FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: JMD-HER 387 OD

Product name(s): Jockey 387 OD

Chemical active substances:
2,4-D, 250 g/L (as 2,4-D 2EHE, 377 g/L)
Iodosulfuron-methyl-sodium, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: December 2022, March 2024

MS Finalisation date: December 2023; March 2024 August 2024

Version history

When	What
12.2023	zRMS assessment
03.2024	Final version of RR after commenting period
03.2024	List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review updated by Applicant
08.2024	zRMS addition

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

2,4-D

Stability of Residues

2,4-D residues were shown to be stable at least 18 months in high water, high starch and dry matrices, when stored at -18 °C, and at least 12 months in high oil matrices when stored at -23 °C to -27 °C. 2,4-D residues were found to be chemically stable in beef matrices when stored frozen for 4 months (EFSA Journal 2014;12(9):3812). Sufficient stability has been demonstrated to support the residue data presented in this document.

No further data are required to support the proposed uses.

Metabolism in plants

No new data submitted in the framework of this application.

Plant and animal residue definition for monitoring and risk assessment: Sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D (Reg. (EU) 2022/1363, EFSA Journal 2014;12(9):3812)

No further data are required to support the proposed uses.

Magnitude of residues in plants

Proposed GAPs:

Winter wheat, winter rye, winter triticale, spring wheat, spring triticale

BBCH 23-31; 1 application 100.5 - 188.5 g as./ha; PHI: N/A

No new data are submitted in the framework of this application. Applicant refers to the unprotected EU data.

GAP on which MRL/EU assessment is based: 1 x 0.75 kg a.e./ha, BBCH 29-32, PHI not specified

Residues ((8 trials on wheat, 4 trials on barley and 1 trial on oats): 6x <0.02, <0.04, 6x <0.05 mg/kg

Overdosed trials were considered in the risk assessment in this application since all residue values were below the LOQ.

The residues arising from the proposed use will not exceed the MRLs established for cereals (Reg. (EU) 2022/1363: 2 mg/kg – wheat, rye, triticale mg/kg).

According to SANTE/2019/12752 rev.1 extrapolation the residue trials on barley may be extrapolate to oat, rye and wheat and residue trials on wheat may be extrapolate to oat, rye and barley, before forming of the edible part.

Sufficient trials on cereals are available to support the proposed uses.

Magnitude of residues in livestock

The new animal model calculation modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded. Supplementary livestock feeding studies are not required.

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

As quantifiable residues of 2,4-D are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

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

All crops under consideration, may be grown in rotation but, according to the soil degradation studies evaluated in the framework of the peer review, the DT90 value calculated of 2,4-D, was 67.7 days which is below the trigger value of 100 days.

Other / special studies

Cereals have not melliferous capacity. Studies are not required.

Estimation of exposure through diet and other means

The proposed uses of 2,4-D in the formulation JMD-HER 387 OD do not represent unacceptable acute and chronic risks for consumers (calculation was conducted using EFSA PRIMo rev.3.1).

Iodosulfuron-methyl-sodium

Stability of Residues

The storage stability report shows that iodosulfuron-methyl and its metabolite triazine amine (AE F059411) are stable in wheat grain, green material and straw for at least 24 months under deep-freezer storage conditions (≤-18°C).

The Applicant refers to data included in the Registration Report of Atlantis 12 OD.

NOTE: The data protection of Atlantis 12 OD should be confirmed by the competent authority at national level before registration.

Metabolism in plants

No new data submitted in the framework of this application.

EU Endpoints Plant	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not relevant
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016; Reg. (EU) No 289/2014)
Plant residue definition for risk assessment	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016) Triazine amine (IN-A4098) is a potential candidate for the plant residue definition for risk assessment, and a

	final decision is pending further clarification regarding the toxicological properties and the related consumer risk. Pending the conclusion on the IN-A4098 toxicity, also the metabolite AE 0031838 (hydroxymethyl triazine amine) observed up to 15% TRR in grain may require a reassessment.
Conversion factor from enforcement to RA	1 (EFSA, 2012, 2016)

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

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

No further data are required to support the proposed uses.

Magnitude of residues in plants
Proposed GAPs:
Winter wheat, winter rye, winter triticale, spring wheat, spring triticale
BBCH 23-31; 1 application 8-9 g as./ha; PHI: N/A
No new data are submitted in the framework of this application. Applicant refers to the unprotected EU data.
GAP on which EU a.s. assessment is based: 1 × 0.010-0.015 kg as/ha, BBCH 32-39, PHI not relevant, outdoor
Residues (12 trials on wheat, 1 trial on barley and 1 trial on rye): 14 × <0.01 mg/kg
The residues arising from the proposed use will not exceed the MRLs established for cereals (Reg. (EU) No 289/2014: 0.01 mg/kg – wheat, rye, triticale mg/kg).
According to SANTE/2019/12752 rev.1 extrapolation the residue trials on barley may be extrapolate to oat, rye and wheat and residue trials on wheat may be extrapolate to oat, rye and barley, be-fore forming of the edible part.

Sufficient trials on cereals are available to support the proposed uses.
Magnitude of residues in livestock
The calculated dietary burdens were found to not exceed the trigger value of 0.004 mg/kg bw (0.1 mg/kg dry matter (DM) for all groups of livestock. Further investigation of residues is therefore not required.
Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation
As residues in wheat grain are below the LOQ (<0.01 mg/kg) at the intended maximum application rate of 9 g a.s./ha, studies on the effects of processing on the nature of the residues are not required.
Magnitude of residues in representative succeeding crops
Iodosulfuron-methyl residue levels in rotational commodities were not expected to exceed 0.01 mg/kg, provided that iodosulfuron-methyl-sodium is applied in compliance with the representative GAPs.
Other / special studies
Cereals have not melliferous capacity. Studies are not required.
Estimation of exposure through diet and other means
The proposed uses of iodosulfuron-methyl-sodium in the formulation JMD-HER 387 OD do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation JMD-HER 387 OD are presented in Table 7.1-1. A list of all intended uses within the EU is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment.
An exceedance of the current MRL of 2 mg/kg for rye, wheat and triticale for 2,4-D as laid down in Reg. (EU) 396/2005 (with its amendments) is not expected.
The chronic and the short-term intakes of 2,4-D residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authority agrees with the authorization of the intended uses.

An exceedance of the current MRL of 0.01 mg/kg for rye, wheat and triticale for iodosulfuron-methyl-sodium as laid down in Reg. (EU) 396/2005 (with its amendments) is not expected.
The chronic and the short-term intakes of iodosulfuron-methyl-sodium residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authority agrees with the authorization of the intended uses.

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

In the case of the stability of iodosulfuron-methyl, the Applicant refers to the data contained in the Atlantis 12 OD Registration Report. The data protection of Atlantis 12 OD should be confirmed by the competent authority at national level before registration.

~~List of data submitted or referred to by the applicant and relied on, but already evaluated should be completed before registration.~~ The list was completed in *iodosulfuron 2-4 D_fRR Part A JMD-HER 387 OD_Pestila_ PL_03.2024 v2* updated in 08.2024.

Data gaps

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)**	**g as/hL min max**	**water L/ha min max**	**g as/ha min max**		
1	Winter wheat, Winter rye, Winter triticale	PL	JMD-HER 387 OD	F	weeds (for details please refer to Section B0 and B3)	OD	377 g/l of 2,4-D and 10 g/l of iodosul-furon-methyl-sodium	broadcast spraying	BBCH 23-31 Spring, post emergence	1	n.a.	100.5 - 188.5 g 2,4-D 2.67 - 5 g iodosulfuron-methyl-sodium	200 - 300 l/ha	301.6 - 377 g 2,4-D 8 - 10 g iodosulfuron-methyl-sodium	NR	A
2	Spring wheat, Spring triticale	PL	JMD-HER 387 OD	F	weeds (for details please refer to Section B0 and B3)	OD	377 g/l of 2,4-D and 10 g/l of iodosul-furon-methyl-sodium	broadcast spraying	BBCH 23-31 Spring, post emergence	1	n.a.	100.5 - 188.5 g 2,4-D 2.67 - 5 g iodosulfuron-methyl-sodium	200 - 300 l/ha	301.6 - 377 g 2,4-D 8 - 10 g iodosulfuron-methyl-sodium	NR	A
3	Winter wheat	BG	JMD-HER 387 OD	F	weeds (for details please refer to Section B0 and B3)	OD	377 g/l of 2,4-D and 10 g/l of iodosul-furon-methyl-sodium	broadcast spraying	BBCH 23-31 Spring, post emergence	1	n.a.	100.5 - 188.5 g 2,4-D 2.67 - 5 g iodosulfuron-methyl-sodium	200 - 300 l/ha	301.6 - 377 g 2,4-D 8 - 10 g iodosulfuron-methyl-sodium	NR	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 JMD-HER 387 OD is composed of 2,4-D and iodosulfuron-methyl-sodium.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of 2,4-D and iodosulfuron-methyl-sodium

Reference value	Source	Year	Value	Study relied upon	Safety factor
2,4-D					
ADI	EFSA Journal 2014;12(9):3812	2014	0.02 mg/kg bw per day	Dog, 1-year	100
ARfD	EFSA Journal 2014;12(9):3812	2014	0.3 mg/kg bw	Rat and rabbit developmental toxicity studies	100
Iodosulfuron-methyl-sodium					
ADI	EFSA Journal 2016;14(4):4453	2016	0.03 mg/kg bw per day	Rat. 2-year	100
ARfD	EFSA Journal 2016;14(4):4453	2016	3.15 mg/kg bw per day	Rat, developmental	100

7.1.2.1 Summary for 2,4-D

Table 7.1-3: Summary for 2,4-D

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, Winter rye, Winter triticale	Yes	Yes (13 trials N-EU)	Yes	Yes	Yes	No	No
2	Spring wheat, Spring triticale	Yes	Yes (13 trials N-EU)	Yes	Yes	Yes		No
3	Winter wheat	Yes	Yes (13 trials N-EU)	Yes	Yes	Yes		No

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

As residues of 2,4-D 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 iodosulfuron-methyl-sodium

Table 7.1-4: Summary for iodosulfuron-methyl-sodium

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter wheat, Winter rye, Winter triticale	Yes	Yes (14 trials N-EU)	Yes	Yes	Yes	No	No
2	Spring wheat, Spring triticale	Yes	Yes (14 trials N-EU)	Yes	Yes	Yes		No
3	Winter wheat	Yes	Yes (14 trials N-EU)	Yes	Yes	Yes		No

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

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

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

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

7.1.2.3 Summary for JMD-HER 387 OD

Table 7.1-5: Information on JMD-HER 387 OD (KCA 6.8)

Crop	PHI for JMD-HER 387 OD proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for JMD-HER 387 OD proposed by zRMS	zRMS Comments (if different PHI proposed)
		2,4-D	Iodosulfuron-methyl-sodium		
Cereals	F**	Yes	Yes		

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

When application is made according to GAP table (BBCH 23–31), the waiting period is covered by the vegetation period.

