REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/MEZO 30 OD

Product name(s): Vidal 30 OD, Pacyfik 30 OD

Chemical active substance:

Mesosulfuron-methyl, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

authorization

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023

zRMS Assessment: 26/07/2024

MS Finalisation date: 19/11/2024

Version history

When	What
July 2024	zRMS Assessment
November 2024	Following commenting period

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7 Metabolism and residue data (KCA section 6)

No new data has been provided within the framework of this application.

Storage stability
Storage stability of mesosulfuron-methyl was demonstrated for a period of 13 months at –18°C in dry commodities (wheat)

Metabolism in plants and animals
The metabolites detected in plants were also found in animal metabolism studies.
The residue for enforcement and risk assessment in cereals is defined as mesosulfuron-methyl.
The residue definition for both monitoring and risk assessment for animal commodities is proposed as mesosulfuron-methyl.

Magnitude of residues in plants
No new data has been submitted in the framework of this application.
Wheat and rye are the major crops in northern Europe. A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye and triticale before and after forming of the edible part.

Sufficient number trials on wheat are presented in EFSA Journal 2012:

Commodity	Source	Residue zone	Residue levels (mg/kg)	Comments
Wheat grain (extrapolated to rye and triticale)	EFSA, 2012	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 20 g as/ha, BBCH 13-32 (39), PHI 90d, outdoor Res. 18 x <0.01	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.
Wheat straw (extrapolated to rye and triticale)			GAP on which MRL/EU a.s. assessment is based: 1 x 20 g as/ha, BBCH 13-32 (39), PHI 90d, outdoor Res. 18 x <0.05	

The proposed use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) No 289/2014) for wheat grain will not be exceeded.
The extrapolation to Spelt, Triticum spelta; Emmer wheat, Triticum dicoccum; Einkorn wheat, Trit-icum monococcum; Durum wheat Triticum durum; Rye, Secale cereale; is possible from Winter wheat Triticum aestivum (SANTE/2019/12752).
The proposed uses are considered acceptable.

Magnitude of residues in livestock
Dietary burden calculation are not necessary, because magnitude of the residues in plants is below LOQ level.

Magnitude of residues in processed commodities
Studies on Industrial Processing and/or Household Preparation are not relevant, because residues in magnitude of the residues in the plant matrices are below LOQ (<0.01 mg/kg).

Magnitude of residues in representative succeeding crops
No field rotational crop studies are considered necessary.

Other / special studies
Studies are not required.

Estimation of exposure through diet and other means

The chronic intakes of mesosulfuron-methyl residues are unlikely to present a public health concern.

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/H/MEZO 30 OD are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for: Winter wheat *Triticum aestivum,* Spelt *Triticum spelta, Emmer wheat Triticum dicoccum, Einkorn wheat Triticum monococcum, Durum wheat Triticum durum Spring Rye Secale cereale*. A list of all intended uses within the central is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for Mesosulfuron-methyl as laid down in Reg. (EU) 289/2014 is not expected.
The chronic and the short-term intakes of Mesosulfuron-methyl residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS-PL agrees with the authorization of the intended use(s).

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

Data gaps

Noticed data gaps are:
None

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Winter wheat *Triticum aestivum*	PL	CHR/H/MEZO 30 OD	F	Monaocots and dicots weeds	OD	30 g/L	Spray, Medium sprayer	BBCH 21-32	Min: - Max; 1	n/a		min: 100 max; 400	Min:- Max: 0,015 kg a.s./ha		
Minor uses according to Article 51 (zonal uses)																
2	Spelt Triticum spelta (3SPWC) Emmer wheat Triticum dicoccum (TRZDI) Einkorn wheat Triticum monococcum (TRZMO) Durum wheat Triticum durum (TRZDW) Spring Rye Secale cereale (SECCS)	PL	CHR/H/MEZO 30 OD	F	Monaocots and dicots weeds	OD	30g/L	Spray, Medium sprayer	BBCH 21-32	Min:- Max: 1	n/a		min: 100 max; 400	Min:- Max: 0,015 kg a.s./ha		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 CHR/H/MEZO 30 OD is composed of Mesosulfuron-methyl.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Mesosulfuron-methyl.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesosulfuron-methyl					
ADI	EFSA Journal 2016;14(10):4584	2016	1 mg/kg bw per day	mouse, 18-montth	
ARfD	No ARfD set on EU level				

7.1.2.1 Summary for Mesosulfuron-methyl.

Table 7.1-3: Summary for Mesosulfuron-methyl.

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter wheat *Triticum aestivum*	Yes	Yes	Yes	Yes	Yes	No	No
2	Spelt *Triticum spelta* Emmer wheat *Triticum dicoccum* Einkorn wheat *Triticum monococcum* Durum wheat *Triticum durum* Spring Rye *Secale cereale*	Yes	Yes	Yes	Yes	Yes	No	No

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

The effects of processing on the nature of Mesosulfuron- methyl residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for risk assessment.

zRMS comment: The dietary risk assessment shows that the TMDI was below of the 10% ADI. Processing studies on the nature of the residues are not required.

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.

