FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: FLD-HER 306 SE

Product name: Konik 306 SE

Chemical active substances:

2,4-D, 300 g/L
florasulam, 6.25 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

v.2 - supplement

Applicant:

Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k.

Submission date: 15/09/2020 v.2 - 18/03/2021

MS Finalisation date: 08/2021; 11/2021

Version history

When	**What**
2021/03/18	Supplement of Appendix 1 - List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review
August 2021	ZRMs evaluated the dRR submitted by Applicant.
November 2021	Final Registration Report

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

zRMS conclusions/corrections are marked in grey

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) 2019/1791, EFSA Journal 2014;12(9):3812)

No further data are required to support the proposed uses.

Magnitude of residues in plants

Spring wheat, Spring triticale, Spring barley, Oat

Proposed GAP:

BBCH 12-32, 1 application, 120-180 g as./ha, PHI: N/A

Winter wheat, Winter triticale, Winter barley, Rye

Proposed GAP:

BBCH 21-32, 1 application, 120-180 g as./ha, PHI: N/A

EU GAPs

Winter cereals, Spring cereals (EFSA Journal 2014;12(9):3812; SANCO/11961/2014 – rev. 5, 6/10/2017)

BBCH 21-32 (winter cereals), 11-32 (spring cereals); 1 application 750 g as./ha; PHI: N/A

Proposed GAPs for cereals are less critical than EU GAPs (in relation to application rates).

Sufficient trials on cereals (wheat, barley and oats) are available to support the proposed uses.

All studies were performed with higher application rates compared to the intended rate. They were considered in the risk assessment since all residue values were below the LOQ. Residues of 2,4-D are comparable in trials conducted with different formulations and in different European regions.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (Reg. (EU) 2019/1791: barley, oat - 0.05 mg/kg; wheat including triticale and rye -2.0 mg/kg.

According to the SANTE/2019/12752 extrapolation from 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 cereals is intended at early growth stages (up to BBCH 32), therefore extrapolation is possible.

Maize

Proposed GAP:

BBCH 12-16, 1 application, 120-180 g as./ha, PHI: N/A

GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11-16, PHI n.a., outdoor

Proposed GAP for maize is less critical than EU GAPs (in relation to application rates).

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

All studies were performed with higher application rates compared to the intended rate. They were considered in the risk assessment since all residue values were below the LOQ. Residues of 2,4-D are comparable in trials conducted with different formulations and in different European regions.

The residues arising from the proposed uses will not exceed the MRLs established for maize (Reg. (EU) 2019/1791; 0.05 mg/kg).

Magnitude of residues in livestock

The new animal model calculation (Excel spreadsheet Animal model 2017) 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. Calculations provident by the applicant are accepted.

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.

Estimation of exposure through diet and other means

Calculations (EFSA PRIMo rev.3.1)

Input values:

IEDI: Plant (proposed uses) and animal commodities: MRLs (Reg. (EU) 2019/1791)

IESTI: only proposed uses – MRLs (calculation made by zRMS)

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: %ARfD 9,63% Wheat 0,11% Maize/corn 0,09% Barley Processed commodities: %ARfD 8,1% Wheat / milling (flour) 3,7% Wheat / milling (wholemeal)-baking 0,4% Maize / oil

	0,1% Barley / cooked 0,0% Maize / processed (not specified) 0,0% Barley / milling (flour)
NTMDI (% ADI) **	Not relevant.
NEDI (% ADI)**	Not relevant.
NESTI (% ARfD) **	Not relevant.

The proposed uses of 2,4-D in the formulation Konik 306 SE do not represent unacceptable acute and chronic risks for consumers.

<u>Florasulam</u>

Stability of Residues

Florasulam residues stable in wheat matrices (whole plant, straw and grain) for a period of at least 18.7 months (EFSA Journal 2015; 13(1):3984)

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 and animals

The data evaluated during the Annex I inclusion and renewal process of the active substance are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Plant and animal residue definitions for monitoring: Florasulam (Reg. (EU) No 1317/2013)

Plant residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam and provisionally 4-OH- phenyl-florasulam (data gap)

Animal residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam pending assessment with regard to 4-OH-phenyl-florasulam

Conversion factor (monitoring to risk assessment): For milk, liver, kidney and eggs: 1

The data gap concerns the further toxicological evaluation of the plant metabolite 4-OH- phenyl-florasulam.

Magnitude of residues in plants

<u>Spring wheat, Spring triticale, Spring barley, Oat</u>

Proposed GAP:

BBCH 12-32, 1 application, 2.5-3.75 g as./ha, PHI: N/A

<u>Winter wheat, Winter triticale, Winter barley, Rye</u>

Proposed GAP:

BBCH 21-32, 1 application, 2.5-3.75 g as./ha, PHI: N/A

The proposed use of florasulam on wheat and barley is less critical than the critical GAP evaluated in the framework of the renewal of the substance.

EU GAP (RAR): 1 x 6.25 g as/ha, BBCH 45, PHI N/A

EU GAP (review of the MRLs according to article 12): 1x 7.5 g as/ha, up to BBCH 49, PHI N/A

Due to the early growth stage of application, data were pooled from residue trials on wheat and barley.

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

Residues from trials are all below 0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (0.01 mg/kg; Regulation (EU) No 1317/2013 of 16 December 2013)

According to the SANTE/2019/12752 extrapolation from 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 cereals is intended at early growth stages (up to BBCH 32), therefore extrapolation is possible.

Maize

Proposed GAP:

BBCH 12-16, 1 application, 2.5-3.75 g as./ha, PHI: N/A

EU GAP (RAR):

BBCH 11-20, 1 application 5.0 g as./ha, PHI: N/A

The proposed use of florasulam on maize is less critical than the critical GAP evaluated in the framework of the renewal of the substance.

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

Residues in grain from trials are all below 0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for maize (0.01 mg/kg)

Magnitude of residues in livestock

The new animal model calculation (Excel spreadsheet Animal model 2017) 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. Calculations provident by the applicant are accepted.

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

As quantifiable residues of florasulam 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.

EFSA Journal 2015; 13(1):3984: *In the section on residues data gaps were identified with regard to residues in animal commodities and rotational crops. Nonetheless, the margin of safety in the consumer risk assessment is considered big even if the potentially relevant toxicological burden for consumers via their diet might have been underestimated in the current assessment.*

Residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

Estimation of exposure through diet and other means

Input values:

All MRLs of plant and animal commodities (Reg. (EU) No 1317/2013)

Florasulam	
TMDI (% ADI) according to EFSA PRIMo rev.3.1	Highest TMDI: 2% (NL toodler), highest contributor: milk cattle (1%)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	-
IESTI (% ARfD) according to EFSA PRIMo	Not conducted as no ARfD is allocated
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of florasulam in the formulation Konik 306 SE do not represent unacceptable chronic risks for consumers.

Proposed uses are accepted

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAP with respect to consumer intake and risk assessment for the preparation FLD-HER 306 SE is presented in Table 7.1-1. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs as laid down in Reg. (EU) 396/2005:

- for 2,4-D (last update Reg. (EU) 2019/1791) at 2 mg/kg in wheat (including triticale) and rye grain and at 0.05 mg/kg in barley, oats and maize grain,
- for florasulam (last update Reg. (EU) 1317/2013) at 0.01 mg/kg in wheat (including triticale), rye, barley, oat and maize grain,

are not expected.