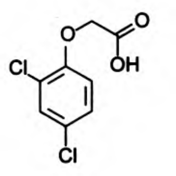
The product does not pose a risk to the succeeding crops in the normal rotation cycle.
In case of the necessity of early liquidation of the treated plantation as a result of plant damage caused by frosts, diseases or pests, after ploughing (to a depth of 25 cm), spring wheat or spring barley can be grown.

Assessment

7.2 2,4-D

General data on 2,4-D are summarized in the table below.

Table 7.2-1: General information on active 2,4-D

Active substance (ISO Common Name)	2,4-D
IUPAC	(2,4-dichlorophenoxy) acetic acid
Chemical structure	
Molecular formula	$C_8H_6Cl_2O_3$
Molar mass	221 g/mol
Chemical group	phenoxy acetic compounds
Mode of action (if available)	Selective, systemic, absorbed through roots and increases biosynthesis and production of ethylene causing uncontrolled cell division and so damages vascular tissue. Synthetic auxin.
Systemic	Yes
Company (ies)	European Union 2,4-D Task Force *
Rapporteur Member State (RMS)	RMS: Greece, Co-RMS: Poland
Approval status	Approved (01/01/2016) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0540 Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D 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/?uri=CELEX:32015R2033
Restriction	Only uses as herbicide may be authorised.
Review Report	SANCO/11961/2014 – rev. 5 06/10/2017
Current MRL regulation	Reg. (EU) 2019/1791 Reg. (EU) 2022/1363 will apply from 25/02/2023
Peer review of MRLs according to Article 12 of Reg No	Yes.

396/2005 EC performed	
EFSA Journal: Conclusion on the peer review	Yes, EFSA Journal 2014;12(9):3812
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2011;9(11):2431
Current MRL applications on intended uses	Not applicable.

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

A summary of the storage stability data on 2,4-D is given in the following table. Data has been previously evaluated at EU level and is described in detail in the RAR (Greece, 2013), in the final Addendum to the RAR (Greece, 2014), in EFSA's Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D (EFSA Journal 2014;12(9):3812) and in EFSA's RO on the review of the existing MRLs for 2,4-D according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2011;9(11):2431.

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			
Sugar cane, grass, wheat and maize forage	High water content	12 months	RAR, Greece, 2014 EFSA 2014
Wheat, rice, maize and sorghum grain	High starch content	12 months	
Soya bean	High lipid content	12 months	
Cereal straw, hay	Dry matrices	12 months	
Cereal greens	High water content	18 months	
Cereal grain	High starch content	18 months	
Cereal straw	Dry matrices	18 months	
Animal Products			
Ruminant	Milk and tissues	4 months	RAR, Greece, 2014 EFSA 2014

Conclusion on stability of residues during storage

Storage stability of 2,4-D was demonstrated for the following periods in the commodities listed in table above when frozen (approximately -18°C). The storage stability of 2,4-D has been investigated in different groups, including high water, high oil, and high starch content commodities, other plant commodities and animal tissues. The available residue trials supporting the intended uses were performed in compliance with the above reported storage conditions.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

A summary of the metabolism of 2,4-D in plants is given in the following table. Data has been previously evaluated at EU level and is described in detail in the RAR (Greece, 2013), in the final Addendum to the RAR (Greece, 2014), in EFSA's Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D (EFSA Journal 2014;12(9):3812) and in EFSA's RO on the review of the existing MRLs for 2,4-D according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2011;9(11):2431.

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								
Fruits and fruiting vegetable	Apple	U-^{14}Cphenyl labelled	Application around the trunk	2.13	2	56	-	RAR, Greece, 2014 EFSA 2014
Root and tuber vegetables	Potato	U-^{14}Cphenyl labelled	F	0.07	2	82	-	
	Potato	U-^{14}Cphenyl labelled	F	0.14 and 0.28	2	29	-	
Pulses and oilseeds	Soya bean	1-^{14}C-2,4-D	Injection, G	21 µg/plant or callus	1	Plants: 14 Callus: 7	-	
Cereals	Wheat	U-^{14}Cphenyl labelled	F	1.68	1	0, 10, 28, 49	-	
	Wheat	Unlabelled	F	0.5	1	1, 2, 3, 5, 9, 19, 35	-	
	Wheat	1-^{14}C-2,4-D	Injection, G	21 µg/plant or callus	1	Plants: 14 Callus: 7	-	

Summary of plant metabolism studies reported in the EU

According to the final Addendum to the RAR (Greece, 2014) and EFSA Journal 2014;12(9):3812 residue levels were too low for identification in apples (total residues: 0.009 mg/kg) and in potatoes (total residues: 0.0054 mg/kg). In wheat grain, nearly 50% of the TRR was associated with natural products (protein, starch and cellulose fractions). The remaining residue consisted primarily of polar unknowns and unextractable compounds. Parent 2,4-D accounted for 6% TRR and was the only component identified. In wheat forage and wheat straw, parent 2,4-D was the main component of the residue (72-77% TRR, free + conjugated). The remaining residue comprised a large number of distinct metabolites, out of which 4-OH-2,5-D was the major metabolite of 2,4-D. It accounted for 8% TRR. Other metabolites were defined as hydroxylated derivatives of 2,4-D and unknowns, none of them exceeding 2.5% of the TRR.

The results obtained for soya beans and maize plants, revealed similar metabolic pathways, i.e. conjugation of 2,4-D, and, to a much lesser extent, hydroxylation of the phenyl ring. Based on these studies, it is concluded that metabolic pathways are similar in all tested crops.

Summary of new plant metabolism studies

Not relevant. New studies were not provided.

Conclusion on metabolism in primary crops

Metabolism studies demonstrated that the final residue in plants comprises both esters and 2,4-D in its acid form, the residue for both enforcement and risk assessment in all plant commodities is defined as the sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D.
The metabolism of 2,4-D in plants is sufficiently addressed to support the proposed uses of the product JMD-HER 387 OD.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

A metabolism study on rotational crops was not available and no new data were submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

According to the soil degradation studies evaluated in the framework of the peer review, the DT_{90} value calculated of 2,4-D, was 67.7 days which is below the trigger value of 100 days. Relevant soil metabolites were also not identified. Further investigation of residues in rotational crops is not required as relevant residues in these crops are not expected.

Summary of new plant metabolism studies

Not relevant. New studies were not provided.

Conclusion on metabolism in rotational crops

No studies on rotational crops are available and none are required due to the fast degradation of 2,4-D in soil.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No processing study is available, and no new data is submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

Based on available residue data, no quantifiable residues of 2,4-D are expected in edible parts of crops, there is no need to investigate effects of industrial and/or household processing.

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

Table 7.2-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (wheat) Root/tuber crops (potato) Fruit crops (apple) Pulses/oilseeds (soya beans)
Rotational crops covered	Not required (DT_{90} < 100 days).
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable.
Processed commodities	Due to low residues at harvest, no study is required.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable.
Plant residue definition for monitoring	2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as 2,4-D (Reg. (EU) 2022/1363).
Plant residue definition for risk assessment	Sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D (EFSA Journal 2014;12(9):3812).
Conversion factor from enforcement to RA	None.

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

Available data

No new data submitted in the framework of this application.

A summary of the metabolism of 2,4-D in livestock is given in the following table. Data has been previously evaluated at EU level and is described in detail in the RAR (Greece, 2013), in the final Addendum to the RAR (Greece, 2014), in EFSA's Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D (EFSA Journal 2014;12(9):3812) and in EFSA's RO on the review of the existing MRLs for 2,4-D according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2011;9(11):2431.

Table 7.2-5: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	U-^{14}Cphenyl labelled	1	24	3	Milk	daily	RAR, Greece, 2014 EFSA 2014
						Urine and faeces	daily	
						Tissues	after sacrifice	
Laying poultry	Hens	U-^{14}Cphenyl labelled	15	1.4	7	Eggs	daily	
						Excreta	daily	
						Tissues	after sacrifice	

Summary of plant metabolism studies reported in the EU

In both goat and poultry, 2,4-D was extensively excreted in urine and faeces (≥90% TRR); less than 0.1% of the administered radioactivity was recovered in milk, eggs and tissues, resulting in TRRs below 0.2 mg/kg in all animal matrices, except for kidney (0.7 mg/kg and 1.4 mg/kg for poultry and goat, respectively).

The parent 2,4-D, free and conjugated, was identified as the major compound in the residue in milk (47% TRR), eggs (23% TRR), chicken liver, fat and kidney (18, 25 and 76% TRR). In addition, 4-chlorophenoxyacetic acid was identified in milk (6.9% TRR) and 2,4-DCP was found in milk, eggs and chicken liver up to 7.3% TRR.

Summary of new animal metabolism studies

Not relevant. New studies were not provided.

Conclusion on metabolism in livestock

The metabolic patterns identified for goats and hens were consistent with the rat metabolism and therefore considered applicable to pigs as well. Considering that 2,4-D conjugates were identified in animal matrices, the same residue definitions as for plant commodities were proposed for products of animal origin.
The metabolism of 2,4-D in livestock is sufficiently addressed to support the proposed uses of the product JMD-HER 387 OD.

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

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

Endpoints	
Animals covered	Lactating goats.
	Laying hens.
Time needed to reach a plateau concentration	28 days in milk.
	No data for eggs.
Animal residue definition for monitoring	2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as 2,4-D) (Regulation (EU) 2022/1363).
Animal residue definition for risk assessment	Sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D (EFSA, 2014).
Conversion factor	Not applicable.
Metabolism in rat and ruminant similar	Yes.
Fat soluble residue	No.