7.1.2.2 Summary for CHR/H/MEZO 30 OD

Table 7.1-4: Information on CHR/H/MEZO 30 OD (KCA 6.8)

Crop	PHI for CHR/H/MEZO 30 OD proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CHR/H/MEZO 30 OD proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mesosulfuron-methyl		
Winter wheat *Triticum aestivum*	N/A			
Spelt *Triticum spelta* Emmer wheat *Triticum dicoccum* Einkorn wheat *Triticum monococcum* Durum wheat *Triticum durum* Spring Rye *Secale cereale*	N/A			

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

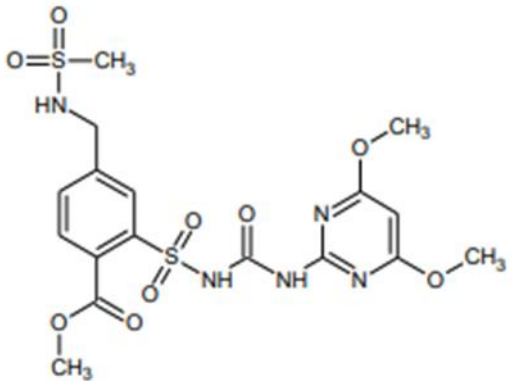
Table 7.1-5: Waiting periods before planting succeeding crops

Not required.

7.2 Mesosulfuron- methyl

General data on Mesosulfuron-methyl are summarized in the table below (last updated 2016/09/20)

Table 7.2-1: General information on Mesosulfuron-methyl

Active substance (ISO Common Name)	Mesosulfuron
IUPAC	mesosulfuron-methyl: methyl-2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-(methanesulfonamido)-p-toluate mesosulfuron: 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-methanesulfonamido-p-toluic acid
Chemical structure	
Molecular formula	C17H21N5O9S2
Molar mass	503.55 g/mol
Chemical group	Sulfonylurea herbicide
Mode of action (if available)	Herbicide
Systemic	Yes
Company (ies)	Bayer CropScience AG
Rapporteur Member State (RMS)	RMS: FR Co-RMS: Poland
Approval status	Approved COMMISSION IMPLEMENTING REGULATION (EU) 2017/755
Restriction (e.g. is restricted to use as "...")	Regulation (EU) 2017/755 of 28/04/2017 Restriction is not required
Review Report	EFSA Journal 2016;14(10):4584 SANTE/11827/2016 Rev 2 (23 March 2017)
Current MRL regulation	Regulation (EU) No 289/2014
Peer review of MRLs according to Article 12 of Reg No 289/2014 EU performed	Yes

EFSA Journal : Conclusion on the peer review	Yes** (EFSA Journal 2016;14(10):4584)
EFSA Journal: conclusion on article 12	Yes** ~~(EFSA Journal 2022;20(3):7107)~~ EFSA Journal 2012;10(11):2976
Current MRL applications on intended uses	Regulation (EU) No 289/2014

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

The following studies: ~~Werde~~ Wrede, A. (2003) M-216176-01-1; ~~Werde~~ Wrede A. (2007) M-198612-04-1; ~~Werde~~ Wrede A. (2000) M-198617-04-1 were presented in core assessment and latest supplements of registration report Part B, Section 7: Metabolism and Residues of Atlantis 12 OD revised in 03/2020.
We are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal.
According to Official Journal of the European Union C 229/2 Period of protection is 30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation, therefore no new study was provided.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat (grain)	High starch content	40 months	KCA 6.1/05 ~~Werde~~ Wrede, A. (2003) M-216176-01-1
Wheat (straw)	Dry commodities	40 months	KIIIA 6.1/04 ~~Werde~~ Wrede A. (2007) M-198612-04-1
Wheat (shoot)	High water content	40 months	KIIIA 6.1/03 ~~Werde~~ Wrede A. (2000) M-198617-04-1

Conclusion on stability of residues during storage

In all type of the wheat samples residues of the Mesosulfuron-methyl are stable during deep freeze storage at -18°C.

zRMS comment: In the framework of the peer review, storage stability of mesosulfuron-methyl was demonstrated for a period of 13 months at –18°C in dry commodities (wheat) EFSA, 2012)

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

For all presented studies analysis time were less than 24 hours between extraction and analysis or it was shown that study extracts are stable. If it was not the case sufficient information is provided in study and presented in RAR of Mesosulfuron.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

The following studies: Braun P. J., Koehn D. M., Buerkle L. W., Buerkle L, (2000), C008761, Koehn D. M., Selzer, J., Buerkle, L.W. (2000), Gildemeister, H. (2003) M-260002-01-1, were presented in core assessment and latest supplements of registration report Part B, Section 7: Metabolism and Residues of Atlantis 12 OD revised in 03/2020.
We are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal.
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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	2-14C-pyrimidyl	Foliar F	0.01 kg/ha	1	0,35/36,49,95 days	Active applied with non-labelled safener mefenpyr-diethyl	KCA 6.2.1 /01 Braun P. J., Koehn,D.M., Buerkle L. W., Buerkle L, (2000), C008761, KCA 6.2.1/02 Koehn D. M., Selzer J., Buerkle, L.W. (2000) C009588,
	Wheat	2-14C-pyrimidyl	Foliar F	0.01 kg/ha	2	0,35/36,49,95 days		
	Wheat	phenyl-14C labelled	Foliar F	0.03 kg/ha	1	0, 41/42, 57/58,/103/104 days		
	Wheat	phenyl-14C labelled	Foliar F	0.03 kg/ha	2	0, 41/42, 57/58,103/104 days		

								KCA 6.2.1 /03 Gildemeister H. (2003) M-260002-01-1,

Summary of plant metabolism studies reported in the EU

The wheat plants were treated a late tillering stage at rates between 10 g a.s/ha and 2x30g a.s/ha. The highest TRR for pyrimidyl-label study was identified in straw (0.019 mg eq/kg). Residue in grain were much lower (0.001 mg eq/kg). Non- extractable residue amounted to 33% to 70% of the TRR in straw and grain respectively.

