

# REGISTRATION REPORT

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

Detailed summary of the risk assessment

Product code: FLORAS 50 SC

Product name(s): Floras 50 SC, HerbiFlo 50 SC

Chemical active substance:

Florasulam, 50 g/L

Central

Zonal Rapporteur Member State: POLAND

#### **CORE ASSESSMENT**

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 30/11/2023, updated April 2024

MS Finalisation date: April 2024 (initial Core Assessment)

June 2024 (final Core Assessment)

### Version history

When	What
November 2023	Initial dRR – Elvita Sp. z o.o.
April 2024	Applicants' update.
April 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck-through</del> and <b>shaded</b> for transparency.
June 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

The plant protection product Floras 50 SC, registered only in Poland, contains active substance:

- Florasulam (CAS number: 145701-23-1), for which after the renewal of the approval (01/01/2016), the data protection period in Poland expired on 02/28/2020, on the basis of renewal of certain authorisation of plant protection products registered in Poland.

#### Florasulam

##### 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

Cereals:

Proposed GAPs:

1 x 5 g as/ha, BBCH 12-32, 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.

##### Magnitude of residues in livestock

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

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

As quantifiable residues of 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

Evaluator's calculations (EFSA PRIMo rev.3.1)

Input values:

All MRLs of plant and animal commodities (Reg. (EU) 2022/1363 ~~Reg. (EU) No 1317/2013~~).

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

### 7.1.1 Critical GAP(s) and overall conclusion

#### **Selection of critical uses and justification**

The critical GAPs with respect to consumer intake and risk assessment for the preparation Floras 50 SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for Cereals. A list of all intended uses within the Central zone is given in Part B, Section 0.

#### **Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRL regarding intended uses for active substances as laid down in ~~Reg. (EU) 1317/2013~~ Reg. (EU) 2022/1363 is not expected.

The chronic and the short-term intakes of active substances residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

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

#### **Data gaps**

According to the EFSA Journal 2015; 13(1):3984 noticed data gaps are:

- Data and/or information addressing the toxicity of the major plant metabolite 4-OH-florasulam and the potential exposure of livestock and subsequently the consumer through animal commodities to metabolite 4-OH-florasulam,
- Rotational crop data considering the crop groups and plant back intervals as required by current guidance.

It should be highlighted that these data gaps have not been considered here and will be addressed at the next renewal of the active substance.

**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	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Winter wheat	F	<i>Anthemis arvensis, Brachiaria nana, Brassica napus, Capsella bursa-pastoris, Descurainia sophia, Fallopia convolvulus, Galium aparine, Tripleurospermum inodorum, Myosotis arvensis, Papaver rhoeas, Fallopia convolvulus, Sinapis arvensis, Stellaria media, Thlaspi arvense, Veronica persica.</i>	Foliar spraying; small drops	BBCH 12-32	1	-	a) 0.1	Florasulam: 5.0	200- 400	-	Herbicide for use with field sprayers	A
2	Poland	Spring barley	F	<i>Anthemis arvensis, Amaranthus retroflexus, Brassica napus, Capsella bursa-pastoris, Chenopodium album, Descurainia sophia, Fallopia convolvulus, Galeopsis tetrahit, Galium aparine, Galinsoga parviflora, Tripleurospermum inodorum, Silene latifolia subsp. Alba, Myosotis arvensis, Polygonum aviculare, Fallopia convolvulus, Persicaria maculosa, Sinapis arvensis, Stellaria media, Thlaspi arvense, Veronica persica.</i>	Foliar spraying; small drops	BBCH 12-32	1	-	a) 0.1	Florasulam: 5.0	200- 400	-	Herbicide for use with field sprayers	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

Floras 50 SC is composed of one active substance – Florasulam.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of active substances**

Reference value	Source	Year	Value	Study relied upon	Safety factor
Florasulam					
ADI	EFSA	2015	0.05 mg/kg/day	1-year dog	100
ARfD	Not necessary				

### 7.1.2.1 Summary for active substances

**Table 7.1-3: 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	Winter wheat	Yes	Yes	Yes	Yes	Yes	No	No
2	Spring Barley	Yes	Yes	Yes	Yes	Yes	No	No

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

### 7.1.2.2 Summary for Floras 50 SC

**Table 7.1-4: Information on Floras 50 SC (KCA 6.8)**

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		Florasulam		
Winter wheat	n/a	Yes	F	-
Spring Barley	n/a	Yes	F	-

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

**Table 7.1-5: Waiting periods before planting succeeding crops**

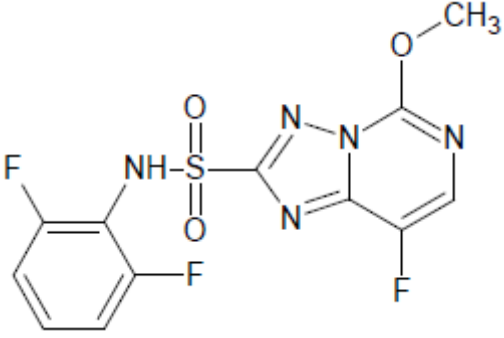
No waiting period is required.



## 7.2 Active substances

General data on active substance are summarized in the tables below.