The chronic and the short-term intakes of 2,4-D and florasulam 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.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

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	Spring wheat Spring triticale Spring barley Oat	PL	FLD-HER 306 SE	F	Weeds (detailed infor-mation is provided in Part B Section 0 and Section 3)	SE	300 g/l of 2,4-D and 6.25 g/l of florasulam	spraying	Spring BBCH 12-32	1	n.a.	40-90 g 2,4-D/hL and 0.83-1.875 g florasulam/hL	200-300 L/ha	120-180 g 2,4-D/ha and 2.5-3.75 g florasulam/ha	NR	A
2	Winter wheat Winter triticale Winter barley Rye	PL	FLD-HER 306 SE	F	Weeds (detailed infor-mation is provided in Part B Section 0 and Section 3)	SE	300 g/l of 2,4-D and 6.25 g/l of florasulam	spraying	Spring BBCH 21-32	1	n.a.	40-90 g 2,4-D/hL and 0.83-1.875 g florasulam/hL	200-300 L/ha	120-180 g 2,4-D/ha and 2.5-3.75 g florasulam/ha	NR	A
3	Maize	PL	FLD-HER 306 SE	F	Weeds (detailed information is provided in Part B Section 0 and Section 3)	SE	300 g/l of 2,4-D and 6.25 g/l of florasulam	spraying	Spring BBCH 12-16	1	n.a.	40-90 g 2,4-D/hL and 0.83-1.875 g florasulam/hL	200-300 L/ha	120-180 g 2,4-D/ha and 2.5-3.75 g florasulam/ha	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 FLD-HER 306 SE is composed of 2,4-D and florasulam.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
2,4-D					
ADI	EFSA Journal 2014;12(9):3812 34	2014	0.02 mg/kg bw per day	Dog, 1-year	100
ARfD	EFSA Journal 2014;12(9):3812 34	2014	0.3 mg/kg bw	Rat and rabbit developmental toxicity studies	100
florasulam					
ADI	EFSA Journal 2015; 13(1):3984	2015	0.05 mg/kg bw per day	1 year dog	100
ARfD	EFSA Journal 2015; 13(1):3984	2015	Not necessary	-	-

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	Spring wheat Spring triticale Spring barley Oat	Yes	Yes (13)	Yes	Yes	Yes	No	No
2	Winter wheat Winter triticale Winter barley Rye	Yes	Yes (13)	Yes	Yes	Yes		No
3	Maize	Yes	Yes (6 below LOQ)	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

According to EFSA Journal 2014;12(9):3812 as residues in cereal and maize 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.
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.

Analytical methods for commodities of high starch content such as cereal grains are available and acceptable for 2,4-D.

7.1.2.2 Summary for florasulam

Table 7.1-4: Summary for florasulam

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	Spring wheat Spring triticale Spring barley Oat	Yes	Yes (12)	Yes	Yes	Yes	No	No
2	Winter wheat Winter triticale Winter barley Rye	Yes	Yes (12)	Yes	Yes	Yes		No
3	Maize	Yes	Yes (9)	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 florasulam 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 use, no significant modification of the intake is calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Analytical methods for commodities of high starch content such as cereal grains are available and acceptable for florasulam.

7.1.2.3 Summary for FLD-HER 306 SE

Table 7.1-5: Information on FLD-HER 306 SE (KCA 6.8)

Crop	PHI for FLD-HER 306 SE proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for FLD-HER 306 SE proposed by zRMS	zRMS Comments (if different PHI proposed)
		2,4-D	florasulam		
Wheat Triticale Barley Oat Rye	NR	NR	NR		
Maize	NR	NR	NR		

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

According to the final addendum to the RAR (Greece, 2014) for 2,4-D no pre-harvest interval is required for cereals because the last recommended application is at least 60 days before harvest. Considering the interval between the last application and harvest it is expected that no residues will occur in the edible part of the plant. Therefore, no preharvest interval is proposed for cereals.

According to RAR (Poland, 2013) for florasulam for cereals and maize PHI is not required. Interval dependent on maximum growth stage at application.

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for FLD-HER 306 SE
Crop group	**Led by 2,4-D**	**Led by florasulam**	
Cereals	NR	NR	
Maize	NR	NR	

NR: not relevant

According to the final addendum to the RAR (Greece, 2014) no waiting period is required. The treatment is applied post-emergence, usually in late spring, on plants that are already well developed and therefore unlikely to be susceptible to crop failure. Consequently, succeeding crops will only be sown as part of a normal rotation after harvest of the target crop, at the earliest 4-6 months after the 2,4-D treatment.

2,4-D is not persistent in the soil and rapidly degrades. In addition, that portion of 2,4-D that degrades undergoes virtually complete destruction with carbon dioxide as the main resulting degradation product.

Assuming a minimum interval of 4 months between treatment and planting of the succeeding crop, 2,4-D will have undergone degradation and the amount left in the soil will be negligible in comparison with the amount initially applied. Such a low concentration of residues in the soil cannot be expected to result in significant effects on any succeeding crops. Therefore, no waiting period is required.

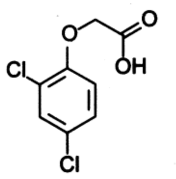
According to RAR (Poland, 2013) for florasulam no specific plant-back restrictions related to florasulam are required between last application and sowing or planting succeeding crops.

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 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	221.0 g/mol
Chemical group	Alkylchlorophenoxy
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 2012*: – Nufarm GmbH & Co KG – Dow AgroSciences B.V. – Makhteshim Agan Agro Poland S.A.
Rapporteur Member State (RMS)	RMS: Greece, Co-RMS: Poland
Approval status	Approved 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:32011R0540 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	None
Review Report	SANCO/11961/2014 – rev. 5 6/10/2017

Current MRL regulation	Regulation (EU) No 2019/1791
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 2014;12(9):3812 24
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 were 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 final addendum to the RAR (Greece, 2014) and 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).

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 Journal 2014;12(9):3812
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 Journal 2014;12(9):3812

Summary of plant metabolism studies reported in the EU

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.

Conclusion on stability of residues during storage

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) and 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).

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 vegeta-ble	Apple	U-^{14}C-phenyl labelled	Application around the trunk	2.13	2	56	-	RAR (Greece, 2014) EFSA Journal 2014;12(9):3812
Root and tuber vegetables	Potato	U-^{14}C-phenyl labelled	Foliar	0.07	2	82	-	
	Potato	U-^{14}C-phenyl labelled	Foliar	0.14 and 0.28	2	29	-	
Pulses and oilseeds	Soya bean	1-^{14}C-2,4-D	Injection, greenhouse	21 µg/plant or callus	1	Plants: 14 Callus: 7	-	
Cereals	Wheat	U-^{14}C-phenyl labelled	Foliar	1.68	1	0, 10, 28, 49	-	
	Wheat	Unlabelled	Foliar	0.5	1	1, 2, 3, 5, 9, 19, 35	-	
	Wheat	1-^{14}C-2,4-D	Injection, greenhouse	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.

Conclusion on metabolism in primary crops

The intended uses are covered by the available metabolism studies reported in the EU.

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 for 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.

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

No processing study is available. As 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	Fruits (apples), Root and tuber vegetables (potatoes), Cereals (wheat) and Pulses/oilseeds (soya beans)
Rotational crops covered	No study is available and none is required due to the fast degradation in soil (DT_{90} = 67.7 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) 2019/1791)
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 were 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) and 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)

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 samp-ling**	
EU data								
Lactating ruminants	Goat	U-^{14}C-phenyl labelled	1	24	3	Milk	daily	EFSA Journal 2014;12(9):3812
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	U-^{14}C-phenyl	15	1.4	7	Eggs	daily	
						Excreta	daily	

		labelled				Tissues	at 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.

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.

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) 2019/1791)
Animal 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	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.
A summary of the magnitude of residues of 2,4-D is given in the following table. All studies are described in details in the final Addendum to the RAR (Greece, 2014) and 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).

Table 7.2-7: Summary of EU reported and new data supporting the intended uses of FLD-HER 306 SE 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 calcu-lator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Cereals - grain (barley, oat, wheat)	EFSA Journal 2014;12(9):3812; Final Addendum to the RAR (Greece, 2014)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11/21-32, PHI n.a., outdoor E: 6x <0.02, <0.04, 6x <0.05 RA: 6x <0.02, <0.04, 6x <0.05	N/A				
	New trials	N-EU	No new data.					
	Overall supporting data for cGAP	N-EU	E: 6x <0.02, <0.04, 6x <0.05 RA: 6x <0.02, <0.04, 6x <0.05	0.04	0.05	-	**0.05** (barley, oat) and **2.0** (wheat)	Yes
Cereals - grain (triticale, rye)	EFSA Journal 2014;12(9):3812; Final Addendum to the RAR	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11/21-32, PHI n.a., outdoor E: 6x <0.02, <0.04, 6x <0.05	N/A				