In wheat grain residues were too low for identification (extractable portion 0.0004 mg eq/kg at the 2 x 0.010kg as/ha rate) however the nature of the residue was investigated in straw. The residues in straw (95 DAT, 2 x 0.010kg as/ha rate) comprised of parent (0.0003 mg eq/kg, 1.8% TRR) and metabolite AE F160459 (0.0016 mg eq/kg, 8.6% TRR) together with a range of non- identifiable fractions (strongly to moderately polar) consisting of at least eight components each of which did not exceed a residue level of 0.003 mg eq/kg (16% TRR). Of the non-extractable radioactivity a major portion was released by enzymatic and subsequent acid or alkaline hydrolysis. The chromatographic residue pattern of the extracted residues did not change following release, suggesting the extractable residue did not consist of conjugated metabolites.

In the phenyl label study TRR was 0.0012 and 0.0457 mg eq/kg in grain and straw respectively, at harvest following treatment at 2 x 0.030 kg as/ha. Levels of non-extractable residues amounted to 78% (0.0009 mg/kg) and 15% (0.007 mg/kg) of TRR in grain and straw, respectively. Again the composition of the residue was only investigated in straw; it comprised of parent (0.0014 mg eq/kg, 3%TRR), metabolite AE F160459 (0.0058 mg eq/kg, 13% TRR), metabolite AE F140584 (0.0040 mg eq/kg, 9% TRR) and metabolite AE F147447 (0.0083 mg eq/kg, 18% TRR). The non-identifiable residues in straw (29% of TRR) consisted of at least five components (very to moderately pola), each of which did not exceed a residue level of 0.0042 mg eq/kg (9% TRR).

The major metabolites detected in treated plants were cleavage and hydrolysis products of the parent compound such as metabolite AE F160459 and AE F140584 and metabolite AE F147447, formed from metabolite AE F140584 by hydrolysis of the ester followed by ring closure to form the substituted saccharine compound.

The results of the metabolism studies show the besides parent, were characterized in straw (at harvest) at extremely low levels. The same metabolites were also the main components in immature plants (forage stage). However, at this stage parent contributed a higher proportion of TRR.

zRMS comment: The residue for enforcement and risk assessment in cereals is defined as mesosulfuron-methyl (EFSA, 2012).