**Table 7.2-1: 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 <sub>12</sub> H <sub>8</sub> O <sub>3</sub> N <sub>5</sub> F <sub>3</sub> S
Molar mass	359.3 g/mol
Mode of action (if available)	Florasulam blocks the action of the enzyme - acetolactate synthetase (ALS), which is involved in the biosynthesis of amino acids, which causes as a consequence, inhibition of weed growth and development. It is picked up by weed leaves and then quickly moved in the plant, stopping weed growth and development.
Systemic	Yes
Company (ies)	Dow AgroSciences*
Rapporteur Member State (RMS)	Poland
Approval status	Approved Date: 01.01.2016 Commission Directive (EU) 2015/1397
Restriction	Only uses as herbicide may be authorised.
Review Report	<del>SANCO/4406/2001</del> SANTE/10542/2015 Rev 1, 14 July 2015
Current MRL regulation	REGULATION (EU) No <del>1317/2013</del> 2022/1363
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, 2015)**
EFSA Journal: conclusion on article 12	Yes (EFSA, <del>2015</del> 2012) **
Current MRL applications on intended uses	EFSA Journal 2015; 13(1):3984

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

\*\* If yes: EFSA, YYYY - see list of references

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

The stability of residues for the active substance Florasulam was reviewed during the Annex I inclusion process (Monograph, November 1999) and no further data is required. Freezer storage stability of Florasulam was demonstrated in cereal (plant, grain and straw) for a period of 18 to 23 months.

Freezer storage stability study indicated that residues of Florasulam are stable for up to 18.7 months in wheat forage, wheat grain and wheat straw (EFSA Journal 2015; 13(1):3984). The Article 12 review of the existing MRLs for Florasulam stated that Florasulam was stable in cereal grain, cereal straw and immature cereal plant during storage at -18°C to -25°C for a period of 18 to 23 months.

**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
<b>Data relied on in EU</b>			
<b>Plant products</b>			
Cereal, grain	High starch content	<del>18-23</del> 18.7 months	EFSA Journal 2015
Cereal, immature plant	High water content	<del>18-23</del> 18.7 months	EFSA Journal 2015
Cereal, straw	Dry content	<del>18-23</del> 18.7 months	EFSA Journal 2015
<b>Animal Products</b>			
Not required, no residues expected in animal products			

#### zRMS comments:

The stability of residues for the active substance florasulam were reviewed at the EU level. According to the EFSA Journal 2015; 13(1):3984 – “Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam”: *Florasulam residues stable in wheat matrices (whole plant, straw and grain) for a period of at least 562 days (18.7 months).* These data are sufficient to support the residue trials on cereals. No additional data are required.

### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No new residue trials have been performed.

#### zRMS comments:

In residues studies for florasulam, batch recoveries were carried out in parallel with the analytical batches for the crop residue studies and acceptable recoveries were achieved, indicating acceptable stability of residue in extracts. No additional data are required.

## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

No new data submitted in the framework of this application.

**Table 7.2-3: Summary of plant metabolism studies**

Table 7/2-3: Summary of plant metabolism studies								
Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Winter wheat	[ <sup>14</sup> C-phenyl]-florasulam and [ <sup>14</sup> C-triazolpyrimidine]-florasulam.	Foliar treatment, F	50 g a.s./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)	EFSA Journal 2015
						Immature plants: 0,30 DAT Crop maturity straw, grain and shaff): 129 DAT	Application at BBCH 30 (stem elongation-early application)	

**zRMS comments:**

The metabolism of florasulam in wheat (cereals) after foliar application of [<sup>14</sup>C-phenyl]-florasulam and [<sup>14</sup>C-triazolopyrimidine]-florasulam at a rate of 50 g a.s./ha was evaluated in the RAR. The data are sufficient to support the intended uses of FLORAS 50 SC on cereals. No further data are required.

According to the EFSA Journal 2015; 13(1):3984: „*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*”.

The residue definition for plant for monitoring: Florasulam (EFSA, 2015, Reg. (EU) 2022/1363)

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

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

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 and reviewed during the Annex I inclusion (Belgium 1999) and renewal process (Poland, 2013). Trials on rotational crops have indicated that a waiting period between the last application and sowing or planting a succeeding crop of 30 days will not lead to significant residues of Florasulam.

According to the EFSA Journal 2015; 13(1):3984:

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.

A PBI of 365 d was not addressed and persistent soil metabolites have not been analysed (data gap).

However for the time being EFSA stated in its conclusion on the peer review of the active substance that there is no risk for the consumer, resulting from the additional uptake of Florasulam derived residues by plants from the soil as the safety margin is big.

**Table 7.2-3: Summary of metabolism studies in rotational crops**

Table 7/2-3: 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	[ <sup>14</sup> C-phenyl]-florasulam and [ <sup>14</sup> C-triazolpyrimidine]-florasulam.	Not reported	0.0075	30	195	-	EFSA Journal 2015
Root and tuber vegetables	Carrot					156	-	
Pulses and oilseeds	Sunflower					168	-	
Cereals	Spring wheat					168	-	

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

**zRMS comments:**

The data summarised in EFSA Journal 2015;13(1):3984 and presented by Applicant above are sufficient and acceptable. As the application rate in the metabolism study was 7.5 g as/ha it can be concluded that quantifiable florasulam residues (above 0.01 mg/kg) in rotational crops at harvest are not expected when used at the proposed rate of 5 g florasulam/ha and the intake of florasulam has been sufficiently addressed. A specific residue definition for rotational crops is not deemed necessary due to the very low residue levels expected.