extrapolation from Cereals - grain (barley, oat, wheat)	(Greece, 2014)		RA: 6x <0.02, <0.04, 6x <0.05					
	New trials	N-EU	No new data.					
	Overall supporting data for cGAP	N-EU	E: 6x <0.02, <0.04, 6x <0.05 RA: 6x <0.02, <0.04, 6x <0.05	0.04	0.05	-	**2.0**	Yes
Cereal - straw (barley, oats and wheat)	EFSA Journal 2014;12(9):3812; Final Addendum to the RAR (Greece, 2014)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11/21-32, PHI XF, outdoor E: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4 RA: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4	N/A				
	New trials	N-EU	No new data.					
	Overall supporting data for cGAP	N-EU	E: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4 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	-	-	-
Cereals - straw (triticale, rye) extrapolation from Cereals - straw (barley, oat, wheat)	EFSA Journal 2014;12(9):3812; Final Addendum to the RAR (Greece, 2014)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11/21-32, PHI XF, outdoor E: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4 RA: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4	N/A				
	New trials	N-EU	No new data.					
	Overall supporting data for cGAP	N-EU	E: <0.02, 0.025, 4x<0.05, 0.081, 2x <0.10, 0.19, 0.28, 0.65, 1.4 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	-	-	-
Maize - grain	EFSA Journal 2014;12(9):3812; Final Addendum to the RAR (Greece, 2014)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11-16, PHI n.a., outdoor E: 4x < 0.02, 2x < 0.05 (overdosed trials) RA: 4x < 0.02 2x < 0.05 (overdosed trials)	N/A				
	New trials	N-EU	No new data.					
	Overall supporting data	N-EU	E: 4x < 0.02, 2x <0.05 RA: 4x < 0.02, 2x <0.05	0.02	0.05	-	**0.05**	Yes

	for cGAP							
Maize - forage	EFSA Journal 2014;12(9):3812; Final Addendum to the RAR (Greece, 2014)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11-16, PHI n.a., outdoor E: 3x <0.02, <0.05, 0.15 0.06 (overdosed trial) RA: 3x <0.02, <0.05, 0.15 0.06 (overdosed trial)	N/A				
	New trials	N-EU	No new data.					
	Overall supporting data for cGAP	N-EU	E: 3x <0.02, 0.05, 0.06, 0.15 RA: 3x <0.02, 0.05, 0.06, 0.15	0.035	0.15	-	-	-

* Source of EU MRL: Commission Regulation (EU) 2019/1791 of 17 October 2019

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 treatment			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

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

Lp.	Country, year	Application per treatment			Crop	Crop growth stage	Residues mg/kg		Reference/ Study code
		Form. type	No	g ai/ha			Grain	Forage	
1	DE, 2010	SL	1	752	maize	16	<0.02*	<0.02*	**Final Addendum to the RAR (Greece, 2014) /** S10-02224
2	PL, 2010	SL	1	792	maize	16	<0.02*	<0.02*	**Final Addendum to the RAR (Greece, 2014) /** S10-02224
3	DE, 2010	SL	1	731	maize	16	<0.02*	<0.02*	**Final Addendum to the RAR (Greece, 2014) /** S10-02224
4	UK, 2010	SL	1	793	maize	16	<0.02*	0.15	**Final Addendum to the RAR (Greece, 2014) /** S10-02224
5	N-FR, 1999	SL	1	1163	maize	16	<0.05*	<0.05*	**Final Addendum to the RAR (Greece, 2014) /** 9033 CT1
6	N-FR, 1999	SL	1	1210	maize	14-15	<0.05*	0.06	**Final Addendum to the RAR (Greece, 2014) /** 9033 AN1

* LOQ value

7.2.3.2 Conclusion on the magnitude of residues in plants

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

Cereals

A total of 13 trials on cereals (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 32), therefore extrapolation is possible.
The residues arising from the proposed uses will not exceed the MRLs established for barley, oat (0.05 mg/kg) and wheat (including triticale), rye (2.0 mg/kg)

Maize

A total of 6 trials are available on maize (4 carried out according to the critical GAP and 2 with higher application rates from final Addendum to the RAR (Greece, 2014) which is more critical than the proposed GAP. Since all 6 residue values in maize grain are below LOQ, all were considered in the risk assessment. The residue data are sufficient to support the proposed use. The residue data are valid with regard to storage stability.
The residues arising from the proposed uses will not exceed the MRLs established for maize (0.05 mg/kg).

The data submitted show that no exceedance of the MRL is to be envisaged. The intended uses on cereals and maize are considered acceptable.

All residue values for intended uses achieved from supervised residue trials are below LOQ. Product FLD-HER 306 SE is intended to apply on crops which have not melliferous capacity (according to SAN-

TE/11956/2016 rev. 9, 14 September 2018) therefore, it is very unlikely that residues of 2,4-D will be present in honey.

7.2.4 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 FLD-HER 306 SE was performed by Excel spreadsheet Animal model 2017 and was focused only on intended uses of FLD-HER 306 SE i.e. barley, oat, wheat, triticale, rye and maize. Input values (STMR and HR) used for dietary calculation are provided below in Table 7.2-8. Results of dietary burden calculation for FLD-HER 306 SE are included in Table 7.2-9.

Table 7.2-8 Summary of input values for the dietary burden calculation

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
Corn, field, forage/silage	0.035	STMR	0.15	HR
Cereals, grain	0.04	STMR	0.04	STMR
Corn, pop, grain	0.02	STMR	0.02	STMR
Brewers's grain, dried	0.04 x 3.3	STMR x PF*	0.04 x 3.3	STMR x PF*
Corn, field milled by-pdts	0.02 x 1	STMR x PF*	0.02 x 1	STMR x PF*
Corn, field hominy meal	0.02 x 6	STMR x PF*	0.02 x 6	STMR x PF*
Corn, field gluten feed	0.02 x 2.5	STMR x PF*	0.02 x 2.5	STMR x PF*
Corn, field gluten, meal	0.02 x 1	STMR x PF*	0.02 x 1	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 Summary of results of the dietary burden calculation for FLD-HER 306 SE

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)
Cattle (all diets)	0.006	0.023	0.16	0.59	Dairy cattle	Barley, straw	Y
Cattle (dairy only)	0.006	0.023	0.15	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	0.006	0.19	0.25	Swine (breeding)	Corn, field, forage/silage	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 7.2-12.

7.2.4.2 Livestock feeding studies

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 enforce-ment		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 565 kg animal consuming 17.9 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 7 until day 28 (3 cows, 7 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 and maize 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

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 address aspects of the residue situation that might arise from the use of FLD-HER 306 SE. Therefore, other special studies are not needed.

All residue values for intended uses achieved from supervised residue trials were below LOQ. Product FLD-HER 306 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				

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Tier I				
Barley	0.05	EU MRL*	0.05	EU MRL*
Oat	0.05	EU MRL*	0.05	EU MRL*
Wheat (including triticale)	2.0	EU MRL*	2.0	EU MRL*
Rye	2.0	EU MRL*	2.0	EU MRL*
Maize	0.05	EU MRL*	0.05	EU MRL*
All other commodities	variable	EU MRL*	variable	EU MRL*
Tier II				
Wheat (including triticale)	0.04	STMR	Not relevant. IESTI < 100 % of ARfD.	
Rye	0.04	STMR		
All other commodities	variable	EU MRL*		

* Commission Regulation (EU) 2019/1791 of 17 October 2019

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 Oranges: 44% (based on UK infant Diet) Wheat: 10% (based on UK 4-6 years Diet) Rye: 4% (based on (based on UK infant Diet) Processed commodities Oranges / juice: 18% (based on DE child Diet) Wheat / milling (flour): 8% (based on DE child Diet) Wheat / milling (wholemeal)-baking: 4% (based on 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). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population.