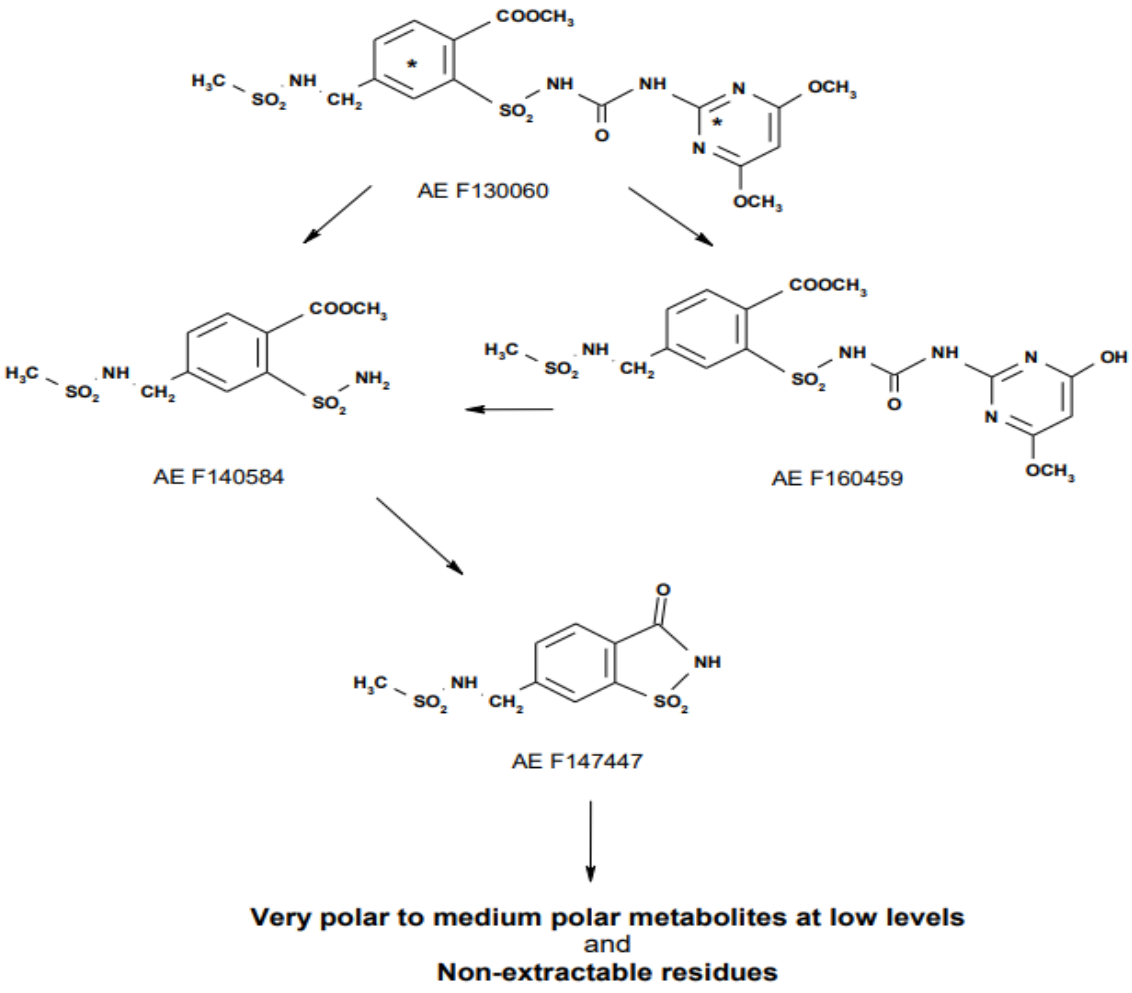
Summary of new plant metabolism studies

Not necessary.

Conclusion on metabolism in primary crops

All metabolites detected in plants were also found in animal metabolism studies. In consideration of all these factors the peer review concluded that the residue should be defined as Mesosulfuron. In the framework of Directive 91/414/EEC the active substance was defined as Mesosulfuron. EFSA highlighted in MRL review in the framework of Reg. 396/2005 that the only variant reported was Mesosulfuron-methyl.

Figure 7.2-1: Metabolic pathway of mesosulfuron-methyl in wheat



7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

The following studies: Frey J. A., Harrison C.L., Buerkle L. W. (2000), C008238, Frey J. A., Harrison C. L., Buerkle L. W., (2000), C008240, Frey J. A., Harrison C. L. (2000),C008242, Frey J. A., Harrison C. L, (2000),C008243, Frey J. A., Harrison, C. L, (2006), C008239, Frey J. A., Harrison C.L., (2000), C008241, were presented in core assessment and latest supplements of registration report Part B, Section 7: Metabolism and Residues of Atlantis 12 OD revised in 03/2020.

We are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal.
According to Official Journal of the European Union C 229/2 Period of protection is 30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation, therefore no new study was provided.

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	U-phenyl-14C and 2-14C-pyrimidyl-	Bare soil, F	0.0015	32, 120, 365	162, 411	32 DAT spinach not harvested	KCA 6.6.2 /01 Frey J. A., Harrison C.L., Buerkle L. W. (2000), C008238, KCA 6.6.2 /02 Frey, J. A., Harrison C. L., Buerkle L. W. (2000), C008240 KCA 6.6.2 /03 Frey J. A., Harrison C. L. (2000), C008242, KCA 6.6.2 /04 Frey J. A., Harrison C. L, (2000), C008243, KCA 6.6.2 /05 Frey J. A., Harrison, C. L, (2006), C008239,
Root and tuber vegetables	Carrot					139, 237, 487	-	
Cereals (small grain)	Wheat					131,238, 482	-	

								KCA 6.6.2 /06 Frey J. A., Harrison C.L. (2000) C008241,

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

Summary of plant metabolism studies reported in the EU

Confined crop rotation studies for Mesosulfuron-methyl were performed using both the U-phenyl-14C-labelled and the 2- 14C-pyrimidyl-labelled active ingredients. In both cases the substance was applied to bare soil at a rate of 15 g a.s./ha, with wheat, carrots, and spinach being planted 1, 4, and 12 months later. Rotated crops sown 1 month after application: Carrots and wheat developed normally while spinach showed severe growth damages due to the sensitivity of this plant against the active substance. Carrots and wheat were harvested in ripe condition 108/99 days after sowing (139/131 days after soil treatment). The total radioactive residues (TRR) in all plant matrices were very low. Residues above 0.01 mg equiv./kg were seen only in wheat straw.

zRMS comment: Occurrence of mesosulfuron-methyl residues in rotational crops was investigated during the peer review of mesosulfuron. It was concluded that metabolic patterns in primary and succeeding crops are similar and that significant residues in rotational crops are not expected (EFSA, 2012).

Summary of new plant metabolism studies

Not necessary.

Conclusion on metabolism in rotational crops

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

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

The dietary risk assessments show that the TMDI was below of the 10% ADI. Processing studies on the nature of the residues are not required, therefore no new study was provided.

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

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

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Leafy vegetables (Spinach), Root and tuber vegetables (Carrot), Cereals (small grain) (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes

Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	No 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	~~CF=1 (RAR 2016, EFSA 2016)~~ Not applicable

~~* If residue pattern in processed commodities is not similar to that in raw commodities~~
~~** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).~~
~~*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.~~

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

Available data

The following studies: KCA 6.2.2 /01; (1999), C005417,KCA 6.2.3 /01, (1999), C005418, were presented in core assessment and latest supplements of registration report Part B, Section 7: Metabolism and Residues of Atlantis 12 OD revised in 03/2020.
We are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal.
According to Official Journal of the European Union C 229/2 Period of protection is 30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation, therefore no new study was provided.

