.2.1.1 Stability of mesosulfuron methyl in wheat grain extracts

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Data evaluated and accepted during the mesosulfuron AIR process (RAR, RMS France, 2016)

Reference:	***KCA 6.1/02***
Title:	*Modification 001 of analytical method 01360 for the determination of amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl, and foramsulfuron in samples from plant origin by HPLC-MS/MS*
Report:	*Stuke, S.; 2015; MR-15/090; M-537921-01-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *Guidance document on residue analytical methods, SANCO/825/00/rev. 8.1, European Commission, Directorate General Health and Consumer Protection 16/11/2010* *US EPA Residue Chemistry Test Guideline OCSPP 860.1340: Residue Analytical Method* *OECD Guideline, ENV/JM/MONO (2007) 17, Aug 13, 2007*
Deviations:	*not specified*
GLP/GEP:	*yes*
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

Within the course of the analytical method validation (Method no. 01360/M001), the stability of mesosulfuron-methyl was checked for the tested sample material wheat grain over a period of 15 days when stored at 4 °C ± 3 °C in the dark.
The stability was checked by comparing the recoveries at 10LOQ (0.10 mg/kg) of the initial day of analysis and analysis of the final samples after storage at 4 °C ± 3 °C under dark conditions over 15 days. To check the stability freshly prepared matrix standards were analyzed together with the aged recovery samples.
Full details of the analytical method 01360/M001 are given in Part B5 of this dossier.

Results and discussions

The table below shows the recoveries comparing initial day of analysis and analysis after storage at 4 °C ± 3°C under dark conditions over 15 days.

An increase of about 17% of mesosulfuron-methyl in wheat grain was observed.This result can be due to different matrix effects in fresh matrix standards compared to the older recovery samples.

Table A 14: Stability of mesosulfuron-methyl in wheat grain extracts, m/z 504 → 182

Sample material	***FL (mg/kg)***	***Storage period***	***Recovery rates (%)***					***Mean deviation (%)***
Wheat grain	*0.10*	*Day 0 (initial analysis)*	*88*	*102*	*96*	*98*	*105*	
		15 days reanalyses	*103*	*107*	*115*	*121*	*125*	
		Deviation day 0/15 days	*17.0*	*4.9*	*19.8*	*23.5*	*19.0*	*16.9*

FL = Fortification Level

Conclusion

It can be concluded that mesosulfuron-methyl was found to be stable in final extracts of wheat grain for at least 15 days at 4 °C ± 3 °C in the dark. Nevertheless, it is recommended that they should be analysed as soon as possible after preparation.

A 2.2.1.2.2 Storage stability of residues in animal sample extracts

No new data submitted in the framework of this application.

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

A 2.2.2.1 Nature of residue in primary crops

No new data submitted in the framework of this application.

A 2.2.2.2 Nature of residue in rotational crops

No new data submitted in the framework of this application.

A 2.2.2.3 Nature of residues in processed commodities

No new data submitted in the framework of this application.

A 2.2.2.4 Nature of residues in livestock

No new data submitted in the framework of this application.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Cereals

Table A 15: Comparison of intended and critical EU GAPs

Type of GAP	***Number of applications***	***Application rate per treatment (kg as/ha)***	***Interval between application***	***Growth stage at last application***	***PHI (days)***
*Representative uses (EFSA, 2016)***	*1*	*0.015*	*-*	*39*	*-*
*cGAP EU (Art. 12, EFSA, 2012) **	*1*	*0.020*	*-*	*39*	*90*
Intended cGAP** for 102000008429 in Central Zone (33)	*1*	*0.012*	*-*	*39*	*-*

a.s.: Active substance
** Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0*
*** Residue trials conducted at GS 32-39*