- Tier I - input values for all commodities were derived from EU MRL (Reg. (EU) 2019/1791). The potential chronic dietary exposure was compared to the ADI of 0.02 mg/kg bw/day and TMDI values were achieved. 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. With regard to the acute exposure, no exceedance was identified. The highest % of ARfD was identified for oranges (44%) in DE child 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) 2020/192 (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 FLD-HER 306 SE does not represent unacceptable chronic and acute risks for the consumer.

zRMS comment
IESTI calculation (input values: only proposed uses – MRLs)
Results:
<u>Unprocessed commodities: %ARfD</u>
9,63% Wheat
0,11% Maize/corn
0,09% Barley
<u>Processed commodities: %ARfD</u>
8,1% Wheat / milling (flour)
3,7% Wheat / milling (wholemeal)-baking
0,4% Maize / oil
0,1% Barley / cooked
0,0% Maize / processed (not specified)
0,0% Barley / milling (flour)

Acute risk assessment /children — Details - acute risk assessment /children

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

Acute risk assessment /children — Hide IESTI new calculations

Acute risk assessment / adults / general population — Show IESTI new calculations

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 E

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

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

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Wheat	2 / 2	29
0,1%	Maize/corn	0,05 / 0,05	0,34
0,09%	Barley	0,05 / 0,05	0,26

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

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Wheat	2 / 2	17
0,08%	Barley	0,05 / 0,05	0,24
0,04%	Maize/corn	0,05 / 0,05	0,11

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

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Wheat	2 / 2	29
0,1%	Maize/corn	0,05 / 0,05	0,34
0,09%	Barley	0,05 / 0,05	0,26

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

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Wheat	2 / 2	17
0,08 %	Barley	0,05 / 0,05	0,24
0,04 %	Maize/corn	0,05 / 0,05	0,11

Expand/collapse list

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

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

Processed commodities

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

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Wheat / milling (flour)	2 / 2	24
4%	Wheat / milling (wholemea	2 / 2	11
0,4%	Maize / oil	0,05 / 1,25	1,2
0,1%	Barley / cooked	0,05 / 0,05	0,18
0,0%	Maize / processed (not spe	0,05 / 0,05	0,11
0,0%	Barley / milling (flour)	0,05 / 0,05	0,09

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

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3 %	Wheat / bread/pizza	2 / 2	8,8
3 %	Wheat / pasta	2 / 2	7,6
2 %	Wheat / bread	2 / 2	7,0
0,2%	Maize / oil	0,05 / 1,25	0,63
0,1%	Barley / beer	0,05 / 0,01	0,36

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

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Wheat / milling (flour)	2 / 2	24
4%	Wheat / milling	2 / 2	11
0,4%	Maize / oil	0,05 / 1,25	1,2
0,06%	Barley / cooked	0,05 / 0,05	0,18
0,04%	Maize / processed (not	0,05 / 0,05	0,11
0,03%	Barley / milling (flour)	0,05 / 0,05	0,09

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

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat / bread/pizza	2 / 2	8,8
3%	Wheat / pasta	2 / 2	7,6
2%	Wheat / bread (wholemeal)	2 / 2	7,0
0,2%	Maize / oil	0,05 / 1,25	0,63
0,1%	Barley / beer	0,05 / 0,01	0,36

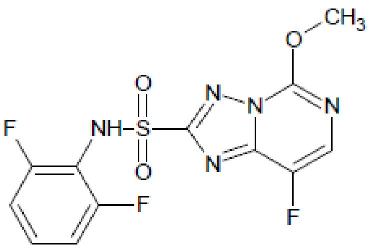
Expand/collapse list

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.

7.3 Florasulam

General data on florasulam are summarized in the table below.

Table 7.3-1: General information on florasulam

Active substance (ISO Common Name)	florasulam
IUPAC	2′,6′,8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-c] pyrimidine-2-sulfonanilide
Chemical structure	
Molecular formula	$C_{12}H_8O_3N_5F_3S$
Molar mass	359.3 g/mol
Chemical group	Triazolopyrimidine
Mode of action (if available)	Selective, absorbed by roots and shoots. Inhibitor of acetolactate synthase ALS (acetohydroxyacid synthase AHAS).
Systemic	Yes
Company (ies)	Dow AgroSciences*
Rapporteur Member State (RMS)	RMS: Poland, Co-RMS: Belgium
Approval status	Approved Commission Implementing Regulation (EU) 2015/1397 of 14 August 2015 renewing the approval of the active substance florasulam 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:32015R1397 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/TXT/?qid=1439971687275&uri=CELEX:02011R0540-20150730
Restriction	None
Review Report	SANTE/10542/2015 Rev 1 14 July 2015
Current MRL regulation	Regulation (EU) No 1317/2013
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes. EFSA Journal 2012;10(3):2626
EFSA Journal : Conclusion on the peer review	Yes. EFSA Journal 2015; 13(1):3984
EFSA Journal: conclusion on article 12	No

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.

A summary of the storage stability data on florasulam is given in EFSA's Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam (EFSA Journal 2015; 13(1):3984) as well as in RAR (Poland, 2013). Data has been previously evaluated at EU level and is described in detail in the DAR (Belgium, 1999). Storage stability of florasulam was demonstrated in cereal grain, cereal straw and immature cereal plants for a period of 18 to 23 months at temperatures ranging from -18°C to -25°C.

Conclusion on stability of residues during storage

According to RMS, the storage conditions for all available residue trials were in compliance with the storage stability data. Decline of residues during storage of residue trials samples is therefore not expected.

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.

A summary of the metabolism of florasulam in plants is given in the following table. Metabolism studies for wheat were conducted and evaluated in the DAR (Belgium, 1999). The metabolism of florasulam was investigated in winter wheat after foliar application of [^{14}C-phenyl]-florasulam and [^{14}C-triazolopyrimidine]-florasulam at a rate of 50 g a.s./ha.

Table 7.3-2: 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	Winter wheat	[^{14}C-phenyl]-florasulam and [^{14}C-triazolo-pyrimidine]-florasulam	foliar treatment, F	50 g as/ha	1	Immature plants: 0, 30 DAT Crop maturity (straw, grain and shaff): 65 DAT	Application at BBCH 49 (post flag leaf emergence/first awns visible-late application).	DAR (Belgium, 1999) EFSA Journal 2015; 13(1):3984
						Immature plants: 0, 30 DAT Crop maturity (straw, grain and shaff): 129 DAT	Application at BBCH30 (stem elongation-early application).	

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

Summary of plant metabolism studies reported in the EU

According to EFSA Journal 2015; 13(1):3984 the metabolism of florasulam was investigated in winter wheat after foliar application of [^{14}C-phenyl]-florasulam and [^{14}C-triazolopyrimidine]-florasulam. Treatment was done of two subsets at two different growth stages that would both fall within the GAP conditions applied for. At the immature plant stage (forage), florasulam (28-33% TRR) and metabolite 4-OH-phenyl-florasulam plus glucose-conjugate (19-42% TRR) were the major residues. In the mature wheat plants (straw), parent florasulam was only recovered in one of the two experimental subsets with later application (7-14% TRR). Metabolite 4-OH-phenyl-florasulam plus glucose-conjugate was major (up to 36% TRR). Residues in wheat grain were too low to permit any identification. The presence of increasing proportions of metabolite ASTP with time (up to 19% TRR at harvest) indicated that a cleavage of the molecule occurred with progressing metabolism. 4-OH-phenyl-florasulam is a minor rat metabolite and there is no toxicological data available for this metabolite to sufficiently conclude on its toxicological properties. While present in significant proportions in the metabolism study at the relevant PHIs for commodities used as livestock feed items (e.g. cereal straw, forage, grass, hay, silage), the actual levels upon using florasulam under GAP conditions in the field remain unclear since residue trials did not determine residues of 4-OH-phenyl-florasulam (free and conjugated). Considering that potential feed items are relevant commodities for all uses applied for, the plant residue definition for risk assessment should provisionally include both florasulam and 4-OH-phenyl-florasulam, pending the submission of sufficient evidence demonstrating the inclusion of this metabolite will not be necessary to appropriately describe the toxicological dietary burden. The plant residue definition for enforcement and MRL setting may keep per default the parent florasulam as the compound to be monitored in food commodities (cereal grains), disregarding feed items since currently not monitored.

Conclusion on metabolism in primary crops

According to EFSA Journal 2015; 13(1):3984 it was concluded that there is minimal transport or storage of florasulam in the grain. Although residue levels are expected to be very low, based on results of the wheat metabolism study it was agreed that the residue definition for enforcement as well as risk assessment was the parent molecule, florasulam.

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.

The metabolism of florasulam in rotational crops (spring wheat, sunflower, cabbage and carrot) has been evaluated in the DAR (Belgium, 1999). A rotational crop study investigating the nature of residues following a plant-back interval of 30 days is available. A summary of the metabolism in rotational crops of florasulam in plants is given in the following table.

Table 7.3-3: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Cabbage	[^{14}C-phenyl]-florasulam and [^{14}C-triazolo-pyrimidine]-florasulam	n.r.	0.0075	30	195	-	DAR (Belgium, 1999) EFSA Journal 2015; 13(1):3984
Root and tuber vegetables	Carrot					156	-	
Pulses and oilseeds	Sunflower					168	-	
Cereals	Spring wheat					168	-	

n.r.: Not reported.
*: Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

At maturity, in spring wheat (ears and straw), sunflower (heads and stems), cabbage (heads) and carrots (leaves and roots) no radioactivity was detected or TRR was ranging between 0.001 (spring wheat) and 0.006 (carrots) mg/kg florasulam equivalent. Residues exceeding 0.01 mg/kg are therefore not expected in rotational crops and specific plant-back restrictions related to the use of florasulam are not required.