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

During the Annex I inclusion process it was concluded that as quantifiable residues of florasulam are not expected in cereal grains, there is no need to investigate the effect of industrial and/or household processing.

**Table 7.2 5: Nature of the residues in processed commodities.**

No new data submitted in the framework of this application.

**zRMS comments:**

The nature of residues in processed commodities was not considered in the RAR as levels in the RAC were <0.01 mg/kg. No further studies are required to support the proposed uses.

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

No new data submitted in the framework of this application.

**Table 7.2-6: Summary of the nature of residues in commodities of plant origin.**

<b>Endpoints</b>	
Plant groups covered	Cereals
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 applicable
Plant residue definition for monitoring	Florasulam (EFSA, 2015; Reg. (EU) 2022/1363)
Plant residue definition for risk assessment	Florasulam (EFSA, 2015) Florasulam and provisionally 4-OH-phenyl-florasulam (data gap) (EFSA, 2015)
Conversion factor from enforcement to RA	Not applicable

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

No new data submitted in the framework of this application.

**Table 7.2-4: Summary of animal metabolism studies**

Table 7.2-4: Summary of animal metabolism studies								
Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[ <sup>14</sup> C-phenyl]-florasulam	1	0.11-0.22 *	5	Milk	twice daily	EFSA Journal 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	
		[ <sup>14</sup> C-triazolpyrimidine]-florasulam.	1	0.11-0.22 *	5	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[ <sup>14</sup> C-phenyl]-florasulam	10	5.79 **	5	Eggs	daily	EFSA Journal 2015
						Excreta		
						Tissues	at sacrifice	
		[ <sup>14</sup> C-triazolpyrimidine]-florasulam.	10	5.79 **	5	Eggs	daily	
						Excreta		
						Tissues	at sacrifice	
* considering a weight of 50-90 kg for a goat, the rate is comprised between 0.11 and 0.22 mg/kg bw/d for the administered dose of 11 mg/animal/day								
** considering a weight of 1.9 kg for a hen, the rate is approximately 5.79 mg/kg bw/d for the administered dose of 11 mg/animal/day								

### zRMS comments:

The livestock metabolism of florasulam was studied in lactating goats and laying hens. The livestock metabolism for the crop under consideration (cereals) is considered to be sufficiently covered by EU data and therefore no additional data are required.

EFSA concluded in EFSA Journal 2015;13(1):3984 that “*The finalisation of the livestock residue definition for risk assessment is pending with regard of further evidence to occurrence, behaviour and/or toxicity of 4-OH-phenyl-florasulam. For monitoring, parent florasulam alone might be sufficient for inclusion in the residue definition for enforcement/MRL setting*”.

The residue definition for animals for monitoring: Florasulam (EFSA, 2015, Reg. (EU) 2022/1363)

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

EFSA (2015): “*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.*”

Therefore, no further consideration is required with regard to the change in the residue definitions for risk assessment.

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

**Table 7.2-5: 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	3 days in milk
	6 days in eggs
Animal residue definition for monitoring	Florasulam (EFSA, 2015; Reg. (EU) 2022/1363)
Animal residue definition for risk assessment	Florasulam pending assessment with regard to 4-OH-phenyl-florasulam (EFSA, 2015)
Conversion factor	1 for milk, liver, kidney and eggs (EFSA, 2015)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

### 7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

**Table 7.2-9: Summary of EU reported and new data supporting the intended uses of Floras 50 SC (Florasulam) 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) and rye, oats and triticale	RMS, 2010, 2011 EFSA, 2010, 2011	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 6,25 kg as/ha, BBCH 45, PHI N/A	N/A				
	Overall supporting data for cGAP	N-EU	17 x <0.01* (see DAR) 12 x <0.01* (new field studies assessed during re-evaluation)	0.01*	-	-	0.01*	Yes
Cereals – grain (barley and wheat) and rye, oats and triticale	RMS, 2010, 2011 EFSA, 2010, 2011	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 6,25 kg as/ha, BBCH 45, PHI N/A	N/A				
	Overall supporting data for cGAP	S-EU	11 x <0.01* (see DAR) 12 x <0.01* (new field studies assessed during re-evaluation)	0.01*	-	-	0.01*	Yes
Cereals – straw (barley and wheat) and rye, oats and triticale	RMS, 2010, 2011 EFSA, 2010, 2011	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 6,25 kg as/ha, BBCH 45, PHI N/A	N/A				
	Overall supporting data for cGAP	N-EU	17 x <0.05* (see DAR) 12 x <0.01* (new field studies assessed during re-evaluation)	0.05* 0.01*	-	-	0.01*	Yes
Cereals – straw (barley and wheat) and rye, oats and triticale	RMS, 2010, 2011 EFSA, 2010, 2011	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 6,25 kg as/ha, BBCH 45, PHI N/A	N/A				
	Overall supporting data for cGAP	S-EU	11 x <0.05* (see DAR) 12 x <0.01* (new field studies assessed during re-evaluation)	0.05* 0.01*	-	-	0.01*	Yes

\*) – LOQ, Regulation (EU) No 1317/2013 Reg. (EU) 2022/1363

Renewal Assessment Report on the active substance Florasulam prepared by the rapporteur Member State Poland in the framework of Regulation (EC) No 1107/2009, November 2013.