A 2.2.3.1.1 Study 13-2127

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.2/01***
Title:	*Amendment no. 2: Determination of the residues of BYH 18636 , iodosulfuron-methyl-sodium, mefenpyr-diethyl and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 12.6 and thiencarbazone-methyl WG 70 in the field in Germany, Spain and Portugal*
Report:	*Stuke, S.; Kerkering, S.; 2018; 13-2127; M-503498-03-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*Yes, see Appendix 5*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 16: Summary of the 13-2127 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: mesosulfuron-methyl (determined as mesosulfuron-methyl, calculated as mesosulfuron-methyl)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 mesosulfuron-methyl		
	(a)	(b)				(c)	(d)		(d)		(e)	(f)
13-2127-01 Germany 49377 Langförden OT Repke Europe, North F 2013	Wheat, winter Julius	1) 09.10.2012 2) 21.06.2013 - 04.07.2013 3) 12.08.2013 - 02.09.2013	15	400	3.8	31.05.2013/0	39	green material grain straw	39 54 59 89 89	0.27 0.093 <0.05 <0.01 <0.05	0 7 14 86 86	(g) 13-2127 (h) WG (iodosulfuron-methyl-sodium .6 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 136 days Analyte 1 green material: 216 days Analyte 1 grain: 135 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % iodosulfuron-methyl-sodium .6 % mefenpyr-diethyl 9 %

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1		
	(a)	(b)				(c)	(d)		(d)	mesosulfuron-methyl	(e)	(f)
13-2127-02 Germany 51399 Burscheid Europe, North F 2013	Wheat, winter Winnetou	1) 29.10.2012 2) 17.06.2013 - 24.06.2013 3) 10.08.2013 - 31.08.2013	15	300	5.0	03.06.2013/0	39	green material grain straw	39 51 61 89 89	0.27 0.067 <0.05 <0.01 <0.05	0 7 14 82 82	(g) 13-2127 (h) WG (iodosulfuron-methyl-sodium .6 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 137 days Analyte 1 green material: 213 days Analyte 1 grain: 136 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % iodosulfuron-methyl-sodium .6 % mefenpyr-diethyl 9 %

(a)	According to CODEX Classification / Guide	(e)	Days after last application (Label pre-harvest interval, PHI, underline)	(h)	Formulation type	(l)	Method validation
(b)	Only if relevant	(f)	Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included	(i)	Application method	(m)	Storage (max)
(c)	Year must be indicated			(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code	(g)	Study reference	(k)	LOQ		P based on production date
G	greenhouse F field	*	prior to last treatment	**	residue in control	#	no data available

A 2.2.3.1.2 Study 13-2129

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD.

Reference:	***KCA 6.3.1.2/02***
Title:	*Amendment no. 2: Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methylsodium and mesosulfuron-methyl in/on winter wheat after spraying of IMS & MSM & MPR WG 15 and thiencarbazone-methyl WG 70 in the field in Belgium, the Netherlands and Italy*
Report:	*Stuke, S.; Kerkering, S.; 2018; 13-2129; M-506719-03-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* *EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)* *OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial* *US EPA OCSPP Guideline No. 860.1500*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 17: Summary of the 13-2129 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range of 70-110%. All RSD values were below 20%.
Analyte 1: mesosulfuron-methyl (determined as mesosulfuron-methyl, calculated as mesosulfuron-methyl)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)	PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 mesosulfuron-methyl		
13-2129-01 Belgium 6210 Villers-Perwin Europe, North F 2013	Wheat, winter Matrix	1) 20.10.2012 2) 18.06.2013 - 03.07.2013 3) 05.08.2013 - 12.08.2013	9.0	250	3.6	03.06.2013/0	39	green material grain straw	39 45 65 89 89	0.18 0.070 <0.05 <0.01 <0.05	0 7 17 66 66	(g) 13-2129 (h) WG (iodosulfuron-methyl-sodium 3 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 153 days Analyte 1 green material: 217 days Analyte 1 grain: 152 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % iodosulfuron-methyl-sodium 3 % mefenpyr-diethyl 9 %