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-7: Summary of EU reported and new data supporting the intended uses of JMD-HER 387 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, rye and triticale extrapolated from cereal grain (barley, oats and wheat)	EFSA, 2014 Final Addendum to the RAR (Greece, 2014)	N-EU	GAP on which MRL/EU assessment is based: 1 x 0.75 kg a.e./ha, BBCH 11/21-32, PHI not specified, but not required, outdoor E/RA: 6x <0.02, <0.04, 6x <0.05	N/A				
	Overall supporting data for cGAP	N-EU	E/RA: 6x <0.02, <0.04, 6x <0.05	0.04	0.05	-	2	Yes
Cereal straw (barley, oats and wheat)	EFSA, 2014 Final Addendum to the RAR (Greece, 2014)	N-EU	GAP on which MRL/EU assessment is based: 1 x 0.75 kg a.e./ha, BBCH 11/21-32, PHI not specified, outdoor E/RA: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4	N/A				
	Overall supporting data for cGAP	N-EU	E/RA: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4	0.081	1.4	-	-	-

* Source of EU MRL: Reg. (EU) 2019/1791 (Reg. (EU) 2022/1363 will apply from 25/02/2023)

Table 7.2-7.1 Residue trials in EU-N used for support of cereals registration (Final Addendum to the RAR (Greece, 2014))

Lp.	Country, year	Application per treat-ment			Crop	Crop growth stage	Residues mg/kg		Reference/ Study code
		Form. type	No	g ai/ha			Grain	Straw	
1	PL, 2005	SL	1	927	wheat	29	<0.04*	0.025	**Final Addendum to the RAR (Greece, 2014) /** C/01/05
2	PL, 2007	SL	1	760.6	wheat	29	<0.02*	<0.1*	**Final Addendum to the RAR (Greece, 2014) /** 20074503/PL1-FPWW
3	UK, 2010	SL	1	784	wheat	32	<0.02*	0.65	**Final Addendum to the RAR (Greece, 2014) /** S10-02109
4	DE, 2010	SL	1	805	wheat	32	<0.02*	<0.02*	**Final Addendum to the RAR (Greece, 2014) /** S10-02109
5	PL, 2010	SL	1	783	wheat	32	<0.02*	0.28	**Final Addendum to the RAR (Greece, 2014) /** S10-02109
6	PL, 2010	SL	1	796	wheat	32	<0.02*	1.4	**Final Addendum to the RAR (Greece, 2014) /** S10-02109
7	AT, 1992	SL	1	720	wheat	31	<0.05*	0.081	**Final Addendum to the RAR (Greece, 2014) / DAR, Greece** Agrolinz 1166
8	AT, 1992	SL	1	750	wheat	31	<0.05*	<0.05*	**Final Addendum to the RAR (Greece, 2014) / DAR, Greece** Agrolinz 1153
9	PL, 2007	SL	1	618.3	barley	29	<0.02*	<0.1*	**Final Addendum to the RAR (Greece, 2014) /** 20074503/PL1-FPSH
10	AT, 1992	SL	1	750	oat	31	<0.05*	<0.05*	**Final Addendum to the RAR (Greece, 2014) / DAR, Greece** Agrolinz 1153
11	AT, 1992	SL	1	750	barley	31	<0.05*	<0.05*	**Final Addendum to the RAR (Greece, 2014) / DAR, Greece** Agrolinz 1153
12	AT, 1992	SL	1	750	barley	32	<0.05*	0.19	**Final Addendum to the RAR (Greece, 2014) / DAR, Greece** Agrolinz 1153
13	AT, 1992	SL	1	720	barley	31	<0.05*	<0.05*	**Final Addendum to the RAR (Greece, 2014) / DAR, Greece** Agrolinz 1166

* LOQ value

7.2.3.2 Conclusion on the magnitude of residues in plants

Cereals

A total of 13 trials on cereals in N-EU zone (8 trials on wheat, 4 trials on barley and 1 trial on oats) are available. All trials were performed according to the critical EU GAP from final Addendum to the RAR (Greece, 2014) which is more critical than the proposed GAP.

All residue values were below the LOQ and are sufficient to support the proposed use. The residue data are valid with regard to storage stability.
According to SANCO 7525/VI/95 Rev. 10.3; 13 June 2017 the residue trials on barley may be extrapolate to oat, rye and wheat and residue trials on wheat may be extrapolate to oat, rye and barley, before forming of the edible part. Application to cereal is intended at early growth stages (up to BBCH 31), therefore extrapolation is possible.
The residues arising from the proposed uses will not exceed the MRLs established for wheat (including triticale) and rye (2.0 mg/kg).

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

Active substance 2,4-D is authorised in EU for use on crops that might be fed to livestock. Dietary burden calculation was performed in EFSA reasoned opinion on the review of the existing maximum residue levels for 2,4-D according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2011;9(11):2431). According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance 2,4-D. The median and maximum dietary burdens were calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009).

Dietary burden calculation for purpose of maintain authorisation of JMD-HER 387 OD was performed by Excel spreadsheet Animal model 2017 and was focused only on intended uses of JMD-HER 387 OD i.e. barley, wheat, triticale and rye. Input values (STMR and HR) used for dietary calculation are provided below in Table 7.2-8. Results of dietary burden calculation for JMD-HER 387 OD are included in Table 7.2-9.

Table 7.2-8: Input values for the dietary burden calculation (considering the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D				
Cereals, straw	0.081	STMR	1.4	HR
Cereals, grain	0.04	STMR	0.04	STMR
Brewers’s grain, dried	0.04 x 3.3	STMR x PF*	0.04 x 3.3	STMR x PF*
Distiller’s grain, dried	0.04 x 3.3	STMR x PF*	0.04 x 3.3	STMR x PF*
Wheat gluten, meal	0.04 x 1.8	STMR x PF*	0.04 x 1.8	STMR x PF*
Wheat, milled by-pdts	0.04 x 7	STMR x PF*	0.04 x 7	STMR x PF*

* default value from Animal model 2017

Table 7.2-9: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg DM)	Maximum dietary burden (mg/kg DM)	Most critical diet	Highest contributing commodity	Trigger 0.004 mg/kg bw/d exceeded (Y/N)
Risk assessment residue definition: sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D							
Cattle (all diets)	0.005	0.023	0.14	0.59	Dairy cattle	Barley, straw	Y
Cattle (dairy only)	0.005	0.023	0.14	0.59	Dairy cattle	Barley, straw	Y
Sheep (all diets)	0.009	0.046	0.20	1.07	Lamb	Barley, straw	Y
Sheep (ewe only)	0.006	0.036	0.18	1.07	Ram/Ewe	Barley, straw	Y
Swine (all diets)	0.005	0.005	0.18	0.18	Swine (finishing)	Wheat, milled by pdts	Y
Poultry (all diets)	0.007	0.017	0.10	0.25	Poultry layer	Wheat, straw	Y
Poultry (layer only)	0.007	0.017	0.10	0.25	Poultry layer	Wheat, straw	Y

The calculated dietary burdens were found to exceed the trigger value of 0.004 mg/kg bw (0.1 mg/kg dry matter (DM) for all groups of livestock. Further investigation of residues is therefore required.
A summary of the available livestock feeding studies is given in the table 7.2-10.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

A summary of the available livestock feeding study is given in the following table. Data has been previously evaluated at EU level and is described in detail in the RAR (Greece, 2013), in the final Addendum to the RAR (Greece, 2014), in EFSA's Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D (EFSA Journal 2014;12(9):3812) and in EFSA's RO on the review of the existing MRLs for 2,4-D according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2011;9(11):2431.

Table 7.2-10: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)(b)	Highest residue (mg/kg)(c)	Calculated MRL (mg/kg)	CF for RA(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)(a)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Greece, 2014; EFSA, 2011; EFSA, 2014)												
Enforcement and risk assessment residue definition: sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D												
Pig meat	0.359	0.738	52.58	3	0.21	0.24	0.21	0.24	0.05	0.05	0.05*	1
			105.1	3	0.41	0.51	0.41	0.51				
			210.1	3	0.76	1.1	0.76	1.1				
Pig fat			52.58	3	0.42	0.51	0.42	0.51	0.05	0.05	0.05*	1
			105.1	3	0.59	0.75	0.59	0.75				
			210.1	3	2.5	3.6	2.5	3.6				
Pig liver			52.58	3	0.12	0.20	0.12	0.20	0.05	0.05	0.05*	1
			105.1	3	1.9	2.4	1.9	2.4				
			210.1	3	3.0	3.5	3.0	3.5				
Pig kidney			52.58	3	3.9	6.5	3.9	6.5	0.05	0.091	0.1	1
			105.1	3	14	18	14	18				
			210.1	3	17	29	17	29				
Ruminant meat	2.70	5.571	52.58	3	0.21	0.24	0.21	0.24	0.05	0.05	0.05*	1
			105.1	3	0.41	0.51	0.41	0.51				
			210.1	3	0.76	1.1	0.76	1.1				
Ruminant fat			52.58	3	0.42	0.51	0.42	0.51	0.05	0.054	0.1	1

			105.1	3	0.59	0.75	0.59	0.75				
			210.1	3	2.5	3.6	2.5	3.6				
Ruminant liver			52.58	3	0.12	0.20	0.12	0.20	0.05	0.05	0.05*	1
			105.1	3	1.9	2.4	1.9	2.4				
			210.1	3	3.0	3.5	3.0	3.5				
Ruminant kidney			52.58	3	3.9	6.5	3.9	6.5	0.195	0.689	1	1
			105.1	3	14	18	14	18				
			210.1	3	17	29	17	29				
Milk	2.291	4.727	52.58	3	0.04 (e)	N/A	0.04 (e)	N/A	0.01	0.01	0.01*	1
			105.1	3	0.12 (e)	N/A	0.12 (e)	N/A				
			210.1	3	0.29 (e)	N/A	0.29 (e)	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Based on a xx kg animal consuming xx kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): Mean residue level from day X until day XX (X cows, Y sampling days).

Table 7.2-11: Overview of the values derived from livestock feeding studies (EFSA Journal 2014;12(9):3812)

	Ruminant:	Poultry[1]:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no – if yes, specify the level)	Yes 3.8 mg/kg DM[2]	No 0.07 mg/kg DM[2]	Yes 0.66mg/kg DM[2]
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	No	No
	Feeding studies: Lactating cow, 4 feeding levels, 28 days Residue levels in matrices: Mean (max) mg/kg in the lowest feeding level (1446 mg/kg feed or 53 mg/kg bw) equivalent to a 325/380N rate for beef/dairy cattle		
Muscle	0.21 (0.24)	-	
Liver	0.12 (0.20)	-	
Kidney	3.8 (6.5)	-	
Fat	0.42 (0.51)	-	
Milk	0.04 (0.07)		
Eggs		-	

[1]: According to the calculated dietary burden, a poultry feeding study was not required.
[2]: Equivalent to 0.138, 0.163, 0.004 and 0.026 mg/kg bw for dairy cattle, beef cattle, chicken and pig, respectively

Conclusion on feeding studies

According to EFSA Journal 2014;12(9):3812 the magnitude of 2,4-D residues in livestock was investigated in a feeding study on lactating cows. Four groups of lactating cows, each consisting of three animals, were dosed for 28 days with 2,4-D at levels at range 53 - 312 mg a.s./kg bw/d. Residues of 2,4-D were detected in most milk and tissues samples analyzed. The highest relative residue level of the various cattle matrices analyzed was found in kidney, followed by liver, fat muscle and milk. The magnitude of residues was generally found to be dose-dependent. The feeding doses were exaggerated, and it can be concluded that significant residues in edible matrices of ruminants and pigs are not expected except in ruminant fat and kidney as well as pig kidney. It is therefore concluded that MRLs for these commodities can be established at the LOQ, except for ruminant fat, ruminant kidney and pig kidney where higher MRLs are proposed. For poultry, no MRLs are proposed as a significant intake was not identified for this type of livestock.

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

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

7.2.5.2 Conclusion on processing studies

According to EFSA Journal 2014;12(9):3812 as residues in cereal grains were all below the LOQ and quantifiable residues of 2,4-D are not expected in edible part of crops, there is no need to investigate the effect of industrial and/or household processing. Processing studies were not required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Due to fast degradation of 2,4-D in soil (see 7.2.2.2) no field rotational crop study is required.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

No field rotational crop study was available and no new data was submitted in the framework of the current application.