EFSA Journal 2012;10(3): 2626

EFSA Journal 2015; 13(1):3984

### 7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on primary uses winter and spring cereals are considered acceptable, for both outdoor uses.

Reports concerning magnitude of residues in plants derived from supervised trials for Florasulam:

**Report:** 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. I. Pronier, 2011, Report Number: GHE-P-12647/14SRX10R05.

Guidelines: Commission Working Documents 7029/VI/95 rev. 5 and 7035/VI/95 rev. 5.

EF-1512 is an EC formulation that contains fluroxypyr 200 g a.s./L. EF-1343 is a SC formulation that contains Florasulam 50 g as/L.

Eight trials were conducted in 2010, four in Northern EU zone (1 in Northern France, 1 in UK, 1 in Germany, 1 in Hungary) and four in Southern EU zone (1 in Southern France, 1 in Spain, 2 in Greece).

For Northern zone trials, a single application of a tank mix of the formulated products EF-1512 (containing nominal concentration of fluroxypyr 200 g a.e./L) and EF-1343 (containing nominal concentration of Florasulam at 50 g a.s./L) was applied at a rate of 200 g a.e./ha of fluroxypyr + 6.25 g a.s./ha of Florasulam at BBCH 32, BBCH 39 or at BBCH 45.

For southern zone trials, a single application of a tank mix of the formulated products EF-1512 (containing nominal concentration of fluroxypyr 200 g a.e./L) and EF-1343 (containing nominal concentration of Florasulam at 50 g a.s./L) was applied at a rate of 200 g a.e./ha of fluroxypyr + 6.25 g a.s./ha of Florasulam at maximum BBCH 45, approximately 60 days before harvest.

Specimens of whole plants were collected at 0, 7, 14 and 28 days after application for decline trials only; grain and straw were collected at harvest in all trials.

The specimens were placed in freezers within 8 hours of sampling and transported frozen to PTRL. Specimens were stored at PTRL in a freezer set to maintain a sample temperature < - 18°C.

Residues of Florasulam were determined by adapting Dow AgroSciences analytical method GRM 04.13 (LC MS/MS method), with the limit of quantification of 0.01 mg/kg and the limit of detection: 0.002 mg/kg.

No Florasulam (>0.01 mg/kg LOQ) was present in any of the analyzed untreated field specimens.

**Report:** 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 – 2011. I. Pronier, 2012, Report Number: GHE-P-12794.

Guidelines: Commission Working Documents 7029/VI/95 rev. 5 and 7035/VI/95 rev. 5

EF-1512 is an EC formulation that contains fluroxypyr 200 g as/L. EF-1343 is a SC formulation that contains Florasulam 50 g as/L.

Sixteen trials were conducted in 2011, eight in Northern EU zone (2 in Northern France, 2 in UK, 2 in Germany, 2 in Hungary) and eight in Southern EU zone (2 in Southern France, 2 in Spain, 4 in Greece).

For Northern zone trials, a single application of a tank mix of the formulated products EF-1512 (containing nominal concentration of fluroxypyr 200 g a.e./L) and EF-1343 (containing nominal concentration of Florasulam at 50 g a.s./L) was applied at a rate of 200 g a.e./ha of fluroxypyr + 6.25 g a.s./ha of Florasulam at BBCH 32 (plot 2), BBCH 39 (plot 3) or at BBCH 45 (plot 4).

For Southern zone trials, a single application of a tank mix of the formulated products EF-1512 (containing nominal concentration of fluroxypyr 200 g a.e./L) and EF-1343 (containing nominal concentration of Florasulam at 50 g a.s./L) was applied at a rate of 200 g a.e./ha of fluroxypyr + 6.25 g a.s. /ha of Florasulam at maximum BBCH 45, approximately 60 days before harvest.



Specimens of whole plants were collected at 0, 7, 14 and 28 days after application for decline trials only; grain and straw were collected at harvest in all trials.

The specimens were placed in freezers within 8 hours of sampling and transported frozen to PTRL. Specimens were stored at PTRL in a freezer set to maintain a sample temperature < - 18°C.

Residues of Florasulam were determined by adapting Dow AgroSciences analytical method GRM 04.13 (LC MS/MS method), with the limit of quantification of 0.01 mg/kg and the limit of detection: 0.002 mg/kg.

No Florasulam (>0.01 mg/kg LOQ) was present in any of the analyzed untreated field specimens.

**zRMS comments:**

The proposed uses for Floras 50 SC (central zone) are winter wheat and spring barley.

Wheat and barley are the major crops in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANTE/2019/12752).

For florasulam, 17 trials in cereals grain and straw (barley and wheat) in NEU were evaluated in the DAR and 12 new field studies in cereals grain and straw (barley and wheat) in NEU were assessed during re-evaluation.

The presented residue trials assessed during re-evaluation have been performed at maximum application rate of 6.58 g florasulam/ha. It cover the intended application rate (5 g florasulam/ha). The application in the residues trials was done up to BBCH 47 (intended: BBCH 12 – 32, PHI – not applicable) and thus cover the intended uses.