Trial No. / Location / EU zone / Year (a)	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment: g a.s./ha	Application rate per treatment: Water (L/ha)	Application rate per treatment: g a.s./hL	Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg): Analyte 1 mesosulfuron-methyl	PHI (days) (e)	Details on trial (f)
13-2129-02 Netherlands 1774 PE Slootdorp Europe, North F 2013	Wheat, winter Winter Malt	1) 01.11.2012 2) 15.07.2013 - 01.08.2013 3) 26.08.2013 - 09.09.2013	9.0	400	2.3	17.06.2013/0	39	green material grain straw	39 55 55 89 89	0.22 <0.05 <0.05 <0.01 <0.05	0 7 14 74 74	(g) 13-2129 (h) WG (iodosulfuron-methyl-sodium 3 % ,mesosulfuron-methyl 3 % ,mefenpyr-diethyl 9 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 131 days Analyte 1 green material: 203 days Analyte 1 grain: 130 days Appl 1 +Biopower 1.0 L/ha Other a.s. in tank mix: BYH 18636 70 % iodosulfuron-methyl-sodium 3 % mefenpyr-diethyl 9 %

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.2.3.1.3 Study 14-2011

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD. The trials in study no. 14-2011 and 14-2017 were not deemed as independent (same location, same date). Only 14-2011 study regarding the Northern zone was consider.

Reference:	***KCA 6.3.1.2/03***
Title:	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 21.15 in Germany, the United Kingdom, southern France and Italy*
Report:	*Braune, M.; van Berkum, S.; 2017; 14-2011; M-594771-01-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market* *OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)* *US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial*
Deviations:	*none*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 18: Summary of the 14-2011 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: mesosulfuron-methyl (determined as mesosulfuron-methyl, calculated as mesosulfuron-methyl)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 mesosulfuron-methyl		
	(a)	(b)				(c)	(d)		(d)		(e)	(f)
14-2011-01 Germany 51399 Burscheid Europe, North F 2014	Wheat, winter Tobak	1) 30.09.2013 2) 26.05.2014 - 02.06.2014 3) 15.07.2014 - 15.08.2014	15	300	5.0	05.05.2014/0	39	green material grain straw	39 45 49 89 89	0.39 <0.05 <0.05 <0.01 <0.05	0 7 14 84 84	(g) 14-2011 (h) WG (iodosulfuron-methyl-sodium .9 % ,mefenpyr-diethyl 13.5 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 2.25 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 337 days Analyte 1 green material: 427 days Analyte 1 grain: 339 days Appl 1 +Biopower 1.0 L/ha

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Portion analyzed	Growth stage at sampling	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1		
	(a)	(b)				(c)	(d)		(d)	mesosulfuron-methyl	(e)	(f)
14-2011-02 United Kingdom SG8 8SS Great Chishill, Royston Europe, North F 2014	Wheat, winter Solstice	1) 11.10.2013 2) 01.06.2014 - 16.06.2014 3) 25.07.2014 - 14.08.2014	15	200	7.4	19.05.2014/0	41	green material grain straw	41 51 65 89 89	0.39 <0.05 <0.05 <0.01 <0.05	0 8 16 72 72	(g) 14-2011 (h) WG (iodosulfuron-methyl-sodium .9 % ,mefenpyr-diethyl 13.5 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 2.25 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 335 days Analyte 1 green material: 413 days Analyte 1 grain: 337 days Appl 1 +Biopower 1.0 L/ha

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.2.3.1.4 Study 14-2017

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for Atlantis 12 OD. The trials in study no. 14-2011 and 14-2017 were not deemed as independent (same location, same date). Only 14-2011 study regarding the Northern zone was consider

Reference:	***KCA 6.3.1.2/04***
Title:	*Determination of the residues of mefenpyr-diethyl, BYH 18636, iodosulfuron-methyl-sodium and mesosulfuron-methyl in/on winter wheat after spray application of IMS & MSM & TCM & MPR WG 26.25 in Germany, the United Kingdom, southern France and Italy*
Report:	*Braune, M.; van Berkum, S.; 2018; 14-2017; M-611796-01-1*
Authority registration No:	
Guideline(s):	*Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market* *OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)* *US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial*
Deviations:	*None*
GLP/GEP:	*yes*
Acceptability:	*yes*
Duplication (if vertebrate study):	