Conclusion on rotational crops studies

According to EFSA Journal 2014;12(9):3812 2,4-D was demonstrated to decline rapidly in soil. The DT_{90} value of 2,4-D was below the trigger value of 100 days for further considerations. Relevant soil metabolites were also not identified. No field studies for the investigation of residues in rotational crops are required and significant residues are not expected in food and feed commodities from rotated crops.

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

The available data for the active substance sufficiently addresses aspects of the residue situation that may arise from the use of JMD-HER 387 OD. Other / special studies are therefore not needed.

All residue values for intended uses achieved from supervised residue trials were below LOQ. Product JMD-HER 387 SE is intended to apply on crops which have not melliferous capacity (according to SANTE/11956/2016 rev. 9, 14 September 2018) therefore, it is very unlikely that residues of 2,4-D will be present in honey.

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

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

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D				
Tier I				
Wheat (including triticale)	2.0	EU MRL*	2.0	EU MRL*
Rye	2.0	EU MRL*	2.0	EU MRL*
All other commodities of plant and animal origin	variable	EU MRL*	Not relevant. Acute risk assessment was performed for intended uses only.	
Tier II				
Wheat (including triticale)	0.04	STMR	Not relevant. IESTI < 100 % of ARfD.	
Rye	0.04	STMR		
All other commodities of plant and animal origin	variable	EU MRL*	Not relevant. Acute risk assessment was performed for intended uses only.	

* Reg. (EU) 2022/1363

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

ADI	0.02 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	114 % (based on DK child diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	46 % (based on NL toddler diet)
ARfD	0.3 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Unprocessed commodities Wheat: 10% (based on UK 4-6 years Diet) Rye: 4% (based on (based on UK infant Diet) Processed commodities Wheat / milling (flour): 8% (based on DE child Diet) Wheat / milling (wholemeal)-baking: 4% (based on NL child Diet) Rye / boiled: 2% (based on NL child Diet) Rye / milling (wholemeal)-baking: 2% (based on NL child Diet)
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

Chronic and acute exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1; 2021/01/06). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population.

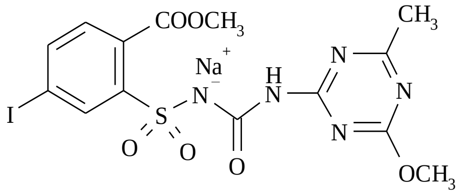
- Tier I - the potential chronic dietary exposure was compared to the ADI of 0.02 mg/kg bw/day and TMDI values were achieved. Input values for all commodities were derived from EU MRL (Reg. (EU) 2022/1363). The highest chronic exposure was calculated for DK child Diet, representing 114% of the ADI. For this diet the highest contributor was rye (55% of ADI). TMDI value is slightly above 100%, thus higher tier exposure calculation for chronic exposure was performed (Tier II).
  The potential acute dietary exposure was compared to the ARfD of 0.3 mg/kg bw and IESTI values were achieved. Input values only for intended uses were derived from EU MRL (Reg. (EU) 2022/1363). With regard to the acute exposure, no exceedance was identified. The highest % of ARfD was identified for wheat (10%) in UK 4-6 years Diet. In view of the above, there is no need to perform a higher tier exposure calculation for acute exposure.
- Tier II - only chronic exposure was re-calculate. Input values (STMR) for wheat and rye were put from supervisor residue trials (Table 7.2 9). Values for all other commodities were put from Reg. (EU) 2022/1363 (EU MRLs). After re-calculation, there is no exceedance of the ADI for 2,4-D.

The proposed uses of 2,4-D in the formulation JMD-HER 387 OD does not represent unacceptable chronic and acute risks for the consumer.

7.3 Iodosulfuron-methyl-sodium

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

Table 7.3-1: General information on iodosulfuron-methyl-sodium

Active substance (ISO Common Name)	iodosulfuron modified ISO: 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	$C_{14}H_{13}IN_5Na_6S$
Molar mass	52.3 g/mol
Chemical group	Sulfonylurea
Mode of action (if available)	Selective to cereals. Inhibits plant amino acid synthesis - aceto-hydroxyacid synthase AHAS
Systemic	Yes
Company (ies)	Bayer CropScience*
Rapporteur Member State (RMS)	Sweden (Renewal)
Approval status	Approved (01/04/2017) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0540 Commission Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0823-20140526 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	-
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 Journal: Conclusion on the peer review	Yes, EFSA Journal 2016; 14(4):4453
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2012; 10(11):2974
Current MRL applications on intended uses	Not applicable

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

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

EFSA Journal 2016;14(4):4453:
Regarding the magnitude of residues, the cGAP was supported by a sufficient number of residue trials, which allowed the estimation of the expected residue concentrations of iodosulfuron-methyl and of metsulfuron-methyl in the relevant plant commodities. Quantifiable residues of both compounds are not expected above the LOQ of 0.01 mg/kg in grains, and in straw of 0.05 mg/kg. However, a new storage stability study on iodosulfuron-methyl residues in cereals is requested to support the findings in the residue trials (data gap). A distinct conclusion regarding the stability of iodosulfuron-methyl residues in cereals was not possible on the basis of the available studies. In addition, in some cases information on the experimental designs (storage temperature prior to analysis) should be provided to fully validate the cereal residue trials (data gap).
Because data gap was identified in this area during the renewal of approval process, a new stability study was submitted in the framework of application acc. Art. 43 of the plant protection product Atlantis 12 OD (product code: 102000008429). Regarding above these data should be considered as confirmatory data. According to the *COMMISSION NOTICE Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (2019/C 229/01), point 16: Active substance confirmatory information submitted for NAS or EAS (assessed post approval) for approvals issued under Reg. (EC) No 1107/2009 - The situation arises when confirmatory information is submitted after the granting of an authorisation. In the case where the confirmatory information is necessary for the authorisation, confirmatory information will be protected in line with the main active substance data package (…) for renewed active substances, 30 months from the date of amended authorisation or from the date of decision to maintain the authorisation in each Member State*.
The authorisation for Atlantis 12 OD was renewed on August 24th, 2020 (decision MRiRW nr R – 555/2020d), therefore this data should no longer be protected and may be used for purpose of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat Shoot	High water content	26 months	EFSA, 2012 RAR, Sweden, 2015
Wheat Straw	No group	28 months	
Wheat Grain	Dry commodity	Up to 24 months	
Confirmatory data			
Plant products			
Wheat green material	High water content	24 months	RR Atlantis 12 OD (product code: 102000008429), MS Finalisation date: 12/2019; MS Revision: 03/2020
Wheat grain	High starch content	24 months	
Wheat straw	Other	24 months	

Conclusion on stability of residues during storage

The storage stability report shows that iodosulfuron-methyl and its metabolite triazine amine (AE F059411) are stable in wheat grain, green material and straw for at least 24 months under deep-freezer storage conditions (≤-18°C).

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

According to the RAR (Sweden, 2016) enough data was available from the first DAR (Germany, 2000). Metabolism of iodosulfuron-methyl was investigated for foliar treatment on cereals (wheat) using either 2-14C-triazinyl or U-14C-phenyl labelled iodosulfuron-methyl-sodium.

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-	Foliar, F	20 g/ha	1	6, 26 and	Forage: 3,	DAR Ger-

		triazinyl		+ safener$^{(b)}$		48 days	7, 22 Hay: 35 Mature: 49 Harvest: 77	many, 2000 EFSA, 2012 RAR, Swe- den, 2015 EFSA, 2016
		U-^{14}C-phenyl	Foliar, G	20 g/ha + safener$^{(b)}$	1		Forage: 0, 20, 23, 28 Hay: 43 Harvest: 87	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): The safener used is mefenpyr diethyl at ratio 3/1

Summary of plant metabolism studies reported in the EU

According to EFSA, 2016:
Metabolism was investigated in wheat (cereal crop group) following foliar application using ^{14}C-Phenyl and 1^{4}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.

Summary of new plant metabolism studies

Not relevant. New studies were not provided.

Conclusion on metabolism in primary crops

Considering the representative use in cereals, the relevant residue for both enforcement and risk assessment on this crop group was proposed by default as sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl. The metabolism of iodosulfuron-methyl-sodium in plants is sufficiently addressed to support the proposed uses of the product JMD-HER 387 OD.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of iodosulfuron-methyl is expected to be lower than 49 days which is far below the trigger value of 100 days (DAR, Germany, 2000). However, metsulfuron-methyl was identified as a relevant soil metabolite and for this compound DT_{90} values in the field ranged between 26 and 190 days. Therefore, metabolism of iodosulfuron-methyl in rotational crops - spinach, carrot and wheat - has been evaluated in a confined rotational crop study (DAR Germany, 2000).

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 (a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Spinach	2-^{14}C-triazinyl	Bare soil, F(b)	0.02	29 120 365	408	-	DAR Germany, 2000 EFSA, 2012 RAR, Sweden, 2015 EFSA, 2016
Root and tuber vegetables	Carrot		Bare soil, F(b)	0.02	29 120 365	252, 464	-	
	Sugarbeet		Bare soil, G	0.0054	60	134, 233	Applied with a safener (isoxadifen-ethyl)	
Cereals	Wheat		Bare soil, F(b)	0.02	29 120 365	99, 239, 464	-	
			Bare soil, G	0.0081	65	210, 261	Applied with a safener (isoxadifen-ethyl)	
Pulses and oilseeds	Soybean		Bare soil, G	0.0054	7 14	52, 56, 138, 145	Applied with a safener (isoxadifen-ethyl)	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Or climatic chamber simulating outdoor conditions

Summary of plant metabolism studies reported in the EU

According to EFSA, 2012 and EFSA, 2016:
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 (DAR Germany, 2000).
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.

Summary of new plant metabolism studies

Not relevant. New studies were not provided.

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.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

According to 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.

According to 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.

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

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

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Root/tuber crops (carrot) Leafy crops (spinach) Cereal (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (based on residue identification in rotational cereal straw only).
Processed commodities	Due to low residues at harvest, no study is required.
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, EFSA 2016, Reg. (EU) No. 289/2014).
Plant residue definition for risk assessment	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, EFSA 2016). Triazine amine (IN-A4098) is a potential candidate for the plant residue definition for risk assessment, and a final decision is pending further clarification regarding the toxicological properties and the related consumer risk.

	Pending the conclusion on the IN-A4098 toxicity, also the metabolite AE 0031838 (hydroxymethyl triazine amine) observed up to 15% TRR in grain may require a reassessment.*
Conversion factor from enforcement to RA	1 (EFSA, 2012, EFSA 2016).

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

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

Available data

No new data submitted in the framework of this application.

No metabolism studies in livestock were performed during the first approval of iodosulfuron-methyl-sodium.
In RAR, Sweden, 2015 metabolism studies are available in cow and hen with phenyl labelled iodosulfuron-methyl only (EFSA, 2016).