The residues of florasulam in cereals grain were <0.01 mg/kg in all trials (DAR and new field studies assessed during re-evaluation).

The residues of florasulam in cereals straw were <0.05 mg/kg (DAR) and <0.01 mg/kg in all trials (new field studies assessed during re-evaluation).

The value of EU MRL for florasulam on cereals equals 0.01 mg/kg (Reg. (EU) 2022/1363). The residues arising from the proposed uses will not exceed the MRL established for cereals.

The current EU MRLs for florasulam are sufficient to support the proposed uses.

It should be noted that considering the low levels of florasulam detected in cereal grain, no residues of the plant metabolite 4-OH-phenyl-florasulam are expected to be present in the edible portion of the crop following the uses proposed for Floras 50 SC.

Additional studies are not required to support the proposed uses of Floras 50 SC.

## 7.2.4 Residues in livestock

### 7.2.4.1 Livestock feeding studies (KCA 6.4.1-6.4.3)

**Available data**

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

**Table 7.2-6: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Florasulam				
Grass (fresh)	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)
Grass silage	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Grass hay	0.20	Median residue x 4 (EFSA, 2012)	0.20	Median residue x 4 (EFSA, 2012)
Wheat grain	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Barley grain	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Rye grain	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Oat grain	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Maize grain	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Wheat bran	0.08	Median residue x 8 (EFSA, 2012)	0.08	Median residue x 8 (EFSA, 2012)
Rye bran	0.08	Median residue x 8 (EFSA, 2012)	0.08	Median residue x 8 (EFSA, 2012)
Wheat straw	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)
Barley straw	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)
Rye straw	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)
Oat straw	0.05	Median residue (EFSA, 2012)	0.05	Highest residue (EFSA, 2012)

**Table 7.2-7: Results of the dietary burden calculation**

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Florasulam					
Beef cattle*	0.009	0.009	Grass (fresh)	0.253	Y
Dairy cattle*	0.011	0.011	Grass (fresh)	0.249	Y
Finishing swine*	0.001	0.001	Wheat bran	0.014	N
Layer poultry*	0.002	0.002	Grass silage	0.056	N

\* These categories correspond to those (formerly) assessed at EU level.

### 7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

**Table 7.2-12: Overview of the values derived from livestock feeding studies.**  
Feeding study not required.

#### **zRMS comments:**

The supervised residue trials demonstrated that residues of florasulam in cereal grain and straw were less than the

LOQ of the analytical method (< 0.01 mg/kg) and therefore the intake of florasulam residues by livestock from cereals will be substantially below 0.1 mg/kg in the diet. The critical GAP for Floras 50 SC involves application of florasulam at a maximum rate (5 g as/ha) less critical than the GAP used supported during active substance renewal (6.25 g as/ha for spring applications). Therefore, the proposed GAP for Floras 50 SC will not lead to a significant intake of florasulam by livestock above 0.1 mg/kg feed and livestock feeding studies are not required.

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

As quantifiable residues of florasulam are not expected in cereal grains there is no requirement to investigate the effect of industrial and/or household processing.

### **7.2.5.1 Available data for all crops under consideration**

~~Table 7.2-13: Overview of the available processing studies.~~

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

### **7.2.5.2 Conclusion on processing studies**

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substances:

- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.
- Not submitted and not requested data for active substance.

#### **zRMS comments:**

Processing studies are not required for wheat (grain) or barley (grain) as the residues in the crops from the field trials were <0.1 mg/kg.

No further studies are required to support the proposed uses.

## **7.2.6 Magnitude of residues in representative succeeding crops**

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

### **7.2.6.1 Field rotational crop studies (KCA 6.6.2)**

~~Table 7.2-14: Summary of available studies in field rotational crops.~~

No new data submitted in the framework of this application.

#### **zRMS comments:**

The data summarised in EFSA 2015 are sufficient to describe the potential for residues of florasulam in succeeding crops based on the proposed GAP for Floras 50 SC.

Trials on rotational crops have indicated that a waiting period between the last application and sowing or planting a succeeding crop of 30 days will not lead to significant residues of florasulam.

According to the EFSA Journal 2015; 13(1):3984:

*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.*

*A PBI of 365 d was not addressed and persistent soil metabolites have not been analysed (data gap).*

However for the time being EFSA stated in its conclusion on the peer review of the active substance that there is no risk for the consumer, resulting from the additional uptake of florasulam derived residues by plants from the soil as the safety margin is big.

No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

## 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 Floras 50 SC. Therefore, other special studies are not needed.

### zRMS comments:

According to SANTE/11956/2016 rev. 9, 14 September 2018 wheat and barley are not considered melliferous crops. Therefore, residues in honey are not expected from the use of Floras 50 SC under consideration. No additional data are required.