Table A 19: Summary of the study 14-2017 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range of 70-110%. All RSD values were below 20%.
Analyte 1: mesosulfuron-methyl (determined as mesosulfuron-methyl, calculated as mesosulfuron-methyl)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)	PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 mesosulfuron-methyl		
14-2017-01 Germany 51399 Burscheid Europe, North F 2014	Wheat, winter Tobak	1) 30.09.2013 2) 26.05.2014 - 02.06.2014 3) 15.07.2014 - 15.08.2014	9.0	300	3.0	05.05.2014/0	39	green material grain straw	39 45 49 89 89	0.20 <0.05 <0.05 <0.01 <0.05	0 7 14 84 84	(g) 14-2017 (h) WG (iodosulfuron-methyl 4.31 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 3.75 % ,mefenpyr-diethyl 13.5 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 338 days Analyte 1 green material: 428 days Analyte 1 grain: 340 days Appl 1 +Biopower 1.0 L/ha

Trial No. / Location / EU zone / Year (a)	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)	PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 mesosulfuron-methyl		
14-2017-02 United Kingdom SG8 8SS Great Chishill, Royston Europe, North F 2014	Wheat, winter Solstice	1) 11.10.2013 2) 01.06.2014 - 16.06.2014 3) 25.07.2014 - 14.08.2014	9.0	200	4.5	19.05.2014/0	41	green material grain straw	41 51 65 89 89	0.21 <0.05 <0.05 <0.01 <0.05	0 8 16 72 72	(g) 14-2017 (h) WG (iodosulfuron-methyl 4.31 % ,mesosulfuron-methyl 4.5 % ,thiencarbazone-methyl 3.75 % ,mefenpyr-diethyl 13.5 %) (i) Application method: Spraying (j) Analytical method: 00815/M001 (k) LOQ: Analyte 1 grain: 0.01 mg/kg Analyte 1 green material, straw: 0.05 mg/kg (l) Method Validation Data: 00815/M001, 13-2127, 13-2129 (m) Storage: Analyte 1 straw: 336 days Analyte 1 green material: 414 days Analyte 1 grain: 338 days Appl 1 +Biopower 1.0 L/ha

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application.

A 2.2.7 Other/Special Studies

No new data submitted in the framework of this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