Table 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	[U-^{14}C]-phenyl	1	0.22	7	Milk	twice daily	RAR Sweden, 2015 EFSA, 2016
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[U-^{14}C]-phenyl	5	0.889	14	Eggs (yolk)	twice daily	
						Eggs (white)	twice daily	
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

According to EFSA 2016:
The two major residues identified were parent (11-33% TRR) and AE F145741 (2-13% TRR). The pres-

ence of metabolites bearing only the iodobenzene ring indicated that cleavage of the molecule occurred in the animals. Although a triazinyl radiolabel study with iodosulfuron-methyl is not available it can be assumed that molecules bearing only the triazine ring moiety are formed in animals accordingly. A data gap was not triggered for a triazinyl radiolabel study in livestock, and the animal residue definition was not further discussed in the peer review.

Summary of new animal metabolism studies

Not relevant. New studies were not provided.

Conclusion on metabolism in livestock

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

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

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

	Endpoints
Animals covered	Cow.
	Laying hens.
Time needed to reach a plateau concentration	4 days in milk.
	5 days in eggs.
Animal residue definition for monitoring	Not necessary (EFSA 2012, EFSA 2016). Iodosulfuron-methyl (sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl) (Reg. (EU) No. 289/2014).
Animal residue definition for risk assessment	EFSA, 2016: Study not triggered considering residues of parent iodosulfuron-methyl. Not further assessed. Plant residue definition for risk assessment is pending finalisation, and a reassement of livestock exposure, including fish, may be required.
Conversion factor	Not applicable.
Metabolism in rat and ruminant similar	Yes.
Fat soluble residue	No.

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of JMD-HER 387 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, rye and triticale extrapolated from cereal grain (barley, rye and wheat)	DAR 2000, RAR Sweden 2015, 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	N/A				
	Overall supporting data for cGAP	N-EU	E: 14 × <0.01 RA: 14 × <0.01	0.01	0.01	-	0.01	Yes
Cereal, straw (barley, rye, wheat)	DAR 2000, RAR Sweden 2015, 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	N/A				
	Overall supporting data for cGAP	N-EU	E: 14 × <0.05 RA: 14 × <0.05	0.05	0.05	-	-	-

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

Table 7.3-8.1 Residue trials in EU-N used for support of cereals registration (RAR (Sweden, 2015))

Lp.	Country, year	Application per treatment			Crop	Crop growth stage	Residues mg/kg		Reference/ Study code
		Form. type	No	g ai/ha			Grain	Straw	
1	DE, 1995	WG	1	15	wheat	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A56709 DEU0401-02**
2	DE, 1995	WG	1	15	wheat	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A56709 DEU0601-02**
3	N-FR, 1995	WG	1	15	wheat	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A56709 FRA0001-02**
4	N-FR, 1995	WG	1	15	wheat	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A56709 FRA00002-02**
5	UK, 1995	WG	1	15	wheat	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A56709 GBR0001-02**
6	DE, 1996	WG	1	15	barley	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A59541 DEU0101-03**
7	DE, 1996	WG	1	15	rye	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A59541 DEU0301-03**
8	N-FR, 1996	WG	1	15	wheat	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A59541 FRA0001-03**
9	UK, 1996	WG	1	15	wheat	53	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A59541 GBR0001-03**
10	UK, 1996	WG	1	15	wheat	39	<0.01*	<0.05*	**DAR 2000 and RAR (Sweden, 2015) / A59541 GBR0002-03**
11	SE, 2003	OD	1	10	wheat	39	<0.01*	<0.05*	**RAR (Sweden, 2015) / RA-2615/03 R 2003 0225/8**
12	DE, 2003	OD	1	10	wheat	32	<0.01*	<0.05*	**RAR (Sweden, 2015) / RA-2615/03 R 2003 0492/7**
13	UK, 2003	OD	1	10	wheat	39-43	<0.01*	<0.05*	**RAR (Sweden, 2015) / RA-2615/03 R 2003 0493/5**
14	N-FR, 2003	OD	1	10	wheat	32	<0.01*	<0.05*	**RAR (Sweden, 2015) / RA-2615/03 R 2003 0494/3**

* LOQ value

7.3.3.2 Conclusion on the magnitude of residues in plants

<u>Cereals</u>
A total of 14 trials on cereals (12 trials on wheat, 1 trial on barley and 1 trial on rye) are available in N-EU zone. All trials were performed according to the critical EU GAP from DAR 2000 and RAR (Sweden, 2015). In some studies the applications were made at higher than proposed doses. Overdosed trials may be used to support a less critical GAP, when they indicate that no residues above the LOQ are to be expected.
All residue values were below the LOQ and are sufficient to support the proposed use. The residue data are valid with regard to storage stability.
According to SANCO 7525/VI/95 Rev. 10.3; 13 June 2017 the residue trials on barley may be extrapolate to oat, rye and wheat and residue trials on wheat may be extrapolate to oat, rye and barley, before forming of the edible part. Application to cereal is intended at early growth stages (up to BBCH 31), therefore extrapolation is possible.
The residues arising from the proposed uses will not exceed the MRLs established for rye and wheat (including triticale) 0.01 mg/kg.

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

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Active substance iodosulfuron-methyl-sodium is authorised in EU for use on crops that might be fed to livestock. Dietary burden calculation was performed in EFSA reasoned opinion on the review of the existing maximum residue levels for iodosulfuron according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2012;10(11):2974). According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance iodosulfuron. The median and maximum dietary burdens were therefore calculated for the different types of livestock using to the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of the 2004 JMPR (WHO/FAO, 2005).

Dietary burden calculation for purpose of maintain authorisation of JMD-HER 387 OD was performed by Excel spreadsheet Animal model 2017 and was focused only on intended uses of JMD-HER 387 OD i.e. barley, wheat, triticale and rye. Input values (STMR and HR) used for dietary calculation are provided below in Table 7.2-9. Results of dietary burden calculation for JMD-HER 387 OD are included in Table 7.2-10.

Table 7.3-9: Input values for the dietary burden calculation (considering the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl				
Cereals, straw	0.05	HR (EFSA, 2012)	0.05	HR (EFSA, 2012)
Cereals, grain	0.01	STMR (EFSA, 2012)	0.01	STMR (EFSA, 2012)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Brewers's grain, dried	0.01 x 3.3	STMR x PF*	-	-
Distiller's grain, dried	0.01 x 3.3	STMR x PF*	-	-
Wheat gluten, meal	0.01 x 1.8	STMR x PF*	-	-
Wheat, milled by-pdts	0.01 x 7	STMR x PF*	-	-

* default value from Animal model 2017

Table 7.3-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg DM)	Maximum dietary burden (mg/kg DM)	Most critical diet	Highest con-tributing commodity	Trigger 0.004 mg/kg bw/d exceeded (Y/N)
Risk assessment residue definition: sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl							
Cattle (all diets)	0.002	0.002	0.05	0.05	Dairy cattle	Wheat, milled by pdts	N
Cattle (dairy only)	0.002	0.002	0.05	0.05	Dairy cattle	Wheat, milled by pdts	N
Sheep (all diets)	0.003	0.003	0.07	0.07	Lamb	Wheat, milled by pdts	N
Sheep (ewe only)	0.002	0.002	0.07	0.07	Ram/Ewe	Wheat, milled by pdts	N
Swine (all diets)	0.001	0.001	0.05	0.05	Swine (finishing)	Wheat, milled by pdts	N
Poultry (all diets)	0.002	0.002	0.03	0.03	Poultry layer	Wheat, milled by pdts	N
Poultry (layer only)	0.002	0.002	0.03	0.03	Poultry layer	Wheat, milled by pdts	N

The calculated dietary burdens were found to not exceed the trigger value of 0.004 mg/kg bw (0.1 mg/kg dry matter (DM) for all groups of livestock. Further investigation of residues is therefore not required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The calculated dietary burdens were found to not exceed the trigger value of 0.004 mg/kg bw (0.1 mg/kg dry matter (DM) for all groups of livestock. Further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Available data

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

Conclusion on feeding studies

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

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

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

7.3.5.1 Available data for all crops under consideration

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

7.3.5.2 Conclusion on processing studies

As quantifiable residues of iodosulfuron-methyl are not expected in the treated crops, 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.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

RAR (Sweden, 2015):
Three of the four confined rotational studies were carried out on a bare soil with 20 g a.s./ha (twice the normal application rate). The fourth study was performed with rates (wheat 8.1 g a.s./ha) which is expected to match more closely the residues in soil in a rotational situation (2 to 3 g a.s./ha). Based on these studies, the individual metabolite fractions are not expected to exceed 0.05 mg/kg (LOQ for cereal straw). Iodosulfuron-methyl residue levels in rotational commodities were not expected to exceed 0.01 mg/kg, provided that iodosulfuron-methyl-sodium is applied in compliance with the representative GAPs.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of JMD-HER 387 OD. Therefore, other special studies are not needed.

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

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

7.3.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl				
Wheat (including triticale)	0.01	EU MRL*	0.01	EU MRL*
Rye	0.01	EU MRL*	0.01	EU MRL*
All other commodities of plant and animal origin	variable	EU MRL*	Not relevant. Acute risk assessment was performed for intended uses only.	

* Reg. (EU) No 289/2014

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-12: Consumer risk assessment

ADI	0.03 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev.3.1	6 % (based on NL toddler diet)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	Not relevant. TMDI < 100%.
ARfD	3.15 mg/kg bw per day
IESTI (% ARfD) according to EFSA PRIMo rev.3.1*	Wheat and rye: 0.0 % (for all the groups tested)
NTMDI (% ADI) **	Not relevant.
NEDI (% ADI)**	Not relevant.
NESTI (% ARfD) **	Not relevant.

* include raw and processed commodities if both values are required for PRIMo rev.3.1
** if national model is available

Chronic and acute exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1; 2021/01/06). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population.
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 (Reg. (EU) No 289/2014). The highest chronic exposure was calculated for NL toddler Diet, representing 6% of the ADI. For this diet the highest contributor was milk: cattle (4% of ADI), while wheat was 0.2% of ADI. TMDI values are below 100%, thus higher tier exposure calculation for chronic exposure is not necessary.
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 were derived from EU MRL (Reg. (EU) No 289/2014).

With regard to the acute exposure, no exceedance was identified. The % of ARfD for wheat, barley and rye was 0.00. In view of the above, there is no need to perform a higher tier exposure calculation for acute exposure.