Conclusion on metabolism in rotational crops

According to EFSA Journal 2015; 13(1):3984 the investigation of rotational crops was considered insufficient with regard to the potential for uptake of significant levels in plant commodities, particularly in terms of the persistent metabolites TSA and ASTCA (both with triazole sulfone moiety). Since the available data did not address a plant back interval of 365 days and the application rate in the study seems insufficient considering repeated/multiannual applications, information that may be necessary when persistent soil residues occur. Additional evidence with regard to rotational crops, satisfying the requirement according to current guidance was identified as necessary. Therefore, the residue definition with regard to rotational crops is currently not finalised.

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.

Conclusion on nature of residues in processed commodities

According to DAR (Belgium, 1999) as well as RAR (Poland, 2013) as quantifiable residues of florasulam are not expected in cereal grains and maize grain, there is no need to investigate the effect of industrial and/or household processing.

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

Table 7.3-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (winter wheat)
Rotational crops covered	Four rotational crops (cabbage, carrot, sunflower and wheat).
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not aplicable
Plant residue definition for monitoring	Florasulam (Reg. (EU) No 1317/2013)
Plant residue definition for risk assessment	Florasulam and provisionally 4-OH- phenyl-florasulam (data gap) (EFSA Journal 2015; 13(1):3984)
Conversion factor from enforcement to RA	Not aplicable

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.

The nature of florasulam residue in commodities of animal origin was investigated in the DAR (Belgium, 1999) and is summarized in EFSA Journal 2015; 13(1):3984. The basic characteristics of the metabolism studies design are summarised in following table.

Table 7.3-5: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of samp-ling**	
EU data								
Lactating ruminants	Goat	[phenyl-^{14}C]-florasulam	1	11$^{(a)}$	5	Milk	twice daily	DAR (Belgium, 1999) EFSA Journal 2015; 13(1):3984
						Urine and faeces	daily	
						Tissues	after sacrifice	
		[triazolopyrimidine-^{14}C]-florasulam	1	11$^{(a)}$	5	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	after	

							sacrifice	
Laying poultry	Hens	[phenyl-^{14}C]-florasulam	10	11(b)	5	Eggs	daily	
						Excreta		
						Skin	after sacrifice	
		[triazolopyrimidine-^{14}C]-florasulam	10	11(b)	5	Eggs	daily	
						Excreta		
						Skin	after sacrifice	

(a): considering a weight of 50-90 kg for a goat, the rate is comprised between 0.11 and 0.22 mg/kg bw/d.
(b): considering a weight of 1.9 kg for a hen, the rate is around 5.79 mg/kg bw/d.

Summary of plant metabolism studies reported in the EU

According to EFSA Journal 2015; 13(1):3984 the metabolism of florasulam was investigated in goat and hen with [^{14}C-phenyl]-florasulam and [^{14}C-triazolopyrimidine]-florasulam. Metabolism of florasulam was not extensive, resulting in florasulam being the pertinent residue (80% up to 99% TRR) in the different goat and hen matrices with the exception of goat liver (15% TRR with 82-87% TRR not extracted). Livestock exposure estimates are pending for the cGAP supported for permanent pasture and new leys and further evidence with regard to occurrence, behaviour and/or toxicity of 4-OH-phenyl-florasulam is required.

Conclusion on metabolism in livestock

According to EFSA Journal 2015; 13(1):3984 the finalisation of the livestock residue definition for risk assessment is pending. For monitoring, given there was occurrence of florasulam in grass and silage and florasulam is hardly metabolised by the animals, parent florasulam alone might be sufficient for inclusion in the residue definition for enforcement/MRL setting.

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

Table 7.3-6: Summary on the nature of residues in commodities of animal origin

Endpoints	
Animals covered	Lactating goats
	Laying hens
Animal residue definition for monitoring	Florasulam (Reg. (EU) No 1317/2013)
Animal residue definition for risk assessment	Florasulam pending assessment with regard to 4-OH-phenyl-florasulam (EFSA Journal 2015; 13(1):3984)
Conversion factor	For milk, liver, kidney and eggs: 1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

No new data are submitted in the framework of this application.
A summary of the magnitude of residues of florasulam is given in the following table. Data have been previously evaluated at EU level and are described in the RAR (Poland, 2013), in EFSA's Conclusion on the peer review of the renewal of florasulam (EFSA Journal 2015; 13(1):3984) and in EFSA's Reasoned opinion on the review of the existing MRLs for florasulam according to article 12 of Reg. (EC) No 396/2005 (EFSA Journal 2012;10(3):2626).

Table 7.3-7: Summary of EU reported and new data supporting the intended uses of FLD-HER 306 SE and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Cereals – grain (barley and wheat)	RAR, Poland, 2013 EFSA Journal 2015; 13(1):3984	N-EU	GAP on which EU a.s. assessment is based: 1 x 6.25 g as/ha, up to BBCH 49, PHI: N/A, outdoor E: 12 x < 0.01 RA: 12 x < 0.01	N/A				
	New trials	-	-					
	Overall supporting data for cGAP	N-EU	E: 12 x < 0.01 RA: 12 x < 0.01	0.01	0.01	-	**0.01**	Yes
Cereals – grain (oat, rye, triticale) extrapolation from barley and wheat	RAR, Poland, 2013 EFSA Journal 2015; 13(1):3984	N-EU	GAP on which EU a.s. assessment is based: 1 x 6.25 g as/ha, up to BBCH 49, PHI: N/A, outdoor E: 12 x < 0.01 RA: 12 x < 0.01	N/A				
	New trials	-	-					

	Overall supporting data for cGAP	N-EU	E: 12 x < 0.01 RA: 12 x < 0.01	0.01	0.01	-	**0.01**	Yes
Cereals – straw (barley and wheat)	RAR, Poland, 2013 EFSA Journal 2015; 13(1):3984	N-EU	GAP on which EU a.s. assessment is based: 1 x 6.25 g as/ha, up to BBCH 49, PHI: N/A, outdoor E: 12 x < 0.01 RA: 12 x < 0.01	N/A				
	New trials	N-EU	-					
	Overall supporting data for cGAP	N-EU	E: 12 x < 0.01 RA: 12 x < 0.01	0.01	0.01	-	-	-
Cereals – straw (oat, rye, triticale) extrapolation from barley and wheat	RAR, Poland, 2013 EFSA Journal 2015; 13(1):3984	N-EU	GAP on which EU a.s. assessment is based: 1 x 6.25 g as/ha, up to BBCH 49, PHI: N/A, outdoor E: 12 x < 0.01 RA: 12 x < 0.01	N/A				
	New trials	N-EU	-					
	Overall supporting data for cGAP	N-EU	E: 12 x < 0.01 RA: 12 x < 0.01	0.01	0.01	-	-	-
Maize - grain	RAR, Poland, 2013 EFSA Journal 2015; 13(1):3984	N-EU	GAP on which EU a.s. assessment is based: 1 x 5.00 g as/ha, BBCH 19-20, PHI N/A, indoor E: 9 x <0.01 RA: 9 x <0.01	N/A				
	New trials	-	-					
	Overall supporting data for cGAP	N-EU	E: 9 x <0.01 RA: 9 x <0.01	0.01	0.01	-	**0.01**	Yes
Maize - silage	RAR, Poland, 2013	N-EU	GAP on which EU a.s. assessment is based: 1 x 5.00 g as/ha, BBCH 19-20, PHI N/A, indoor	N/A				

	EFSA Journal 2015; 13(1):3984		E: 9 x <0.01 RA: 9 x <0.01					
	New trials	-	-					
	Overall supporting data for cGAP	N-EU	E: 9 x <0.01 RA: 9 x <0.01	0.01	0.01	-	-	-

* Source of EU MRL: Commission Regulation (EU) No 1317/2013 of 16 December 2013

Table 7.3-7.1 Residue trials in EU-N used for support of cereals registration (RAR, Poland 2013)