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	Diary cow	14C-phenyl labelled	1	0.417 mg/kg bw/d	5	Milk	Twice daily	KCA 6.2.2 /01, (1999), [redacted],
						Urine and faeces	Daily	
						Tissues	After sacrifice	
Laying poultry	Laying Hens	14C-phenyl labelled	6	0.76 mg/kg bw/d)	14	Eggs	Twice daily	KCA 6.2.3 /01, (1999), [redacted],
						Excreta	Daily	
						Tissues	After sacrifice	

Summary of plant metabolism studies reported in the EU

The metabolism of Mesosulfuron-methyl was investigated in laying hens and lactating cows using 14C-labelled Mesosulfuron-methyl . Lactating cows and laying hens were dosed with 0.417 and 0.76 mg/kg bw/d respectively , of Mesosulfuron-methyl , far above exposure the exposure of meat ruminant and poultry. Studies demonstrate the transfer of residues to milk, eggs and tissue is insignificant.

In the hen study the highest TRR was identified in liver (0.023 mg eq/kg). In eqq yolk and eqq white residues were very low (0.012 and 0.011 mg eq/kg, respectively). The highest residue levels were found in liver, where parent Mesosulfuron methyl accounted for up to 22% (0.005 mg eq/kg) of the TRR. Other metabolites identified in tissues include metabolite AE F160459 and metabolite AE F195141 but none accounted for more than 10% TRR and none is expected to contribute significantly to the toxicological burden.

In the lactating cow study the highest TRR was identified in kidney (0.058 mg eq/kg) where parent Mesosulfuron - methyl accounted for up to 40% of the TRR (0.002 mg eq/kg). In milk, residues were very low (0.004 mg eq/kg) and again, parent Mesosulfuron- methyl accounted for the majority of the indentified residue (up to 23% of TRR). Other metabolites identified in tissue include metabolites AE F160459, AE F195141 which accounted for 27% of TRR, 0.009 mg eq/kg in renal fat) and none is expected to contribute significantly to the toxicological burden.

zRMS comment: Mesosulfuron-methyl was identified as the predominant compound of the total residues in milk, liver, kidney and fat. No metabolites' identification was attempted in eggs and in muscle due to the very low recovered residues (0.012 and 0.004 mg eq./kg, respectively). The identified metabolites were recovered at very low concentrations in all matrices (< 0.01 mg/kg). On the basis of the available metabolism studies in lactating ruminants and laying hens conducted with U-14C-phenyl labelled mesosulfuron-methyl only, the residue definition for both monitoring and risk assessment for animal commodities is proposed as mesosulfuron-methyl only (EFSA, 2016).

Summary of new animal metabolism studies

Not relevant.

Conclusion on metabolism in livestock

The metabolism studies on both ruminant and poultry show that parent compound is the main component of the residue in animal tissue and products. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

Based on the results of metabolism studies EFSA has concluded that the residue in animal commodities may be defined as Mesosulfuron-methyl if the livestock dietary burden would be increased in the future.

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

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

	Endpoints
Animals covered	Lactating ruminants
	Laying hens
Time needed to reach a plateau	5 days in milk

concentration	10 days in eggs
Animal residue definition for monitoring	Mesosulfuron-methyl (EFSA, 2016)
Animal residue definition for risk assessment	Mesosulfuron-methyl (EFSA, 2016)
Conversion factor	~~CF= 1 (EFSA 2016)~~ Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

~~* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)~~
~~** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.~~
~~*** If metabolism in rat and ruminant are not similar~~

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

The following study Freitag T. (2004) RA-2677/03 was presented in core assessment and latest supplements of registration report Part B, Section 7: Metabolism and Residues of Atlantis 12 OD revised in 03/2020.
We are obliged to relied upon following study taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal.
According to Official Journal of the European Union C 229/2 Period of protection is 30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation, therefore no new study was provided

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of CHR/H/MEZO 30 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 (grain)	DAR 2000, ER97ECN521, 98ECN521	N-EU	GAP on which MRL is based: 15 g as/ha, 80-103 DAT, outdoor E: <0.01 (9x) RA: <0.01 (9x)	0.01	0.01	0.01	0.01	YES
Wheat (straw)	DAR 2000, ER97ECN521, 98ECN521	N-EU	GAP on which MRL is based: 15 g as/ha, 80-103 DAT, outdoor E: <0.05 (9x) RA: <0.05 (9x)	0.05	0.05	0.05	n.a	

Wheat (forage)	DAR 2000, ER97ECN521, 98ECN521	N-EU	GAP on which MRL is based: 15 g as/ha, 80-103 DAT, outdoor E: <0.05 (5x) RA: <0.05 (5x)	0.05	0.05	0.05	n.a	
Wheat (grain)	KCA 6.3.1 /08 Freitag T. (2004) RA-2677/03	N-EU	GAP on which MRL is based: 10.44g as/L, formulation 42.44 OD, PHI 63-103, outdoor E: <0.01 (4x) RA: <0.01(4x)	0.01	0.01	0.01	0.01	YES
Wheat (straw)	KCA 6.3.1 /08, Freitag T. , (2004), RA-2677/03	N-EU	GAP on which MRL is based: 10.44g as/L, formulation 42.44 OD, PHI 63-103, outdoor E: <0.05 (4x) RA: <0.05(4x)	0.05	0.05	0.05	n.a	
Spelt *Triticum spelta* Emmer wheat *Triticum di-coccum* Einkorn wheat *Triticum monococ-cum* Durum wheat *Triticum du-rum* Spring Rye *Secale cereale*	According to SANTE/2019/12752 all results of the magnitude of residues for these plants material were extrapolated from Winter wheat *Triticum aestivum*.							