TMDI calculations - iodosulfuron-methyl-sodium

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

iodosulfuron

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:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	6%	NL toddler	1,90	4%	Milk: Cattle	0,4%	Apples	0,2%	Maize/corn	6%	
	3%	UK infant	1,03	3%	Milk: Cattle	0,1%	Potatoes	0,1%	Eggs: Chicken	3%	
	3%	NL child	0,97	2%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Apples	3%	
	3%	FR toddler 2 3 yr	0,90	2%	Milk: Cattle	0,1%	Apples	0,1%	Wheat	3%	
	3%	DE child	0,87	1%	Milk: Cattle	0,4%	Apples	0,1%	Wheat	3%	
	3%	FR child 3 15 yr	0,84	2%	Milk: Cattle	0,2%	Wheat	0,1%	Sugar beet roots	3%	
	2%	UK toddler	0,68	1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	2%	
	2%	DK child	0,59	0,8%	Milk: Cattle	0,2%	Rye	0,1%	Swine: Muscle/meat	2%	
	2%	GEMS/Food G11	0,58	0,5%	Milk: Cattle	0,2%	Soyabeans	0,1%	Potatoes	2%	
	2%	ES child	0,56	0,8%	Milk: Cattle	0,1%	Wheat	0,1%	Bovine: Muscle/meat	2%	
	2%	SE general	0,55	0,8%	Milk: Cattle	0,3%	Bovine: Muscle/meat	0,1%	Potatoes	2%	
	2%	RO general	0,53	0,8%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	2%	
	2%	GEMS/Food G07	0,52	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	2%	
	2%	DE women 14-50 yr	0,52	0,8%	Milk: Cattle	0,2%	Sugar beet roots	0,1%	Apples	2%	
	2%	GEMS/Food G15	0,52	0,5%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	2%	
	2%	DE general	0,51	0,8%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Apples	2%	
	2%	GEMS/Food G08	0,51	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Soyabeans	2%	
	2%	GEMS/Food G10	0,51	0,4%	Milk: Cattle	0,2%	Soyabeans	0,1%	Wheat	2%	
	2%	FR infant	0,47	1%	Milk: Cattle	0,1%	Potatoes	0,1%	Apples	2%	
	1%	GEMS/Food G06	0,45	0,2%	Wheat	0,2%	Milk: Cattle	0,1%	Tomatoes	1%	
	1%	NL general	0,43	0,6%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Potatoes	1%	
	1%	IE adult	0,41	0,3%	Milk: Cattle	0,1%	Sweet potatoes	0,1%	Wheat	1%	
	1%	FI adult	0,35	0,9%	Coffee beans	0,0%	Potatoes	0,0%	Rye	1%	
	1,0%	FR adult	0,29	0,3%	Milk: Cattle	0,1%	Wine grapes	0,1%	Wheat	1,0%	
	1,0%	ES adult	0,29	0,3%	Milk: Cattle	0,1%	Wheat	0,0%	Bovine: Muscle/meat	1,0%	
	0,8%	DK adult	0,24	0,4%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,0%	Potatoes	0,8%	
	0,7%	LT adult	0,22	0,3%	Milk: Cattle	0,1%	Potatoes	0,1%	Swine: Muscle/meat	0,7%	
	0,7%	PT general	0,22	0,2%	Potatoes	0,1%	Wheat	0,1%	Wine grapes	0,7%	
	0,6%	UK vegetarian	0,18	0,2%	Milk: Cattle	0,1%	Wheat	0,0%	Potatoes	0,6%	
	0,6%	UK adult	0,18	0,2%	Milk: Cattle	0,1%	Wheat	0,0%	Potatoes	0,6%	
	0,6%	FI 3 yr	0,18	0,2%	Potatoes	0,0%	Bananas	0,0%	Wheat	0,6%	
	0,6%	IT toddler	0,17	0,2%	Wheat	0,1%	Other cereals	0,0%	Tomatoes	0,6%	
	0,5%	FI 6 yr	0,14	0,1%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat	0,5%	
	0,4%	IE child	0,12	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,4%	
	0,4%	IT adult	0,12	0,1%	Wheat	0,0%	Tomatoes	0,0%	Apples	0,4%	
	0,3%	PL general	0,10	0,1%	Potatoes	0,1%	Apples	0,0%	Tomatoes	0,3%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of iodosulfuron is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

IEDI calculations - iodosulfuron-methyl-sodium

Not relevant.

IESTI calculations - Raw commodities - iodosulfuron-methyl-sodium

Show results of IESTI calculation for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.08%	Milk: Cattle	0.02 / 0.02	2.5
0.05%	Potatoes	0.01 / 0.01	1.5
0.05%	Melons	0.01 / 0.01	1.5
0.04%	Pears	0.01 / 0.01	1.4
0.04%	Oranges	0.01 / 0.01	1.3
0.04%	Watermelons	0.01 / 0.01	1.2
0.03%	Apples	0.01 / 0.01	1.1
0.03%	Pineapples	0.01 / 0.01	1.0
0.03%	Bananas	0.01 / 0.01	0.97
0.03%	Peaches	0.01 / 0.01	0.95
0.02%	Mangoes	0.01 / 0.01	0.79
0.02%	Grapefruits	0.01 / 0.01	0.79
0.02%	Table grapes	0.01 / 0.01	0.73
0.02%	Cucumbers	0.01 / 0.01	0.66
0.02%	Carrots	0.01 / 0.01	0.63

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.02%	Milk: Cattle	0.02 / 0.02	0.77
0.01%	Head cabbages	0.01 / 0.01	0.42
0.01%	Watermelons	0.01 / 0.01	0.41
0.01%	Melons	0.01 / 0.01	0.39
0.01%	Milk: Goat	0.02 / 0.02	0.37
0.01%	Swedes/rutabagas	0.01 / 0.01	0.34
0.01%	Table grapes	0.01 / 0.01	0.34
0.01%	Oranges	0.01 / 0.01	0.31
0.01%	Pears	0.01 / 0.01	0.31
0.01%	Milk: Sheep	0.02 / 0.02	0.30
0.01%	Potatoes	0.01 / 0.01	0.30
0.01%	Pineapples	0.01 / 0.01	0.30
0.01%	Yams	0.01 / 0.01	0.28
0.01%	Apples	0.01 / 0.01	0.28
0.01%	Cucumbers	0.01 / 0.01	0.28