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	N-FR, 2010	SC	1	6.58	barley	45	<0.01*	<0.01*	**RAR, Poland 2013** GHE-P-12647
2	UK, 2010	SC	1	6.26	barley	43-47	<0.01*	<0.01*	**RAR, Poland 2013** GHE-P-12647
3	DE, 2011	SC	1	6.0-7.0	barley	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRATII007-14HR
4	UK, 2010	SC	1	6.0-7.0	barley	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRUKIl-011-14HR
5	HU, 2010	SC	1	6.41	wheat	45	<0.01*	<0.01*	**RAR, Poland 2013** GHE-P-12647
6	DE, 2010	SC	1	6.24	wheat	45	<0.01*	<0.01*	**RAR, Poland 2013** GHE-P-12647
7	DE, 2011	SC	1	6.0	wheat	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRATII018-14HR
8	UK, 2011	SC	1	6.0	wheat	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRUKIl-015-14HR
9	N-FR, 2011	SC	1	6.0	wheat	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRFRIl--005-14HR
10	N-FR, 2011	SC	1	6.0	wheat	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRFRIl--031-14HR
11	HU, 2011	SC	1	6.0	wheat	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRHUII-013-14HR
12	HU, 2011	SC	1	6.0-7.0	wheat	32-45	<0.01*	<0.01*	**RAR, Poland 2013** SRUKIl-054-14HR

* LOQ value

Table 7.3-7.2 Residue trials in EU-N used for support of maize registration (RAR, Poland 2013)

Lp.	Country, year	Application per treatment			Crop	Crop growth stage	Residues mg/kg		Reference/ Study code
		Form. type	No	g ai/ha			Grain	Silage	
1	N-FR, 2010	SC	1	5.08	maize	09/19	<0.01*	<0.01*	**RAR, Poland 2013** SRFR10-007-14HR GHE-P-12645
2	UK, 2010	SC	1	5.03	maize	09-11 19/30	<0.01*	<0.01*	**RAR, Poland 2013** SRUK10-010-14HR GHE-P-12645
3	DE, 2010	SC	1	5.02	maize	09/19	<0.01*	<0.01*	**RAR, Poland 2013** SRAT10-012-14HR GHE-P-12645
4	BE, 2010	SC	1	5.08	maize	09/19	<0.01*	<0.01*	**RAR, Poland 2013** G046-10H GHE-P-12645

Lp.	Country, year	Application per treatment			Crop	Crop growth stage	Residues mg/kg		Reference/ Study code
		Form. type	No	g ai/ha			Grain	Silage	
5	N-FR, 2011	SC	1	5.0	maize	09/19	<0.01*	<0.01*	**RAR, Poland 2013** SRFRIl--001-14HR
6	UK, 2011	SC	1	5.0	maize	09-11/ 17-19	<0.01*	<0.01*	**RAR, Poland 2013** SRUKIl-007-14HR
7	UK, 2011	SC	1	5.0	maize	09-11/ 30-31	<0.01*	<0.01*	**RAR, Poland 2013** SRUKIl-008-14HR
8	DE, 2011	SC	1	5.0	maize	09/19	<0.01*	<0.01*	**RAR, Poland 2013** SRATIl-006-14HR
9	HU, 2011	SC	1	5.0	maize	09/19	<0.01*	<0.01*	**RAR, Poland 2013** SRHU11-012-14HR

* LOQ value

7.3.3.2 Conclusion on the magnitude of residues in plants

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

Cereals

A total 12 trials on cereals (8 trials on wheat and 4 trials on barley) are available. Trials were performed according to the critical GAP (RAR Poland, 2013). All residue values in cereals grain are 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, wheat and residue trials on wheat may be extrapolate to oat, rye, barley, before forming of the edible part. Application to cereal grains is intended at early growth stages (up to BBCH 32), therefore extrapolation is possible.
The residues arising from the proposed uses will not exceed the MRLs established for cereals (0.01 mg/kg).

Maize

A total of 9 trials are available on maize. Trials were performed according to the critical GAP (RAR Poland, 2013). All residue values in maize grain are below LOQ and are sufficient to support the proposed use. The residue data are valid with regard to storage stability.
The residues arising from the proposed uses will not exceed the MRLs established for maize (0.01 mg/kg).

The data submitted show that no exceedance of the MRL is to be envisaged. The intended uses on cereals and maize are considered acceptable.

All residue values for intended uses achieved from supervised residue trials are below LOQ. Product FLD-HER 306 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 florasulam will be present in honey.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Florasulam is authorised for uses on several 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 (MRLs) for florasulam according to Article 12 of Regulation (EC) No 396/20 (EFSA Journal 2012;10(3)). 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). As no feeding study is available for florasulam, the estimated maximum intake was compared to the outcomes of metabolism studies in ruminants and poultry. With a maximum burden being about 10-20 times lower than the dose level of the metabolism studies, residue levels should not result in quantifiable residues in milk and tissues of ruminants. MRLs for pigs and poultry products are not deemed necessary, because pigs and poultry are not expected to be exposed to significant levels of florasulam residues (EFSA Journal 2012;10(3):2626). Likewise, significant residues in fish are not anticipated due to a log P_{ow} of florasulam reported at -1.22 (pH 7).
For the intended uses no residues above the LOQ of 0.01 mg/kg were found in grain or straw suitable for feeding purposes. A significant contribution to the livestock animal dietary burden is not expected. Dietary burden calculation for purpose of maintain authorisation of FLD-HER 306 SE was performed by Excel spreadsheet Animal model 2017 and was focused only on intended uses of FLD-HER 306 SE i.e. barley, oat, wheat, triticale, rye and maize. Input values (STMR and HR) used for dietary calculation are provided below in Table 7.2-8. Results of dietary burden calculation for FLD-HER 306 SE are included in Table 7.2-9.

Table 7.3-8 Summary of input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: florasulam				
Cereals, straw	0.01	STMR	0.01	HR
Corn, field, forage/silage	0.01	STMR	0.01	HR
Cereals, grain	0.01	STMR	0.01	STMR
Brewers's grain, dried	0.01 x 3.3	STMR x PF*	0.01 x 3.3	STMR x PF*
Corn, field milled by-pdts	0.01 x 1	STMR x PF*	0.01 x 1	STMR x PF*
Corn, field hominy meal	0.01 x 6	STMR x PF*	0.01 x 6	STMR x PF*
Corn, field gluten feed	0.01 x 2.5	STMR x PF*	0.01 x 2.5	STMR x PF*
Corn, field gluten, meal	0.01 x 1	STMR x PF*	0.01 x 1	STMR x PF*
Distiller's grain, dried	0.01 x 3.3	STMR x PF*	0.01 x 3.3	STMR x PF*
Wheat gluten, meal	0.01 x 1.8	STMR x PF*	0.01 x 1.8	STMR x PF*
Wheat, milled by-pdts	0.01 x 7	STMR x PF*	0.01 x 7	STMR x PF*

* default value from Animal model 2017

Table 7.3-9 Summary of results of the dietary burden calculation for FLD-HER 306 SE

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)
Cattle (all diets)	0.001	0.001	0.03	0.03	Dairy cattle	Wheat, milled by pdts	N
Cattle (dairy only)	0.001	0.001	0.03	0.03	Dairy cattle	Wheat, milled by pdts	N
Sheep (all diets)	0.002	0.002	0.05	0.05	Lamb	Wheat, milled by pdts	N
Sheep (ewe only)	0.001	0.001	0.04	0.04	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 not 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 not required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

According to RAR (Poland, 2013) in livestock feed commodities from the crops and associated GAPs supported (cereals, maize and pasture grass) along with extrapolation of residue results from the livestock, nature of residue studies in goats and hens, residues of florasulam in edible tissues, milk or eggs are not expected to be quantifiable (i.e. <0.01 mg/kg). No livestock feeding studies are required.

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

According to DAR (Belgium, 1999), RAR (Poland, 2013) as quantifiable residues of florasulam are not expected in cereal and maize grain, there is no need to investigate the effect of industrial and/or household processing.

7.3.6 Magnitude of residues in representative succeeding crops

According to RAR (Poland, 2013) a confined rotational crop/metabolism study was conducted in four rotational crops (cabbage, carrot, sunflower and what) and was evaluated during the first Annex I inclusion. Based on the rate of dissipation of florasulam residues in soil and results from a confined rotational crop residue study, it was concluded that residues in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam were required. A reasoned opinion from EFSA (EFSA Journal 2012;10(3):2626) for review of existing MRLs for florasulam indicated that for florasulam the maximum DT_{90} resulting from field dissipation studies was 61 days and did not trigger the requirement for further investigation of residues in succeeding crops. However, 5-OH-florasulam is the primary metabolite of florasulam found in soil and the maximum DT_{90} observed for it in field dissipation studies was 209 days, which since it is above the trigger value of 100 days resulted in the need to conduct further investigation concerning residues in succeeding crops.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

According to RAR (Poland, 2013) no study is required since the results from the confined rotational crop residue study indicated that residues in succeeding crops are not expected to be quantifiable (<0.01 mg/kg).