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

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

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

### 7.2.8.1 Input values for the consumer risk assessment

**Table 7.2-15: Input values for the consumer risk assessment.**

Table 7.2-13: Input values for the consumer risk assessment.		
Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Florasulam		
Plant product Cereal grain	0.01*	EU MRL
Products of animal origin— terrestrial animals Tissue, milk, birds eggs	0.01*	EU MRL
		EU MRL
*—LOQ		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Florasulam*				
Fruits, fresh or frozen; tree nuts (0100000)	0.01	EU MRL (Reg. (EU) 2022/1363)	-	ARfD not set for florasulam
Root and tuber vegetables (0210000)	0.01			
Bulb vegetables (0220000)	0.01			
Fruiting vegetables (0230000)	0.01			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Brassica vegetables (excluding brassica roots and brassica baby leaf crops) (0240000)	0.01			
Lettuces and salad plants (0251000)	0.01			
Spinaches and similar leaves (0252000)	0.01			
Grape leaves and similar species (0253000)	0.01			
Watercresses (0254000)	0.01			
Witloofs/Belgian endives (0255000)	0.01			
Herbs and edible flowers (0256000)	0.02			
Legume vegetables (0260000)	0.01			
Stem vegetables (0270000)	0.01			
Fungi, mosses and lichens (0280000)	0.01			
Algae and prokaryotes organisms (0290000)	0.01			
Pulses (0300000)	0.01			
Oilseeds and oil fruits (0400000)	0.01			
Cereals (0500000)	0.01			
Tea, coffee, herbal infusions, cocoa and carobs (0600000)	0.05			
Hops (0700000)	0.05			
Spices (0800000)	0.05			
Sugar plants (0900000)	0.01			
Tissues from swine (1011000)	0.01			
Tissues from bovine (1012000)	0.01			
Tissues from sheep (1013000)	0.01			
Tissues from goat (1014000)	0.01			
Tissues from equine (1015000)	0.01			
Tissues from poultry (1016000)	0.01			
Tissues from other farmed terrestrial animals (1017000)	0.01			
Milk (1020000)	0.01			
Birds eggs (1030000)	0.01			
Honey and other apiculture products (1040000)	0.05			
Amphibians and Reptiles (1050000)	0.01			
Terrestrial invertebrate animals (1060000)	0.01			
Wild terrestrial vertebrate animals	0.01			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
(1070000)				

\* EFSA Journal 2015;13(1): 3984 proposes a plant residue definition for risk assessment as florasulam and provisionally 4-OH-phenyl-florasulam and the animal residue definition for risk assessment as florasulam pending assessment with regard to 4-OH-phenyl-florasulam.

Inclusion of 4-OH- phenyl-florasulam in the residue definitions for risk assessment in plants and animals is being addressed in the active substance renewal process. This document for Floras 50 SC assumes that ultimately, the definition of residue for risk assessment in plants and animals will be florasulam only.

## 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-16: Consumer risk assessment.**

TMDI (% ADI) according to EFSA PRIMo Model rev. 3.1	0.9 % (NL child) Calculation of the TMDI resulting from Florasulam intake with cereals, animal tissue, milk and bird eggs Florasulam: 2% (based on NL toddler) highest contributor: milk cattle (1%)
IEDI (% ADI) according to EFSA PRIMo	Calculation of IEDI not required. TMDI <100% ADI for florasulam
IENTI (% ARfD) according to EFSA PRIMo*	Not relevant
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

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

\*\* if national model is available

### zRMS comments:

A consumer risk assessment was performed with revision 3.1 of EFSA Pesticide Residues Intake Model (PRIMo Rev. 3.1).

The Reg. (EU) 2022/1363 for florasulam is now in force.

The highest Theoretical Maximum Daily Intake (TMDI) is 2% of the ADI for the NL toddler. The highest contribution (1% of the ADI) is from milk cattle.

An assessment of acute dietary intake has not been made as florasulam is not acutely toxic and an ARfD has not been allocated.

The proposed uses of florasulam in the formulation Floras 50 SC do not represent unacceptable acute and chronic risks for the consumer.

## 7.3 References

Draft assessment report on the active substance Florasulam prepared by the rapporteur Member State Poland.

Commission Regulation (EU) No 1317/2013 of 16 December 2013 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-D, beflubutamid, cyclanilide, diniconazole, Florasulam, metolachlor and S-metolachlor, and milbemectin in or on certain products.

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

~~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), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam. EFSA Journal 2015; 13(1):3984, 138 pp. doi:10.2903/j.efsa.2015.3984.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CA 6.3.1	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 DAS Report No.: 14SRXIOR (Accession Number) 2009991 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
<del>CA 6.3.1</del>	<del>Pronier, I.</del>	<del>2011</del>	<del>Residues of Fluroxypyr and Florasulam in Grass at Intervals Following a Single Application of EF-1512 and EF-1343 Mixture of EF-1512. Northern and Southern Zone - 2010 Dow AgroSciences, European Development Centre DAS Report No.: GHE-P-12648 (Accession Number) 2010771 GLP/GEP (Y/N): Y Published (Y/N): N</del>	<del>N</del>	<del>DAS</del>
Additional study	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 DAS Report No.: GHE-P-12794 (Accession Number) 2013685 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
Additional study	Pronier, I.	2012	Residues of Fluoxypyr and Florasulam in Grass at Intervals Following Single Application of EF- 1512 and EF-1343 Mixture or EF-1512. Northern and Southern Zone - 2011 Dow AgroSciences, European Development Centre DAS Report No.: GHE-P-12797 (Accession Number) 2014658 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS



## **Appendix 2 Detailed evaluation of the additional studies relied upon**

### **A 2.1 Floras 50 SC**

No additional studies submitted.