IESTI calculations - Processed commodities - iodosulfuron-methyl-sodium

Processed commodities

Results for children

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.03%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.03%	Potatoes / fried	0.01 / 0.01	0.93
0.03%	Pumpkins / boiled	0.01 / 0.01	0.89
0.03%	Witloofs / boiled	0.01 / 0.01	0.89
0.03%	Broccoli / boiled	0.01 / 0.01	0.79
0.02%	Cauliflowers / boiled	0.01 / 0.01	0.70
0.02%	Escaroles/broad-leaved er	0.01 / 0.01	0.66
0.02%	Potatoes / dried (flakes)	0.01 / 0.05	0.59
0.02%	Leeks / boiled	0.01 / 0.01	0.57
0.02%	Apples / juice	0.01 / 0.01	0.54
0.02%	Oranges / juice	0.01 / 0.01	0.53
0.02%	Turnips / boiled	0.01 / 0.01	0.51
0.02%	Parsnips / boiled	0.01 / 0.01	0.51
0.02%	Sweet potatoes / boiled	0.01 / 0.01	0.50
0.01%	Florence fennels / boiled	0.01 / 0.01	0.45

Expand/collapse list

Results for adults

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.02%	Pumpkins / boiled	0.01 / 0.01	0.55
0.01%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.01%	Cauliflowers / boiled	0.01 / 0.01	0.42
0.01%	Beetroots / boiled	0.01 / 0.01	0.39
0.01%	Celeries / boiled	0.01 / 0.01	0.34
0.01%	Apples / juice	0.01 / 0.01	0.33
0.01%	Broccoli / boiled	0.01 / 0.01	0.24
0.01%	Coffee beans / extraction	0.05 / 0.01	0.24
0.01%	Courgettes / boiled	0.01 / 0.01	0.23
0.01%	Parsnips / boiled	0.01 / 0.01	0.21
0.01%	Kohlrabies / boiled	0.01 / 0.01	0.21
0.01%	Wine grapes / juice	0.01 / 0.01	0.21
0.01%	Escaroles/broad-leaved	0.01 / 0.01	0.20
0.01%	Florence fennels / boiled	0.01 / 0.01	0.19
0.01%	Turnips / boiled	0.01 / 0.01	0.19

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short term intake of residues of iodosulfuron is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