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 FLD-HER 306 SE. Therefore, other special studies are not needed.

All residue values for intended uses achieved from supervised residue trials are below LOQ. Product FLD-HER 306 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 florasulam will be present in honey.

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

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

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: florasulam				
Barley	0.01	EU MRL*	Not relevant as no ARfD is allocated.	
Oat	0.01	EU MRL*		
Wheat (including triticale)	0.01	EU MRL*		
Rye	0.01	EU MRL*		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize	0.01	EU MRL*		
All other commodities	variable	EU MRL*		

* Commission Regulation (EU) No 1317/2013 of 16 December 2013

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-11: Consumer risk assessment

ADI	0.05 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	2 % (based on NL toddler Diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not relevant. TMDI < 100%.
ARfD	ARfD was not deemed necessary.
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Not relevant. ARfD was not deemed necessary.
NTMDI (% ADI) **	Not relevant
NEDI (% ADI)**	Not relevant
NESTI (% ARfD) **	Not relevant

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

Chronic exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population.
Input values for all commodities were derived from EU MRL (Reg. (EU) 1317/2013). The potential chronic dietary exposure was compared to the ADI of 0.05 mg/kg bw/day and TMDI values were achieved. The highest chronic exposure was calculated for NL toddler Diet, representing 2% of the ADI. For this diet the highest contributor was milk: cattle (1% of ADI). As ARfD was not deemed necessary, acute risk assessment was not performed.

The proposed uses of florasulam in the formulation FLD-HER 306 SE 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.

7.4.1 Acute consumer risk assessment from combined exposure

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

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, Poland. 2013. 2,4-D: Renewal Assessment Report

Greece, Poland. 2014. 2,4-D: Final addendum to the Renewal Assessment Report

EFSA (European Food Safety Authority), 2014 . Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D. EFSA Journal 2014;12(9):3812.

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

Belgium, 1999. Florasulam: (Monograph – Draft Assessment Report)

Poland, 2013. Florasulam: Draft Renewal Assessment Report

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance Florasulam; EFSA Journal 2015;13(1): 3984;

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Florasulam according to Article 12 of Regulation (EC) No 396/2005 EFSA Journal 2012;10(3):2626

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 at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Submitter or source
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		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	Y	European Union 2,4-D Task Force 2012
KCA	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	N	European

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	Submitter or source
6.1/03			Straw Report No. CEMR-1397 (AHM R 99 142) GLP: Y Published: N		Union 2,4-D Task Force 2012
KCA 6.1/04	Butler R.E. Gambie A.	1997	Florasulam. The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Interim Report) DowElanco Europe, Letcombe Regis, Oxon, UK ST96-001, November 1997 DowAgroSciences Report No. GHE-P-6782 GLP: Y Published: N	N	Dow AgroSciences
KCA 6.1/05	Gambie A.	1999	Florasulam. The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Final Report) DowElanco Europe, Letcombe Regis, Oxon, UK ST96-001, May 1999 DowAgroSciences Report No. GHE-P-7904 GLP: Y Published: N	N	Dow AgroSciences
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	Bristol et al.	1982	Determination of Free and Hydrolyzable Residues of 2,4-Dichlorophenoxyacetic Acid and 2,4-	N	SAN

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	Submitter or source
6.2.1/03			Dichlorophenol in Potatoes. J. Agric. Food Chem. 1982, 30, 137-144 GLP: N Published: Y		
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 GLP: Y Published: N	N	European Union 2,4-D Task Force 2012
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 6.2.1/07	Pillar F.	1997	Florasulam. The Metabolism of XDE-570 in Winter Wheat - Final Report DowElanco Europe, Letcombe Regis, Oxon, UK 5U, October 1997 Dow AgroSciences Report No. GHE-P-5729 GLP: Y Published: N	N	Dow AgroSciences

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	Submitter or source
KCA 6.2.2-6.2.5/01		1993 1994	Metabolism of Uniformly 14C-ring Labeled 2,4-Dichlorophenoxyacetic acid in Lactating Goats ABC Laboratories Report 40630 and supplementary report Supplemental Data for the Study, Metabolism of Uniformly 14C-ring Labeled 2,4-Dichlorophenoxyacetic acid in Lactating Goats ABC Laboratories Report 40630-01 GLP: Y Published: N	Y	European Union 2,4-D Task Force 2012
KCA 6.2.2-6.2.5/02		1992	Metabolism of Uniformly Ring Labeled [14C] 2,4-Dichloro phenoxyacetic Acid in Poultry ABC Laboratories 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
KCA 6.2.2-6.2.5/04		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		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 6.2.2-		1994a	Florasulam. Nature of the Residue of [14C]XDE-570 in Lactating Goats DowElanco, Indianapolis, USA and ABC Laboratories Inc, Columbia, USA	Y	Dow AgroSciences

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	Submitter or source
6.2.5/06			MET94017, December 1994a Dow AgroSciences Report No. GH-C 3478 GLP: Y Published: N		
KCA 6.2.2-6.2.5/06		1994b	Florasulam. Nature of the Residue of [14C]XDE-570 in Laying Hens DowElanco, Indianapolis, USA and ABC Laboratories Inc, Columbia, USA MET94018, December 1994b Dow AgroSciences Report No. GH-C 3481 GLP: Y Published: N	Y	Dow AgroSciences
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.	N	European Union 2,4-D Task Force

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	Submitter or source
			20074502/PL1-FPWW GLP: Y Published: N		2012
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	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	Submitter or source
			Published: N		
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	Pronier I.	2011	Residues of Fluroxypyr and Florasulam in spring and winter cereals (wheat and barley) at harvest and at intervals following a single application of EF-1512 and EF-1343 mixture. Northern and Southern zone – 2010. Dow AgroSciences, European Development Centre Report Number: GHE-P-12647/14SRX10R05 (Accession Number) 2009991 GLP: Y Published: N	N	Dow AgroScience
KCA 6.3/11	Pronier I.	2010	Residues of Florasulam in Maize at Harvest and at Intervals Following a Single Application of EF-1343. Northern and Southern Europe - 2010 Dow AgroSciences, European Development Centre DAS Report No.: GHE-P-12800 (Accession Number) 2014676 GLP: Y Published: N	N	Dow AgroScience
KCA 6.3/12	Pronier I.	2012	Residues of Fluroxypyr and Florasulam in Spring and Winter Cereals (Wheat and Barley) at Harvest and Intervals Following a Single Application of EF-1512 and EF-1343 Mixture. Northern and Southeren Zone - 2011 Dow AgroSciences, European Development Centre	N	Dow AgroScience

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	Submitter or source
			DAS Report No.: GHE-P-12794 (Accession Number) 2013685		
KCA 6.3/13	Pronier I.	2012	Residues of Florasulam in maize at harvest and at intervals following a single application of EF-1343. Northern and Southern Europe – 2011. Dow AgroSciences, European Development Centre Report Number: GHE-P-12645/14SRX10R03 GLP: Y Published: N	N	Dow AgroScience
KCA 6.6.1/01	MacDonald A.M.G.	1997	Florasulam. The Uptake of XDE-570 into Four Succeeding Crops DowElanco Europe, Letcombe Regis, Oxon, UK 7U, December 1997 Dow AgroSciences Report No. GHE-P-4889 GLP: Y Published: N	N	Dow AgroSciences

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

No new study has been submitted.

A 2.1.1.1.2 Storage stability of residues in animal products

No new study has been submitted.

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

No new study has been submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new study has been submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new study has been submitted.

A 2.1.2.2 Nature of residues in livestock

No new study has been submitted.

A 2.1.3 Magnitude of residues in plants

No new study has been submitted.

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new study has been submitted.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

No new study has been submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new study has been submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new study has been submitted.

A 2.1.7 Other/Special Studies

No other study has been submitted.

A 2.2 Florasulam

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

No new study has been submitted.

A 2.2.1.1.2 Storage stability of residues in animal products

No new study has been submitted.

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

No new study has been submitted.

A 2.2.2.1.2 Nature of residue in rotational crops

No new study has been submitted.

A 2.2.2.1.3 Nature of residues in processed commodities

No new study has been submitted.