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

zRMS comment: No new data has been submitted in the framework of this application.
Wheat and rye are the major crops in northern Europe. A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye and triticale before and after forming of the edible part.
Sufficient number trials on wheat are presented in EFSA Journal 2012:

Commodity	Source	Residue zone	Residue levels (mg/kg)	Comments
Wheat grain (extrapolated to rye and triticale)	EFSA, 2012	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 20 g as/ha, BBCH 13-32 (39), PHI 90d, outdoor Res. 18 x <0.01	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.
Wheat straw (extrapolated to rye and triticale)			GAP on which MRL/EU a.s. assessment is based: 1 x 20 g as/ha, BBCH 13-32 (39), PHI 90d, outdoor Res. 18 x <0.05	

The proposed use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) No 289/2014) for wheat grain will not be exceeded.
The extrapolation to Spelt, Triticum spelta; Emmer wheat, Triticum dicoccum; Einkorn wheat, Triticum monococcum; Durum wheat Triticum durum; Rye, Secale cereale; is possible from Winter wheat Triticum aestivum (SANTE/2019/12752).
The proposed uses are considered acceptable.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on Winter wheat *Triticum aestivum* are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to Spelt, *Triticum spelta;* Emmer wheat, *Triticum dicoccum;* Einkorn wheat, *Triticum monococcum;* Durum wheat *Triticum durum;* Rye, *Secale cereale;* is possible from Winter wheat *Triticum aestivum*.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Dietary burden calculation are not necessary, because magnitude of the residues in plants is below LOQ level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Not relevant.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or

Household Preparation) (KCA 6.5.2-6.5.3)

Studies on Industrial Processing and/or Household Preparation are not relevant, because residues in magnitude of the residues in the plant matrices are below LOQ (<0.01 mg/kg).

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

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 LOQ. 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.

Available data

No new data submitted in the framework of this application.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/MEZO 30 OD. Therefore, other special studies are not needed.

zRMS comment: Wheat and rye have no melliferous capacity, 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). As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-9: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition Mesosulfuron-methyl		

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Rye, Wheat, Other cereals	0.01	MRL (Reg. (EU) No 289/2014, 2014)
Rye, Wheat , Other cereals	0.01	HR (KCA 6.3.1 /08, Freitag T., (2004), RA-2677/03)
Rye, Wheat, Other cereals	0.01	STMR (KCA 6.3.1 /08, Freitag T., (2004), RA-2677/03)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.0 % (based on DK child)
IEDI (% ADI) according to EFSA PRIMo	0.0 % (based on DK child)
IESTI (% ARfD) according to EFSA PRIMo*	Not necessary
NTMDI (% ADI) **	Not available
NEDI (% ADI)**	Not available
NESTI (% ARfD) **	Not available

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

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

zRMS comment: Calculation presented by the Applicant is acceptable. The chronic intakes of mesosulfuron-methyl residues are unlikely to present a public health concern.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

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

EFSA (European Food Safety Authority), 2016. Review of the existing maximum residue levels (MRLs) for Mesosulfuron-methyl according to Article 12 of Regulation (EU) No 289/2014. EFSA Journal 2016;14(10):4584, doi: 10.2903/j.efsa.2016.4584 Available online: https://www.efsa.europa.eu/en/efsajournal

EFSA (European Food Safety Authority), 2016. General information of Mesosulfuron- methyl, EFSA Journal 2016;14(10):4584, doi: 10.2903/j.efsa.2016.4584 Available online: https://www.efsa.europa.eu/en/efsajournal

EFSA (European Food Safety Authority), 2016. Summary of plant metabolism studies- (Table 7.2.-3), EFSA Journal 2016;14(10):4584, doi: 10.2903/j.efsa.2016.4584 Available online: https://www.efsa.europa.eu/en/efsajournal

EFSA (European Food Safety Authority), 2016. Summary of metabolism studies in rotational crops EFSA Journal 2016;14(10):4584, doi: 10.2903/j.efsa.2016.4584 Available online: https://www.efsa.europa.eu/en/efsajournal

EFSA (European Food Safety Authority), 2016. Conclusion on the nature of residues in commodities of plant origin EFSA Journal 2016;14(10):4584, doi: 10.2903/j.efsa.2016.4584 Available online: https://www.efsa.europa.eu/en/efsajournal

EFSA (European Food Safety Authority), 2016. Conclusion on the nature of residues in commodities of animal origin EFSA Journal 2016;14(10):4584, doi: 10.2903/j.efsa.2016.4584 Available online: https://www.efsa.europa.eu/en/efsajournal