The proposed uses of iodosulfuron-methyl-sodium in the formulation JMD-HER 387 OD do 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 and for two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.4.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.3.1) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.4-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo.3.1)
Wheat (including triticale)	2,4-D	0.1
	iodosulfuron-methyl-sodium	0.0
	Cumulative risk Wheat (HI)	**0.1**
Rye	2,4-D	0.04
	iodosulfuron-methyl-sodium	0.0
	Cumulative risk Rye (HI)	**0.04**

The Hazard Index is <1. Thus, combined exposure to all active substances in JMD-HER 387 OD is not expected to present a consumer risk. No further refinement of the assessment is required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

7.5 References

Greece, 2013. Renewal Assessment Report (RAR) on the active substance 2,4-D prepared by the rapporteur Member State Greece in the framework of Commission Regulation (EU) No 1141/2010, February 2013. Available at www.efsa.europa.eu.

Greece, 2014. Final Addendum to the Renewal Assessment Report on 2,4-D, compiled by EFSA, March 2014. Available at www.efsa.europa.eu.

EFSA (European Food Safety Authority), 2014. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance 2,4-D. Available at www.efsa.europa.eu.

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels (MRLs) for 2,4-D according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(11):2431. Available at www.efsa.europa.eu.

Commission Regulation (EU) 2022/1363 of 3 August 2022 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb and silthiofam in or on certain products.

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

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

Sweden, 2016. Revised renewal assessment report (RAR) on iodosulfuron-methyl-sodium, February 2016. Available online: www.efsa.europa.eu.

EFSA (European Food Safety Authority), 2016. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance iodosulfuron-methyl-sodium. Available online: www.efsa.europa.eu.

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. Available online: www.efsa.europa.eu.

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.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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

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
2,4-D					
KCA 6.1/01	Barker W.	1995	Determination of Frozen Storage Stability for 2.4-Dichlorophenoxy Acetic Acid (2,4-D) in/on Crops Report/file No EN-CAS Project #93-0044 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.1/02	[redacted]	1996	2,4-D: Magnitude of Residue in Meat and Milk of Lactating Dairy Cows Report/file No PTRL Project No 886 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012

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 6.1/03	Rawle N.W.	2002	Storage Stability of Residues of 2,4-DCP, 2,4-D, 2,4-DB and 2,4-DP-p in Cereal Whole Plant, Grain and Straw Report No. CEMR-1397 (AHM R 99 142) GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.2.1/01	Smith G.A.	1991	Metabolism of 14C-(2,4-Dichlorophenoxy)acetic acid, Dimethylamine Salt in Apples ABC Laboratories, Inc. Report N°38072 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.2.1/02	Puglis, J.M. Smith, G.	1992	Metabolism of Uniformly Ring Labeled [14C] 2,4-Dichlorophenoxyacetic Acid 2-Ethylhexyl Ester in Potatoes ABC Laboratories, Inc. Report N°38075 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.2.1/03	Bristol et al.	1982	Determination of Free and Hydrolyzable Residues of 2,4-Dichlorophenoxyacetic Acid and 2,4-Dichlorophenol in Potatoes J. Agric. Food Chem. 1982, 30, 137-144 GLP: N Published: Y	N	SAN
KCA 6.2.1/04a	Puvanesarajah V.	1992	Metabolism of 14C-Ring Labeled 2,4-Dichlorophe- noxyacetic Acid 2-Ethylhexyl Ester in Wheat ABC Laboratories, Inc. Report N°38076 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.2.1/04b	Puvanesarajah V.	1992	Supplemental Data for the Study "Metabolism of Uniformly 14C-Ring Labeled 2,4-Dichlorophenoxy-acetic Acid 2-Ethylhexyl Ester in Wheat" ABC Laboratories, Inc. Report N°38076-01	N	European Union 2,4-D Task Force 2012

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP: Y Published: N		
KCA 6.2.1/05	Grover et al.	1985	Fate of 2,4-D Iso-octyl Ester after Application to a Wheat Field J. Environ. Qual. 14, 203-210 GLP: N Published: Y	N	SAN
KCA 6.2.1/06	Feung C.S.	1978	Comparative metabolic fate of 2,4-Dichloropheno- xyacetic Acid in Plants and Plant Tissue Culture J. Agric. Food Chem.,Vol. 26, N°5, pp 1064-1067. GLP: N Published: Y	N	European Union 2,4-D Task Force 2012
KCA 6.2.2-6.2.5/01	[redacted]	1993 1994	Metabolism of Uniformly 14C-ring Labeled 2,4-Dichlorophenoxyacetic acid in Lactating Goats [redacted] Report 40630 and supplementary report Supplemental Data for the Study, Metabolism of Uniformly 14C-ring Labeled 2,4-Dichlorophenoxyacetic acid in Lactating Goats [redacted] Report 40630-01 GLP: Y Published: N	Y	European Union 2,4-D Task Force 2012
KCA 6.2.2-6.2.5/02	[redacted]	1992	Metabolism of Uniformly Ring Labeled [14C] 2,4-Dichloro phenoxyacetic Acid in Poultry [redacted] Report 38077 GLP: Y Published: N	Y	European Union 2,4-D Task Force 2012
KCA 6.2.2-6.2.5/03	Bjerke et al.	1972	Residue study of phenoxy herbicides in milk and cream. J. Agric. Food Chem., Vol. 20, N°5, 1972, pp 963-967 GLP: N Published: Y	N	European Union 2,4-D Task Force 2012

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	**Owner**
KCA 6.2.2-6.2.5/04	Clark et al.	1975	Residues of chlorophenoxy acid herbicides and their phenolic metabolites in tissues of sheep and cattle. J. Agric. Food Chem., Vol. 23, N°3, 1975, pp 573-578 GLP: N Published: Y	N	European Union 2,4-D Task Force 2012
KCA 6.2.2-6.2.5/05	Leng M.L.	1972	Residues in milk and meat and safety to livestock from the use of phenoxy herbicides in pasture and rangeland Down to earth, Vol.28, N°1, Summer 1972 pp 12-20. GLP: N Published: Y	N	European Union 2,4-D Task Force 2012
KCA 6.3/01a	Buchta A. et al.	2006	Aminopielik Standard 600 SL. Determination of active substance residues in corn, straw and soil Institute of Organic Industry C/01/05 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/01b	Zmijowska A.	2010	Amendment No 1 to the final report Aminopielik Standard 600 SL. Determination of residues of active substance in corn, straw and soil Institute of Industrial Organic Chemistry C/01/05 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/01c	Winiarska K.	2010	Amendment No 2 to the final report Aminopielik Standard 600 SL. Determination of residues of active substance in corn, straw and soil Institute of Industrial Organic Chemistry C/01/05 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/02	Różalski K.	2008a	Residues of 2,4-D and Dicamba after one application of Aminipielik D 450 SL in winter wheat, one site in Poland 2007 GAB Poland Sp. z.o.o. 20074502/PL1-FPWW	N	European Union 2,4-D Task Force 2012

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	**Owner**
			GLP: Y Published: N		
KCA 6.3/03	Klimmek S. Tanguy M.	2011	Determination of residues of 2,4-D in spring wheat after one application of 2,4-D DMA 600 g/L and 2,4-D 2 EHE-600 at 4 sites in Northern Europe 2010 Eurofins Agrosience Report Number: S10-02109 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/04	Pfarl C.	1993	Residues of 2,4-D in cereals treated with 1.0 l Dicopur fluid/ha Agrolinz Report N°1166 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/05	Pfarl C.	1993	Residues of 2,4-D in cereals treated with 1.1 L Spritz Hormin 600/ha and 1.5 L U 46 D-Fluid Agrolinz Report No. 1153 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/06	Różalski K.	2008c	Residues of 2,4-D and Dicamba after one application of Aminipielik D 450 SL in spring barley, one site in Poland 2007 GAB Poland Sp. z.o.o. Report Number: 20074502/PL1-FPSH GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/07	Klimmek S. Tanguy M.	2012	Determination of residues of 2,4-D in maize and processed fraction silage after one application of 2,4-D DMA 600 and 2,4-D 2EHE 600 at 4 sites in Northern Europe 2010 Eurofins Agrosience Report Number: S10-02224 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3/08	Galy H.	2000	Residue levels of MCPA potassium salt & 2,4-D dimethylamine salt in Maize following postemergence treatment with the preparations Agroxone or Marks 2,4-D Amine under Field conditions in Europe in 1999- Field Phase Marks 2,4-D Amine Report No. R9033 TER2 /(AHM R 99 302) GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/09	Nagra B.S.	2001	Determination of Residues of 2,4-D and 2,4-DCP in Maize Samples Report No. CEMR-1167 (AHM R 99 321 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/10	Old J. & Venuti J.	2001b	2,4-D Dimethylamine Salt Residue Decline in Cereals in Southern Europe: Field Phase Report No. AHM R 99 111 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
KCA 6.3/11	Rawle N M.	2002	Determination of Residues of 2,4-D and 2,4-DCO in Wheat and Barley Samples Report No. AHM R 99 125 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
Iodosulfuron-methyl-sodium					
KCA 6.1 /01	Wrede, A.	1998a	Stability of AE F115008 in wheat grain during deep freeze storage of 24 months Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C001041, Edition Number: M-181689-01-1 EPA MRID No.: 45108918 Date: 1998-10-05 GLP/GEP: yes unpublished	N	Bayer CropScience
KCA	Wrede, A.	1998b	Stability of AE F115008 in wheat straw during deep freeze storage of 24 months (interim report) Code:	N	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
6.1 /02			AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C000983, Report includes Trial Nos.: CR96/018 Edition Number: M-181582-01-1 Date: 1998-09-30 GLP/GEP: yes unpublished		CropScience
KCA 6.1 /03	Wrede, A.	1998c	Stability of AE F115008 in wheat shoot during deep freeze storage of 24 months (interim report) Code: AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C000985, Report includes Trial Nos.: CR96/017 Edition Number: M-181587-01-1 Date: 1998-09-30 GLP/GEP: yes unpublished	N	Bayer CropScience
KCA 6.1 /04	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 - Inter-im 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	N	Bayer
KCA 6.2.1 /01	Braun, P. J.; Brueckner, H.; Voelkl, S.	1998	Metabolism in wheat (Triticum aestivum) after treatment at a nominal rate of 1 x 20 g a.s./ha 2-triazinyl-14C-AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C001497,	N	Bayer CropScience

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	**Owner**
			Edition Number: M-182772-01-1 EPA MRID No.: 45108921 Date: 1998-11-16 GLP/GEP: yes unpublished		
KCA 6.2.1 /02	Tarara, G.; Brueckner, H.	1998	Metabolism in wheat (Triticum aestivum) after single treatment at a nominal rate of 20 g a.s./ha U-phenyl-14C-AE F115008 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A67671, Edition Number: M-148037-01-1 EPA MRID No.: 45108922 Date: 1998-11-04 GLP/GEP: yes unpublished	N	Bayer CropScience
KCA 6.2.2 /01	-	1999	Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues Code: (14C)-AE F115008 Bayer CropScience, Report No.: C005548, Report includes Trial Nos.: TOX95291 Edition Number: M-192269-01-1 EPA MRID No.: 45108923 Date: 1999-10-11 GLP/GEP: yes unpublished	Y	Bayer CropScience
KCA 6.2.3 /01	-	1999	Ruminant - Metabolism, distribution and nature of residues in milk and edible tissues (14C) AE F115008 Code: AE F115008 Bayer CropScience, Report No.: C005678, Report includes Trial Nos.: TOX95290	Y	Bayer CropScience