#### **A 2.1.1 Stability of residues**

No study submitted by applicant.

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

##### **A 2.1.2.1 Nature of residue in plants**

No study submitted by applicant.

##### **A 2.1.2.2 Nature of residues in livestock**

No study submitted by applicant.

#### **A 2.1.3 Magnitude of residues in livestock**

No study submitted by applicant.

#### **A 2.1.4 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)**

No study submitted by applicant.

#### **A 2.1.5 Magnitude of residues in representative succeeding crops**

No study submitted by applicant.

#### **A 2.1.6 Other/Special Studies**

No additional studies.

## Input values for dietary risk assessment

Allow expand/collapse function (+)

#### Details - acute risk assessment/adults

Active substance:		<b>Florasulam</b>			
ADI (value, unit, source, year of assessment)		0.05	mg/kg bw per day	EFSA	2010
ARfD (value, unit, source, year of assessment)		no data available	mg/kg bw	EFSA	2010
Residue definition:	enforcement / plants (unprocessed)	Florasulam			
Residue definition:	enforcement / animals (unprocessed)	Florasulam			
Residue definition:	risk assessment / plants (unprocessed)	Florasulam			
Residue definition:	risk assessment / animals (unprocessed)	Florasulam			

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EFSA PRIMo revision 3.1; 2019/03/19

<h2 style="text-align: center;">Florasulam</h2>			
LOQs (mg/kg) range from:		0.1	to: 0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.05	ARID (mg/kg bw):	insert valid entry
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

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 : ---						Exposure resulting from		
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI calculation (based on average food consumption)	1%	GEMS/Food G06	0.73	1%	Wheat	0.0%	Barley				
	1%	IT toddler	0.67	1%	Wheat	0.0%	Barley				
	1%	GEMS/Food G15	0.53	0.9%	Wheat	0.2%	Barley				
	1%	RO general	0.51	1%	Wheat		FRUIT AND TREE NUTS				
	1.0%	GEMS/Food G08	0.50	0.8%	Wheat	0.2%	Barley				
	1.0%	GEMS/Food G07	0.48	0.8%	Wheat	0.1%	Barley				
	0.9%	FR child 3 15 yr	0.46	0.9%	Wheat	0.0%	Barley				
	0.9%	GEMS/Food G10	0.45	0.8%	Wheat	0.1%	Barley				
	0.9%	ES child	0.44	0.9%	Wheat	0.0%	Barley				
	0.9%	DK child	0.44	0.9%	Wheat		FRUIT AND TREE NUTS				
	0.9%	GEMS/Food G11	0.44	0.7%	Wheat	0.2%	Barley				
	0.8%	DE child	0.42	0.8%	Wheat	0.0%	Barley				
	0.8%	IT adult	0.41	0.8%	Wheat	0.0%	Barley				
	0.8%	NL child	0.41	0.8%	Wheat	0.0%	Barley				
	0.8%	NL toddler	0.41	0.8%	Wheat	0.0%	Barley				
	0.8%	PT general	0.39	0.8%	Wheat	0.0%	Barley				
	0.8%	UK toddler	0.39	0.8%	Wheat	0.0%	Barley				
	0.6%	SE general	0.32	0.6%	Wheat		FRUIT AND TREE NUTS				
	0.6%	FR toddler 2 3 yr	0.31	0.6%	Wheat	0.0%	Barley				
	0.6%	ES adult	0.28	0.5%	Wheat	0.1%	Barley				
	0.5%	UK infant	0.26	0.5%	Wheat		FRUIT AND TREE NUTS				
	0.5%	DE general	0.24	0.4%	Wheat	0.1%	Barley				
	0.5%	DE women 14-50 yr	0.23	0.4%	Wheat	0.0%	Barley				
	0.5%	IE adult	0.23	0.5%	Wheat	0.0%	Barley				
	0.4%	NL general	0.22	0.4%	Wheat	0.1%	Barley				
	0.4%	FR adult	0.22	0.4%	Wheat	0.0%	Barley				
	0.4%	UK vegetarian	0.21	0.4%	Wheat	0.0%	Barley				
	0.3%	UK adult	0.17	0.3%	Wheat	0.0%	Barley				
	0.3%	FI 3 yr	0.13	0.2%	Wheat	0.0%	Barley				
	0.2%	IE child	0.12	0.2%	Wheat	0.0%	Barley				
	0.2%	DK adult	0.11	0.2%	Wheat		FRUIT AND TREE NUTS				
	0.2%	LT adult	0.11	0.2%	Wheat	0.0%	Barley				
0.2%	FI 6 yr	0.10	0.2%	Wheat	0.0%	Barley					
0.2%	FR infant	0.08	0.2%	Wheat	0.0%	Barley					
0.1%	FI adult	0.03	0.1%	Wheat	0.0%	Barley					
	Column7				FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
<b>Conclusion:</b> 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.											