EFSA (European Food Safety Authority), 2016. Toxicological reference values for the dietary risk assessment of Mesosulfuron-methyl. EFSA Journal 2016;14(10):4584, doi: 10.2903/j.efsa.2016.4584 Available online: https://www.efsa.europa.eu/en/efsajournal

European Commission, 2016. Draft Renewal Assessment Report (RAR) on the active substance Mesosulfuron-methyl, prepared according to the Commission Regulation (EU) N° 1107/2009, September 2016

EUROPEAN COMMISSION HEALTH & FOOD SAFETY DIRECTORATE-GENERAL Safety of the food chain Pesticides and Biocides. 2019 TECHNICAL GUIDELINES ON DATA REQUIREMENTS FOR SETTING MAXIMUM RESIDUE LEVELS, COMPARABILITY OF RESIDUE TRIALS AND EXTRAPOLATION OF RESIDUE DATA ON PRODUCTS FROM PLANT AND ANIMAL ORIGIN, SANTE/2019/12752

Commission Regulation (EU) No 289/2014 of 21 March 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for foramsulfuron, azimsulfuron, iodosulfuron, oxasulfuron, mesosulfuron, flazasulfuron, imazosulfuron, propamocarb, bifenazate, chlorpropham and thiobencarb in or on certain products Text with EEA relevance

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	Verte-brate study Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 6.1	~~Werde~~ Wrede, A.	2000	Stability of AE F130060 in wheat shoot during deep freeze storage Mesosulfuron-methyl Code: AE F130060 Report No: C028928 Document No: M-198617-04-1 Aventis Crop Science GmbH, Frankfurt am Main, Germany GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.1	~~Werde~~ Wrede A.	2007	Stability of AE F130060 in wheat straw during deep freeze storage Mesosulfuron-methyl Code: AE F130060	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Report No: C028927 Document No: M-198612-04-1 Aventis Crop Science GmbH, Frankfurt am Main, Germany GLP: yes, Unpublished		
KCA 6.1	~~Werde~~ Wrede A.	2003	Stability of AE F130060 in wheat grain during deep freeze storage Mesosulfuron-methyl Code: AE F130060 Report No: C028926 Document No: M-216176-01 Aventis Crop Science GmbH, Frankfurt am Main, Germany GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.1/02	Stuke S., Ballmann C.	2013	Analytical method 01360 for the determination of amidosulfuron, mesosulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl, and foramsulfuron in samples from plant origin by HPLC-MS/MS Report No: MR-13/007 GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.2.1	Braun P. J., Koehn D. M., Buerkle L. W., Buerkle L.	2000	Metabolism in wheat (Triticum aestivum) following single and double treatment at a nominal application rate of 10 g a.s./ha each Code: (2-14C-pyrimidyl)-AE F130060 Report No.: C008761, Aventis CropScience GmbH, Frankfurt am Main, Germany, Bayer CropScience, GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.2.1	Koehn D. M., Selzer J., Buerkle L. W.	2000	Metabolism in wheat (Triticum aestivum) following single and double treatment at a nominal application rate of 30 g a.s./ha Each Code: (U-14C-phenyl)-AE F130060	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Report No.: C009588, Aventis CropScience GmbH, Frankfurt am Main, Germany,Bayer CropScience, GLP: yes, Unpublished		
KCA 6.6.2	Frey J. A., Harrison, C. L., Buerkle L. W.	2000	Residues in rotated crops sown 31 days after application to bare soil at a rate of 15 g a.s./ha (2-14C-pyrimidyl)-AE F130060 Report No: C008238 Aventis CropScience GmbH, Frankfurt am Main, Germany, Bayer CropScience GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.6.2	Frey J. A., Harrison C. L., Buerkle L. W.	2000	Residues in rotated crops sown 32 days after application to bare soil at a rate of 15 g a.s./ha (U-14C-phenyl)-AE F130060 Report No: C008240 Aventis CropScience GmbH, Frankfurt am Main, Germany, Bayer CropScience GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.6.2	Frey J. A., Harrison C. L.	2000	Residues in rotated crops sown 4 months after application to bare soil at a rate of 15 g a.s./ha (2-14C-pyrimidyl)-AE F130060 Report No: C008242 Aventis CropScience GmbH, Frankfurt am Main, Germany, Bayer CropScience GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.6.2	Frey J. A., Harrison C. L.	2000	Residues in rotated crops sown 4 months after application to bare soil at a rate of 15 g a.s./ha (U-14C-phenyl)-AE F130060 Report No: C008243 Aventis CropScience GmbH, Frankfurt am Main, Germany, Bayer CropScience GLP: yes, Unpublished	N	Bayer CropScience