A 2.2.2.2 Nature of residues in livestock

No new study has been submitted.

A 2.2.3 Magnitude of residues in plants

No new study has been submitted.

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new study has been submitted.

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

No new study has been submitted.

A 2.2.5.2 Processing studies on a core set of representative processes

No new study has been submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new study has been submitted.

A 2.2.7 Other/Special Studies

No other study has been submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations – 2,4-D

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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	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)
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 liver	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.

A 3.2 IEDI calculations – 2,4-D

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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 and k	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.

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

Acute risk assessment /children — Details - acute risk assessment /children

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

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

Show results 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)
44%	Oranges	1 / 1	133	10%	Oranges	1 / 1	31
26%	Grapefruits	1 / 1	79	7%	Bovine: Liver	5 / 5	20
20%	Mandarins	1 / 1	59	6%	Mandarins	1 / 1	18
13%	Bovine: Liver	5 / 5	40	6%	Grapefruits	1 / 1	18
12%	Bovine: Edible offals (other	5 / 5	36	6%	Wheat	2 / 2	17
11%	Lemons	1 / 1	34	6%	Bovine: Edible offals (other	5 / 5	17
10%	Potatoes	0,2 / 0,2	31	5%	Swine: Other products	5 / 5	16
10%	Wheat	2 / 2	29	5%	Sheep: Liver	5 / 5	14
7%	Limes	1 / 1	20	4%	Swine: Edible offals (other	5 / 5	13
6%	Bovine: Kidney	5 / 5	19	4%	Swine: Kidney	5 / 5	11
5%	Swine: Edible offals (other	5 / 5	15	4%	Bovine: Kidney	5 / 5	11
4%	Rye	2 / 2	13	3%	Bovine: Other products	5 / 5	10,0
3%	Melons	0,05 / 0,05	7,6	3%	Rye	2 / 2	9,7
2%	Table grapes	0,1 / 0,1	7,3	3%	Lemons	1 / 1	9,0
2%	Pears	0,05 / 0,05	6,9	2%	Swine: Liver	5 / 5	7,1
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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Oranges / juice	1 / 1	53
8%	Wheat / milling (flour)	2 / 2	24
6%	Potatoes / fried	0,2 / 0,2	19
4%	Potatoes / dried (flakes)	0,2 / 0,92	12
4%	Wheat / milling (wholemeal)-l	2 / 2	11
2%	Rye / boiled	2 / 2	7,3
2%	Rye / milling (wholemeal)-bal	2 / 2	7,0
2%	Sugar beets (root) / sugar	0,05 / 0,6	5,5
1%	Pumpkins / boiled	0,05 / 0,05	4,4
1%	Witloofs / boiled	0,05 / 0,05	4,4
1%	Wine grapes / juice	0,1 / 0,1	4,4
1%	Broccoli / boiled	0,05 / 0,05	3,9
1%	Cauliflowers / boiled	0,05 / 0,05	3,5
1%	Escaroles/broad-leaved endi	0,05 / 0,05	3,3
1%	Lemons / jam	1 / 1	3,0

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Oranges / juice	1 / 1	15
4%	Grapefruits / juice	1 / 1	11
3%	Wheat / bread/pizza	2 / 2	8,8
3%	Wheat / pasta	2 / 2	7,6
2%	Wheat / bread (wholemeal)	2 / 2	7,0
0,9%	Pumpkins / boiled	0,05 / 0,05	2,8
0,7%	Sugar beets (root) / sugar	0,05 / 0,6	2,2
0,7%	Cauliflowers / boiled	0,05 / 0,05	2,1
0,7%	Wine grapes / juice	0,1 / 0,1	2,1
0,6%	Beetroots / boiled	0,05 / 0,05	1,9
0,6%	Lemons / juice	1 / 1	1,9
0,6%	Potatoes / chips	0,2 / 0,2	1,7
0,6%	Celeries / boiled	0,05 / 0,05	1,7
0,6%	Apples / juice	0,05 / 0,05	1,7
0,4%	Currants (red, black and	0,1 / 0,1	1,3

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 – florasulam

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

florasulam

LOQs (mg/kg) range from:	0,01	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,05	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2015	Year of evaluation:	2015

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	NL toddler	1,24	1%	Milk: Cattle	0,2%	Apples	0,1%	Maize/corn	2%	
1%	NL child	0,66	0,5%	Milk: Cattle	0,2%	Sugar beet roots	0,1%	Apples	1%	
1%	DE child	0,64	0,4%	Milk: Cattle	0,2%	Apples	0,1%	Wheat	1%	
1%	UK infant	0,61	0,8%	Milk: Cattle	0,1%	Potatoes	0,1%	Wheat	1%	
1%	FR toddler 2 3 yr	0,56	0,6%	Milk: Cattle	0,1%	Apples	0,1%	Wheat	1%	
1%	FR child 3 15 yr	0,55	0,5%	Milk: Cattle	0,1%	Wheat	0,1%	Sugar beet roots	1%	
0,9%	UK toddler	0,45	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,9%	
0,8%	GEMS/Food G11	0,42	0,2%	Milk: Cattle	0,1%	Potatoes	0,1%	Soyabeans	0,8%	
0,8%	DK child	0,41	0,3%	Milk: Cattle	0,1%	Rye	0,1%	Wheat	0,8%	
0,8%	GEMS/Food G07	0,38	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,8%	
0,8%	GEMS/Food G06	0,38	0,1%	Wheat	0,1%	Tomatoes	0,0%	Milk: Cattle	0,8%	
0,8%	GEMS/Food G15	0,38	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,8%	
0,8%	GEMS/Food G08	0,38	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,8%	
0,8%	RO general	0,38	0,2%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,8%	
0,8%	ES child	0,38	0,2%	Milk: Cattle	0,1%	Wheat	0,1%	Cocoa beans	0,8%	
0,7%	SE general	0,37	0,2%	Milk: Cattle	0,1%	Bovine: Muscle/meat	0,1%	Potatoes	0,7%	
0,7%	DE women 14-50 yr	0,37	0,2%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Apples	0,7%	
0,7%	GEMS/Food G10	0,37	0,1%	Milk: Cattle	0,1%	Wheat	0,1%	Soyabeans	0,7%	
0,7%	DE general	0,36	0,2%	Milk: Cattle	0,1%	Sugar beet roots	0,0%	Apples	0,7%	
0,7%	FI adult	0,35	0,6%	Coffee beans	0,0%	Potatoes	0,0%	Rye	0,7%	
0,7%	IE adult	0,33	0,1%	Milk: Cattle	0,1%	Sweet potatoes	0,0%	Wheat	0,7%	
0,6%	NL general	0,30	0,2%	Milk: Cattle	0,1%	Sugar beet roots	0,0%	Potatoes	0,6%	
0,6%	FR infant	0,29	0,3%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples	0,6%	
0,4%	FR adult	0,22	0,1%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat	0,4%	
0,4%	PT general	0,21	0,1%	Potatoes	0,1%	Wheat	0,0%	Wine grapes	0,4%	
0,4%	ES adult	0,21	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Oranges	0,4%	
0,4%	FI 3 yr	0,18	0,1%	Potatoes	0,0%	Bananas	0,0%	Wheat	0,4%	
0,3%	IT toddler	0,16	0,1%	Wheat	0,0%	Other cereals	0,0%	Tomatoes	0,3%	
0,3%	DK adult	0,16	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat	0,3%	
0,3%	LT adult	0,16	0,1%	Milk: Cattle	0,1%	Potatoes	0,0%	Apples	0,3%	
0,3%	UK vegetarian	0,15	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,3%	
0,3%	FI 6 yr	0,14	0,1%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat	0,3%	
0,3%	UK adult	0,14	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,3%	
0,2%	IT adult	0,12	0,1%	Wheat	0,0%	Tomatoes	0,0%	Apples	0,2%	
0,2%	PL general	0,10	0,1%	Potatoes	0,0%	Apples	0,0%	Tomatoes	0,2%	
0,2%	IE child	0,08	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes	0,2%	

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

A 3.6 IEDI calculations – florasulam

Not necessary. TMDI < 100%.

A 3.7 IESTI calculations - Processed commodities – florasulam

Not relevant. ARfD was not deemed necessary.

A 3.8 IESTI calculations - Processed commodities – florasulam

Not relevant. ARfD was not deemed necessary.

Appendix 4 Additional information provided by the applicant

Not relevant.