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	**Owner**
			Edition Number: M-192483-01-1 EPA MRID No.: 45108924 Date: 1999-12-15 GLP/GEP: yes unpublished		
KCA 6.3 /01	Helgers, A.	1998a	AE F115008 00 WG20 A103 WG (wettable granule) 200 g/kg in tank mix with two different formulations of the safener AE F107892 (AE F107892 00 WG15 A101 and AE F107892 00 EC10 A102) Residue trials on wheat to determine residue decline of AE F115008 and AE F107892 following 1 application; European Union (northern zone) 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 6.3/02	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 6.3/03	Freitag, T.	2004b	Determination of residues of iodosulfuron-methyl-sodium and mefenpyr-diethyl in/on wheat following spray application of AE F115008 02 OD35 AI 400 OD and AE F11 5008 02 1L35 A2 400 OD in te field in Sweden, Germany, great Britan and Northern France Bayer CropScience	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No.: RA-2615/06 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		
KCA 6.3/04	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 6.3/05	Helgers, A.	1998c	AE F115008 and AE F107892 EG (emulsifiable granule) and WG (water dispersible granule) 50 and 150 g/kg Code: AE F115008 02 EG20 A401 and Code: AE F115008 02 WG20 A903 Residue trials on cereals with two different coformulations to determine a residue decline of AE F115008 and AE F109872 following 1 application; European Union (southern zone) 1996 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A59542, Edition Number: M-143213-02-1 Date: 1998-03-27 “Amended: 1999-06-11” GLP/GEP: yes unpublished	N	Bayer CropScience
KCA 6.3/06	Davies, P.	2002	Residues in wheat European Union (Southern zone) 2001 Biopower® Iodosulfuron-methyl-sodium (5 %) Meenpyr-diethyl (15 %) Code: AE F11 5008 02 WG20 B301		

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
			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		
KCA 6.3/07	Freitag, T.	2004a	Determination of residues of iodosulfuron-methyl-sodium and mefenpyr-diethyl in/on wheat following spray application of AE F11 5008 02 1L35 A2 400 OD in te field in Italy, Spain and Southern France Bayer CropScience Report No.: RA-2616/03 Report includes Trial Nos.: 0226-03; 0489-03; 0490-03; 0491-03; R20030226/6; R20030489/7; R20030490/0; R20030491/9 Edition Number: M-231305-02-1 Date: 2004-05-10 “Amended: 2007-01-16” GLP/GEP: yes unpublished	N	Bayer CropScience
KCA 6.6.1 /01	Buerkle, L. W.	1998	Residues in rotated crops sown 29 days after application to bare soil at a rate of 20 g a.s./ha AE F115008-triazinyl 2-14C Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C000833, Edition Number: M-181318-01-1 EPA MRID No.: 45108927 Date: 1998-08-25 GLP/GEP: yes unpublished	N	Bayer CropScience
KCA 6.6.1 /02	Buerkle, L. W.; Kellner, G.; Voelkl, S.	1998a	Residues in rotated crops sown 120 days after application to bare soil at a rate of 20 g a.s./ha AE F115008-triazinyl 2-14C Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience,	N	Bayer CropScience

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	**Owner**
			Report No.: C001454, Edition Number: M-182667-01-1 EPA MRID No.: 45108928 Date: 1998-10-06 GLP/GEP: yes unpublished		
KCA 6.6.1 /03	Buerkle, L. W.; Kellner, G.; Voelkl, S.	1998b	Residues in rotated crops sown 1 year after application to bare soil at a rate of 20 g a.s./ha AE F115008-triazinyl 2-14C Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C001331, Edition Number: M-182374-01-1 EPA MRID No.: 45108929 Date: 1998-10-06 GLP/GEP: yes unpublished	N	Bayer CropScience
KCA 6.6.1 /04	Meyer, B. N.; Tull, P. J.	1999	Uptake of [14C]-AE F115008 residues from soil by rotational wheat, soybeans and sugarbeets under con-fined conditions 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	N	Bayer CropScience

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 2,4-D

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

Not relevant. No new study has been provided.

A 2.1.1.1.2 Storage stability of residues in animal products

Not relevant. No new study has been provided.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

Not relevant. No new study has been provided.

A 2.1.2.1.2 Nature of residue in rotational crops

Not relevant. No new study has been provided.

A 2.1.2.1.3 Nature of residues in processed commodities

Not relevant. No new study has been provided.

A 2.1.2.2 Nature of residues in livestock

Not relevant. No new study has been provided.

A 2.1.3 Magnitude of residues in plants

Not relevant. No new study has been provided.

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

Not relevant. No new study has been provided.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

Not relevant. No new study has been provided.

A 2.1.5.2 Processing studies on a core set of representative processes

Not relevant. No new study has been provided.

A 2.1.6 Magnitude of residues in representative succeeding crops

Not relevant. No new study has been provided.

A 2.1.7 Other/Special Studies

Not relevant. No new study has been provided.

A 2.2 Iodosulfuron-methyl-sodium

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

Not relevant. No new study has been provided.

A 2.2.1.1.2 Storage stability of residues in animal products

Not relevant. No new study has been provided.

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

Not relevant. No new study has been provided.

A 2.2.2.1.2 Nature of residue in rotational crops

Not relevant. No new study has been provided.

A 2.2.2.1.3 Nature of residues in processed commodities

Not relevant. No new study has been provided.

A 2.2.2.2 Nature of residues in livestock

Not relevant. No new study has been provided.

A 2.2.3 Magnitude of residues in plants

Not relevant. No new study has been provided.

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

Not relevant. No new study has been provided.

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

A 2.2.5.1 Distribution of the residue in peel/pulp

Not relevant. No new study has been provided.

A 2.2.5.2 Processing studies on a core set of representative processes

Not relevant. No new study has been provided.

A 2.2.6 Magnitude of residues in representative succeeding crops

Not relevant. No new study has been provided.

A 2.2.7 Other/Special Studies

Not relevant. No new study has been provided.

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

A 3.1 TMDI calculations - 2,4-D

Tier I

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

2,4-D

LOQs (mg/kg) range from:	0,01	to:	0,10
Toxicological reference values			
ADI (mg/kg bw/day):	0,02	ARfD (mg/kg bw):	0,3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

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 : 1

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
114%	DK child	22,73	55%	Rye	44%	Wheat	3%	Swine: Liver	3%	
92%	GEMS/Food G06	18,44	72%	Wheat	5%	Oranges	2%	Potatoes	5%	
89%	NL toddler	17,75	39%	Wheat	11%	Oranges	4%	Swine: Liver	14%	
86%	DE child	17,25	42%	Wheat	20%	Oranges	8%	Rye	7%	
79%	FR child 3 15 yr	15,85	46%	Wheat	17%	Oranges	3%	Swine: Other products	5%	
73%	IT toddler	14,64	66%	Wheat	2%	Oranges	1%	Mandarins	2%	
73%	NL child	14,62	41%	Wheat	7%	Oranges	3%	Potatoes	8%	
70%	GEMS/Food G07	14,08	42%	Wheat	7%	Oranges	4%	Potatoes	4%	
68%	GEMS/Food G15	13,63	45%	Wheat	4%	Potatoes	3%	Oranges	4%	
67%	ES child	13,40	44%	Wheat	11%	Oranges	2%	Potatoes	3%	
66%	GEMS/Food G08	13,27	41%	Wheat	6%	Rye	4%	Potatoes	4%	
63%	RO general	12,59	51%	Wheat	4%	Potatoes	1%	Oranges	4%	
62%	GEMS/Food G10	12,42	39%	Wheat	6%	Oranges	3%	Potatoes	5%	
62%	UK toddler	12,35	39%	Wheat	10%	Oranges	3%	Potatoes	4%	
58%	GEMS/Food G11	11,64	36%	Wheat	4%	Potatoes	4%	Oranges	5%	
55%	FR toddler 2 3 yr	11,07	31%	Wheat	7%	Oranges	4%	Mandarins	5%	
54%	IE adult	10,79	23%	Wheat	6%	Sheep: Liver	5%	Oranges	4%	
54%	SE general	10,79	32%	Wheat	4%	Bovine: Muscle/meat	4%	Potatoes	3%	
53%	PT general	10,66	39%	Wheat	5%	Potatoes	3%	Oranges	2%	
50%	UK infant	9,91	26%	Wheat	6%	Oranges	4%	Bovine: Edible offals (other than liv	5%	
47%	IT adult	9,33	41%	Wheat	2%	Oranges	0,8%	Mandarins	2%	
46%	DE women 14-50 yr	9,14	21%	Wheat	10%	Oranges	5%	Rye	4%	
43%	DE general	8,54	19%	Wheat	8%	Oranges	6%	Rye	4%	
37%	ES adult	7,41	23%	Wheat	6%	Oranges	0,9%	Potatoes	2%	
36%	NL general	7,16	19%	Wheat	5%	Oranges	2%	Potatoes	3%	
35%	FR adult	6,93	22%	Wheat	3%	Oranges	1%	Swine: Other products	2%	
30%	UK vegetarian	5,90	20%	Wheat	4%	Oranges	1%	Potatoes	1%	
29%	LT adult	5,77	11%	Rye	11%	Wheat	3%	Potatoes	1%	
29%	FI 3 yr	5,76	12%	Wheat	7%	Rye	5%	Potatoes	2%	
25%	UK adult	5,05	17%	Wheat	3%	Oranges	1%	Potatoes	1%	
24%	FI 6 yr	4,87	10%	Wheat	6%	Rye	4%	Potatoes	2%	
24%	DK adult	4,86	11%	Wheat	5%	Rye	1%	Potatoes	1%	
18%	FI adult	3,66	7%	Rye	3%	Wheat	3%	Coffee beans	4%	
16%	FR infant	3,25	8%	Wheat	2%	Potatoes	1%	Oranges	3%	
14%	IE child	2,77	12%	Wheat	0,6%	Potatoes	0,4%	Oranges	0,6%	
6%	PL general	1,15	3%	Potatoes	0,5%	Apples	0,3%	Lemons	1%	

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 113,6 % of the ADI.
For 1 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations - 2,4-D

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

2,4-D

LOQs (mg/kg) range from:	0,01	to:	0,10
Toxicological reference values			
ADI (mg/kg bw/day):	0,02	ARfD (mg/kg bw):	0,3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