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 6.6.2	Frey J. A., Harrison C. L.	2000	Residues in rotated crops sown 1 year after application to bare soil at a rate of 15 g a.s./ha (2-14C-pyrimidyl)-AE F130060 Report No: C008239 Aventis CropScience GmbH, Frankfurt am Main, Germany, Bayer CropScience GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.6.2	Frey J. A., Harrison, C. L.	2000	Residdues in rotated crops sown 1 year after application to bare soil at a rate of 15 g a.s./ha Code: (U-14C-phenyl)-AE F130060 Report No.: C008241, Aventis CropScience GmbH, Frankfurt am Main, GermanyBayer CropScience, GLP: yes, Unpublished	N	Bayer CropScience
KCA 6.2.1	Gildemeister H.	2003	Comparison of the two wheat metabolism studies with 14C-AE F130060 Report No.: M-260002-01-1, Bayer CropScience Deutschland GmbH, Frankfurt am Main, Germany, Bayer CropScience, GLP: n.a., Unpublished	N	Bayer CropScience
KCA 6.2.3.		1999	Ruminant - Metabolism, distribution and nature of the residues in milk and edible tissues Code: AEF130060 [redacted], GLP: yes, Unpublished	Y	Bayer CropScience
KCA 6.2.2		1999	Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues Code: AE F130060 [redacted], GLP yes,	Y	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			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 France Bayer CropScience, Report No.: RA-2677/03 GLP: yes, Unpublished	N	Bayer Crop Science

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	Verte-brate 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	Verte-brate study Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

All studies which are used in this documentation have been previously evaluated at EU level.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mesosulfuron-methyl

LOQs (mg/kg) range from: to:

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 : ---

	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/IED) calculation (based on average food consumption)	0.0%	DK child	0.10	0.0%	Rye	0.0%	Wheat				
	0.0%	IT toddler	0.08	0.0%	Wheat	0.0%	Other cereals				
	0.0%	GEMS/Food G06	0.07	0.0%	Wheat	0.0%	Rye				
	0.0%	RO general	0.05	0.0%	Wheat		Grapefruits				
	0.0%	DE child	0.05	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	IT adult	0.05	0.0%	Wheat	0.0%	Other cereals				
	0.0%	GEMS/Food G15	0.05	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G08	0.05	0.0%	Wheat	0.0%	Rye				
	0.0%	FR child 3 15 yr	0.05	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	ES child	0.04	0.0%	Wheat		Grapefruits				
	0.0%	NL toddler	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	NL child	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G07	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	PT general	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G10	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	UK toddler	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G11	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	SE general	0.03	0.0%	Wheat	0.0%	Rye				
	0.0%	FR toddler 2 3 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	DE women 14-50 yr	0.03	0.0%	Wheat	0.0%	Rye				
	0.0%	UK infant	0.03	0.0%	Wheat		Grapefruits				
	0.0%	DE general	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	IE adult	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	ES adult	0.02	0.0%	Wheat		Grapefruits				
	0.0%	FR adult	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	LT adult	0.02	0.0%	Rye	0.0%	Wheat				
	0.0%	UK vegetarian	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	NL general	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	FI 3 yr	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	UK adult	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	DK adult	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	FI 6 yr	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	IE child	0.01	0.0%	Wheat		Grapefruits				
	0.0%	FI adult	0.01	0.0%	Rye	0.0%	Wheat				
	0.0%	FR infant	0.01	0.0%	Wheat	0.0%	Rye				
		Column7			Grapefruits		Grapefruits				

A 3.2 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mesosulfuron-methyl

LOQs (mg/kg) range from: to:

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 : ---

	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)	0.0%	DK child	0.10	0.0%	Rye	0.0%	Wheat				
	0.0%	IT toddler	0.08	0.0%	Wheat	0.0%	Other cereals				
	0.0%	GEMS/Food G06	0.07	0.0%	Wheat	0.0%	Rye				
	0.0%	RO general	0.05	0.0%	Wheat		Grapefruits				
	0.0%	DE child	0.05	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	IT adult	0.05	0.0%	Wheat	0.0%	Other cereals				
	0.0%	GEMS/Food G15	0.05	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G08	0.05	0.0%	Wheat	0.0%	Rye				
	0.0%	FR child 3 15 yr	0.05	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	ES child	0.04	0.0%	Wheat		Grapefruits				
	0.0%	NL toddler	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	NL child	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G07	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	PT general	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G10	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	UK toddler	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	GEMS/Food G11	0.04	0.0%	Wheat	0.0%	Rye				
	0.0%	SE general	0.03	0.0%	Wheat	0.0%	Rye				
	0.0%	FR toddler 2 3 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	DE women 14-50 yr	0.03	0.0%	Wheat	0.0%	Rye				
	0.0%	UK infant	0.03	0.0%	Wheat		Grapefruits				
	0.0%	DE general	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	IE adult	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	ES adult	0.02	0.0%	Wheat		Grapefruits				
	0.0%	FR adult	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Other cereals		
	0.0%	LT adult	0.02	0.0%	Rye	0.0%	Wheat				
	0.0%	UK vegetarian	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	NL general	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	FI 3 yr	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	UK adult	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	DK adult	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	FI 6 yr	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	IE child	0.01	0.0%	Wheat		Grapefruits				
	0.0%	FI adult	0.01	0.0%	Rye	0.0%	Wheat				
	0.0%	FR infant	0.01	0.0%	Wheat	0.0%	Rye				
		Column7			Grapefruits		Grapefruits				

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

A 3.3 IESTI calculations - Raw commodities

IESTI calculation with EFSA model is not required, because ARfD is not necessary.

A 3.4 IESTI calculations - Processed commodities

Not required.