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARID. 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 No. of commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new):			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI		Commodities		Highest % of ARID/ADI		Commodities		Highest % of ARID/ADI		Commodities		Highest % of ARID/ADI		Commodities	
Expand/collapse list																
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)								
Processed commodities	Results for children No of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for children No of processed commodities for which ARID/ADI is exceeded (IESTI new):				Results for adults No of processed commodities for which ARID/ADI is exceeded (IESTI new):			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI		Processed commodities		Highest % of ARID/ADI		Processed commodities		Highest % of ARID/ADI		Processed commodities		Highest % of ARID/ADI		Processed commodities	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
	#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!		#ARG!	
Expand/collapse list																
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Florasulam is unlikely to present a public health risk. For processed commodities, no exceedance of the ARID/ADI was identified.																


<b>Florasulam</b>		Input values
		Go back to results - Overview
<b>Toxicological reference values</b>		Details - chronic risk assessment
ADI (mg/kg bw/day)	0.05	
Source of ADI	EFSA	
Year of evaluation	2010	
Comments		

Chronic risk assessment: Rees Day-model									
NEDI/TMDI=Σ 2 highest 97.5th percentile intakes + mean population intake for other foods) <sup>1)</sup>									
TMDI/NEDI Rees-Day-model	Highest calculated TMDI/NEDI values in % of ADI	MS Diet	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	
	2%	UK toddler	*)	2%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS
	0.9%	UK vegetarian	*)	0.9%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS
	0.8%	FI 3 yr	*)	0.7%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS
	0.8%	UK adult	*)	0.7%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS
	0.7%	FI 6 yr	*)	0.6%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS
	0.6%	UK infant	*)	0.6%	Wheat		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS
	0.2%	FI adult	*)	0.2%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS
	*) Calculation according to the UK approach (Rees-Day model equation; TMDI/NEDI = Σ 2 highest 97.5th percentile intakes + mean population intake for other foods) Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								

Chronic risk assessment:TMDI calculation										
	Calculated exposure (% of ADI)		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	commodities not under assessment (in % of ADI)
TMDI/NED/IED (based on average food consumption)	1%	GEMS/Food G06	0.73	1%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	1%	IT toddler	0.67	1%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	1%	GEMS/Food G15	0.53	0.9%	Wheat	0.2%	Barley		FRUIT AND TREE NUTS	
	1%	RO general	0.51	1%	Wheat		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
	1.0%	GEMS/Food G08	0.50	0.8%	Wheat	0.2%	Barley		FRUIT AND TREE NUTS	
	1.0%	GEMS/Food G07	0.48	0.8%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS	
	0.9%	FR child 3 15 yr	0.46	0.8%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.9%	GEMS/Food G10	0.45	0.8%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS	
	0.9%	ES child	0.44	0.9%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.9%	DK child	0.44	0.9%	Wheat		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
	0.9%	GEMS/Food G11	0.44	0.7%	Wheat	0.2%	Barley		FRUIT AND TREE NUTS	
	0.8%	DE child	0.42	0.8%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.8%	IT adult	0.41	0.8%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.8%	NL child	0.41	0.8%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.8%	NL toddler	0.41	0.8%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.8%	PT general	0.39	0.8%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.8%	UK toddler	0.39	0.8%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.6%	SE general	0.32	0.6%	Wheat		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
	0.6%	FR toddler 2 3 yr	0.31	0.6%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.6%	ES adult	0.28	0.5%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS	
	0.5%	UK infant	0.26	0.5%	Wheat		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
	0.5%	DE general	0.24	0.4%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS	
	0.5%	DE women 14-50 yr	0.23	0.4%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.5%	IE adult	0.23	0.5%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.4%	NL general	0.22	0.4%	Wheat	0.1%	Barley		FRUIT AND TREE NUTS	
	0.4%	FR adult	0.22	0.4%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.4%	UK vegetarian	0.21	0.4%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.3%	UK adult	0.17	0.3%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.3%	FI 3 yr	0.13	0.2%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.2%	IE child	0.12	0.2%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
	0.2%	DK adult	0.11	0.2%	Wheat		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
	0.2%	LT adult	0.11	0.2%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS	
0.2%	FI 6 yr	0.10	0.2%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS		
0.2%	FR infant	0.08	0.2%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS		
0.1%	FI adult	0.03	0.1%	Wheat	0.0%	Barley		FRUIT AND TREE NUTS		
	Column7				FRUIT AND TREE NUTS		FRUIT AND TREE NUTS		FRUIT AND TREE NUTS	
The TMDI calculations are for information purpose only. The results of the more refined intake calculations are presented in the spreadsheet "Results".										

## A 3.1 TMDI calculations: Florasulam

New calculation conducted by zRMS:

 European Food Safety Authority EFSA PRImo revision 3.1; 2019/03/19		<b>Florasulam</b> LOQs (mg/kg) range from: 0.01 to: 0.05 <b>Toxicological reference values</b> ADI (mg/kg bw/day): 0.05 ARID (mg/kg bw): not necessary Source of ADI: EFSA Source of ARID: Year of evaluation: 2015 Year of evaluation:		<b>Input values</b> Details - chronic risk assessment Supplementary results - chronic risk assessment Details - acute risk assessment/children Details - acute risk assessment/adults							
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
		No of diets exceeding the ADI : ---									
	Calculated exposure (% of ADI)	MS Diet	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	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	0.1%	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	0.1%	Wheat	0.7%	
	0.6%	NL general	0.30	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	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%		
<b>Conclusion:</b> 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.											

## **Appendix 4   Additional information provided by the applicant**

No additional information.