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)
46%	NL toddler	9,21	11%	Oranges	4%	Swine: Liver	4%	Potatoes	14%	
37%	DE child	7,45	20%	Oranges	3%	Apples	3%	Potatoes	7%	
34%	FR child 3 15 yr	6,83	17%	Oranges	3%	Swine: Other products	2%	Potatoes	5%	
31%	NL child	6,22	7%	Oranges	3%	Potatoes	3%	Mandarins	8%	
30%	IE adult	6,01	6%	Sheep: Liver	5%	Oranges	3%	Grapefruits	4%	
29%	GEMS/Food G07	5,70	7%	Oranges	4%	Potatoes	3%	Bovine: Liver	4%	
25%	FR toddler 2 3 yr	5,03	7%	Oranges	4%	Mandarins	2%	Potatoes	5%	
24%	UK infant	4,77	6%	Oranges	4%	Bovine: Edible offals (other than liver an	3%	Potatoes	5%	
24%	ES child	4,70	11%	Oranges	2%	Potatoes	2%	Swine: Liver	3%	
23%	UK toddler	4,66	10%	Oranges	3%	Potatoes	1%	Mandarins	4%	
23%	GEMS/Food G11	4,52	4%	Potatoes	4%	Oranges	2%	Lemons	5%	
23%	GEMS/Food G10	4,52	6%	Oranges	3%	Potatoes	1%	Bovine: Liver	5%	
21%	GEMS/Food G15	4,27	4%	Potatoes	3%	Oranges	3%	Swine: Liver	4%	
21%	GEMS/Food G06	4,19	5%	Oranges	2%	Potatoes	2%	Mandarins	5%	
21%	GEMS/Food G08	4,12	4%	Potatoes	2%	Oranges	2%	Swine: Muscle/meat	4%	
20%	DE women 14-50 yr	3,99	10%	Oranges	1%	Sugar beet roots	1%	Lemons	4%	
20%	SE general	3,94	4%	Bovine: Muscle/meat	4%	Potatoes	4%	Oranges	3%	
19%	DE general	3,71	8%	Oranges	1%	Potatoes	1%	Swine: Muscle/meat	4%	
16%	DK child	3,28	3%	Swine: Liver	2%	Potatoes	2%	Swine: Muscle/meat	3%	
16%	NL general	3,24	5%	Oranges	2%	Potatoes	1,0%	Swine: Muscle/meat	3%	
14%	ES adult	2,81	6%	Oranges	0,9%	Potatoes	0,7%	Bovine: Muscle/meat	2%	
14%	PT general	2,71	5%	Potatoes	3%	Oranges	1%	Wine grapes	2%	
13%	RO general	2,66	4%	Potatoes	1%	Oranges	1%	Swine: Muscle/meat	4%	
13%	FR adult	2,56	3%	Oranges	1%	Swine: Other products	1%	Wine grapes	2%	
11%	FI 3 yr	2,15	5%	Potatoes	2%	Mandarins	0,7%	Oranges	2%	
9%	UK vegetarian	1,85	4%	Oranges	1%	Potatoes	0,6%	Grapefruits	1%	
9%	FI 6 yr	1,76	4%	Potatoes	2%	Mandarins	0,8%	Oranges	2%	
9%	UK adult	1,75	3%	Oranges	1%	Potatoes	0,7%	Bovine: Muscle/meat	1%	
9%	FR infant	1,71	2%	Potatoes	1%	Oranges	0,8%	Milk: Cattle	3%	
8%	FI adult	1,65	3%	Coffee beans	2%	Oranges	1%	Potatoes	4%	
8%	DK adult	1,62	1%	Potatoes	1,0%	Swine: Liver	0,9%	Swine: Muscle/meat	1%	
8%	IT toddler	1,62	2%	Oranges	1%	Wheat	1%	Mandarins	2%	
8%	LT adult	1,60	3%	Potatoes	1,0%	Swine: Muscle/meat	0,5%	Swine: Liver	1%	
6%	IT adult	1,23	2%	Oranges	0,8%	Wheat	0,8%	Mandarins	2%	
6%	PL general	1,15	3%	Potatoes	0,5%	Apples	0,3%	Lemons	1%	
2%	IE child	0,49	0,6%	Potatoes	0,4%	Oranges	0,2%	Wheat	0,6%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 2,4-D is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.3 IESTI calculations - Raw commodities - 2,4-D

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Wheat	2 / 2	29	6%	Wheat	2 / 2	17
4%	Rye	2 / 2	13	3%	Rye	2 / 2	9,7
0,09%	Barley	0,05 / 0,05	0,28	0,08%	Barley	0,05 / 0,05	0,24
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.4 IESTI calculations - Processed commodities - 2,4-D

Acute risk assessment /children | **Acute risk assessment / adults / general population**

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Wheat / milling (flour)	2 / 2	24	3%	Wheat / bread/pizza	2 / 2	8,8
4%	Wheat / milling (wholemea	2 / 2	11	3%	Wheat / pasta	2 / 2	7,6
2%	Rye / boiled	2 / 2	7,3	2%	Wheat / bread	2 / 2	7,0
2%	Rye / milling (wholemeal)-l	2 / 2	7,0	0,1%	Barley / beer	0,05 / 0,01	0,36
0,1%	Barley / cooked	0,05 / 0,05	0,18				
0,0%	Barley / milling (flour)	0,05 / 0,05	0,09				
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of 2,4-D is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.5 TMDI calculations - iodosulfuron-methyl-sodium

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Iodosulfuron-methyl-sodium

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 : ---

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)
6%	NL toddler	1,90	4%	Milk: Cattle	0,4%	Apples	0,2%	Maize/corn	6%	0,2%
3%	UK infant	1,03	3%	Milk: Cattle	0,1%	Potatoes	0,1%	Eggs: Chicken	3%	0,1%
3%	NL child	0,97	2%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Apples	3%	0,1%
3%	FR toddler 2 3 yr	0,90	2%	Milk: Cattle	0,1%	Apples	0,1%	Wheat	3%	0,1%
3%	DE child	0,87	1%	Milk: Cattle	0,4%	Apples	0,1%	Wheat	3%	0,2%
3%	FR child 3 15 yr	0,84	2%	Milk: Cattle	0,2%	Wheat	0,1%	Sugar beet roots	3%	0,2%
2%	UK toddler	0,68	1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	2%	0,1%
2%	DK child	0,59	0,8%	Milk: Cattle	0,2%	Rye	0,1%	Swine: Muscle/meat	2%	0,3%
2%	GEMS/Food G11	0,58	0,5%	Milk: Cattle	0,2%	Soyabeans	0,1%	Potatoes	2%	0,1%
2%	ES child	0,56	0,8%	Milk: Cattle	0,1%	Wheat	0,1%	Bovine: Muscle/meat	2%	0,1%
2%	SE general	0,55	0,8%	Milk: Cattle	0,3%	Bovine: Muscle/meat	0,1%	Potatoes	2%	0,1%
2%	RO general	0,53	0,8%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	2%	0,2%
2%	GEMS/Food G07	0,52	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	2%	0,2%
2%	DE women 14-50 yr	0,52	0,8%	Milk: Cattle	0,2%	Sugar beet roots	0,1%	Apples	2%	0,1%
2%	GEMS/Food G15	0,52	0,5%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	2%	0,2%
2%	DE general	0,51	0,8%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Apples	2%	0,1%
2%	GEMS/Food G08	0,51	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Soyabeans	2%	0,2%
2%	GEMS/Food G10	0,51	0,4%	Milk: Cattle	0,2%	Soyabeans	0,1%	Wheat	2%	0,2%
2%	FR infant	0,47	1%	Milk: Cattle	0,1%	Potatoes	0,1%	Apples	2%	0,0%
1%	GEMS/Food G06	0,45	0,2%	Wheat	0,2%	Milk: Cattle	0,1%	Tomatoes	1%	0,2%
1%	NL general	0,43	0,6%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Potatoes	1%	0,1%
1%	IE adult	0,41	0,3%	Milk: Cattle	0,1%	Sweet potatoes	0,1%	Wheat	1%	0,1%
1%	FI adult	0,35	0,9%	Coffee beans	0,0%	Potatoes	0,0%	Rye	1%	0,0%
1,0%	FR adult	0,29	0,3%	Milk: Cattle	0,1%	Wine grapes	0,1%	Wheat	1,0%	0,1%
1,0%	ES adult	0,29	0,3%	Milk: Cattle	0,1%	Wheat	0,0%	Bovine: Muscle/meat	1,0%	0,1%
0,8%	DK adult	0,24	0,4%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,0%	Potatoes	0,8%	0,1%
0,7%	LT adult	0,22	0,3%	Milk: Cattle	0,1%	Potatoes	0,1%	Swine: Muscle/meat	0,7%	0,1%
0,7%	PT general	0,22	0,2%	Potatoes	0,1%	Wheat	0,1%	Wine grapes	0,7%	0,1%
0,6%	UK vegetarian	0,18	0,2%	Milk: Cattle	0,1%	Wheat	0,0%	Potatoes	0,6%	0,1%
0,6%	UK adult	0,18	0,2%	Milk: Cattle	0,1%	Wheat	0,0%	Potatoes	0,6%	0,1%
0,6%	FI 3 yr	0,18	0,2%	Potatoes	0,0%	Bananas	0,0%	Wheat	0,6%	0,1%
0,6%	IT toddler	0,17	0,2%	Wheat	0,1%	Other cereals	0,0%	Tomatoes	0,6%	0,2%
0,5%	FI 6 yr	0,14	0,1%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat	0,5%	0,1%
0,4%	IE child	0,12	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,4%	0,0%
0,4%	IT adult	0,12	0,1%	Wheat	0,0%	Tomatoes	0,0%	Apples	0,4%	0,1%
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-methyl-sodium is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.6 IEDI calculations - iodosulfuron-methyl-sodium

Not relevant. TMDI < 100%.

A 3.7 IESTI calculations - Raw commodities - iodosulfuron-methyl-sodium

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation for all crops

Unprocessed commodities

Results for children				Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,00%	Wheat	0,01 / 0,01	0,14	0,00%	Wheat	0,01 / 0,01	0,08
0,00%	Rye	0,01 / 0,01	0,06	0,00%	Rye	0,01 / 0,01	0,05
0,00%	Barley	0,01 / 0,01	0,06	0,00%	Barley	0,01 / 0,01	0,05
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.8 IESTI calculations - Processed commodities - iodosulfuron-methyl-sodium

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,0%	Wheat / milling (flour)	0,01 / 0,01	0,12	0,0%	Barley / beer	0,01 / 0	0,07
0,0%	Wheat / milling (wholemea	0,01 / 0,01	0,06	0,00%	Wheat / bread/pizza	0,01 / 0,01	0,04
0,0%	Rye / boiled	0,01 / 0,01	0,04	0,00%	Wheat / pasta	0,01 / 0,01	0,04
0,0%	Barley / cooked	0,01 / 0,01	0,04	0,00%	Wheat / bread	0,01 / 0,01	0,03
0,0%	Rye / milling (wholemeal)-l	0,01 / 0,01	0,04				
0,0%	Barley / milling (flour)	0,01 / 0,01	0,02				
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Iodosulfuron-methyl-sodium is unlikely to present a public health risk.

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

Appendix 4 Additional information provided by the applicant

Not relevant.