TMDI calculations - mesosulfuron - methyl

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

mesosulfuron

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

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	0,19%	NL toddler	1,90	0,12%	Milk: Cattle	0,01%	Apples	0,01%	Maize/corn	0,2%	
	0,10%	UK infant	1,03	0,08%	Milk: Cattle	0,00%	Potatoes	0,00%	Eggs: Chicken	0,1%	
	0,10%	NL child	0,97	0,05%	Milk: Cattle	0,01%	Sugar beet roots	0,01%	Apples	0,1%	
	0,09%	FR toddler 2 3 yr	0,90	0,06%	Milk: Cattle	0,00%	Apples	0,00%	Wheat	0,1%	
	0,09%	DE child	0,87	0,04%	Milk: Cattle	0,01%	Apples	0,00%	Wheat	0,1%	
	0,08%	FR child 3 15 yr	0,84	0,05%	Milk: Cattle	0,00%	Wheat	0,00%	Sugar beet roots	0,1%	
	0,07%	UK toddler	0,68	0,04%	Milk: Cattle	0,00%	Wheat	0,00%	Potatoes	0,1%	
	0,06%	DK child	0,59	0,03%	Milk: Cattle	0,01%	Rye	0,00%	Swine: Muscle/meat	0,1%	
	0,06%	GEMS/Food G11	0,58	0,02%	Milk: Cattle	0,01%	Soyabeans	0,00%	Potatoes	0,1%	
	0,06%	ES child	0,56	0,02%	Milk: Cattle	0,00%	Wheat	0,00%	Bovine: Muscle/meat	0,1%	
	0,06%	SE general	0,55	0,02%	Milk: Cattle	0,01%	Bovine: Muscle/meat	0,00%	Potatoes	0,1%	
	0,05%	RO general	0,53	0,02%	Milk: Cattle	0,01%	Wheat	0,00%	Potatoes	0,1%	
	0,05%	GEMS/Food G07	0,52	0,01%	Milk: Cattle	0,00%	Wheat	0,00%	Potatoes	0,1%	
	0,05%	DE women 14-50 yr	0,52	0,02%	Milk: Cattle	0,00%	Sugar beet roots	0,00%	Apples	0,1%	
	0,05%	GEMS/Food G15	0,52	0,01%	Milk: Cattle	0,00%	Wheat	0,00%	Potatoes	0,1%	
	0,05%	DE general	0,51	0,02%	Milk: Cattle	0,00%	Sugar beet roots	0,00%	Apples	0,1%	
	0,05%	GEMS/Food G08	0,51	0,01%	Milk: Cattle	0,00%	Wheat	0,00%	Soyabeans	0,1%	
	0,05%	GEMS/Food G10	0,51	0,01%	Milk: Cattle	0,01%	Soyabeans	0,00%	Wheat	0,1%	
	0,05%	FR infant	0,47	0,03%	Milk: Cattle	0,00%	Potatoes	0,00%	Apples	0,0%	
	0,04%	GEMS/Food G06	0,45	0,01%	Wheat	0,00%	Milk: Cattle	0,00%	Tomatoes	0,0%	
	0,04%	NL general	0,43	0,02%	Milk: Cattle	0,00%	Sugar beet roots	0,00%	Potatoes	0,0%	
	0,04%	IE adult	0,41	0,01%	Milk: Cattle	0,00%	Sweet potatoes	0,00%	Wheat	0,0%	
	0,04%	FI adult	0,35	0,03%	Coffee beans	0,00%	Potatoes	0,00%	Rye	0,0%	
	0,03%	FR adult	0,29	0,01%	Milk: Cattle	0,00%	Wine grapes	0,00%	Wheat	0,0%	
	0,03%	ES adult	0,29	0,01%	Milk: Cattle	0,00%	Wheat	0,00%	Bovine: Muscle/meat	0,0%	
	0,02%	DK adult	0,24	0,01%	Milk: Cattle	0,00%	Swine: Muscle/meat	0,00%	Potatoes	0,0%	
	0,02%	LT adult	0,22	0,01%	Milk: Cattle	0,00%	Potatoes	0,00%	Swine: Muscle/meat	0,0%	
	0,02%	PT general	0,22	0,01%	Potatoes	0,00%	Wheat	0,00%	Wine grapes	0,0%	
	0,02%	UK vegetarian	0,18	0,01%	Milk: Cattle	0,00%	Wheat	0,00%	Potatoes	0,0%	
	0,02%	UK adult	0,18	0,01%	Milk: Cattle	0,00%	Wheat	0,00%	Potatoes	0,0%	
	0,02%	FI 3 yr	0,18	0,00%	Potatoes	0,00%	Bananas	0,00%	Wheat	0,0%	
	0,02%	IT toddler	0,17	0,01%	Wheat	0,00%	Other cereals	0,00%	Tomatoes	0,0%	
	0,01%	FI 6 yr	0,14	0,00%	Potatoes	0,00%	Cocoa beans	0,00%	Wheat	0,0%	
	0,01%	IE child	0,12	0,01%	Milk: Cattle	0,00%	Wheat	0,00%	Potatoes	0,0%	
	0,01%	IT adult	0,12	0,00%	Wheat	0,00%	Tomatoes	0,00%	Apples	0,0%	
	0,01%	PL general	0,10	0,00%	Potatoes	0,00%	Apples	0,00%	Tomatoes	0,0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of mesosulfuron is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

IEDI calculations - mesosulfuron - methyl

Not relevant.

IESTI calculations - Raw commodities - mesosulfuron - methyl

Not relevant.

IESTI calculations - Processed commodities - mesosulfuron - methyl

Not relevant.

Appendix 4 Additional information provided by the applicant

Not relevant. No additional information submitted.