

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: RNB 072 A

Product name(s): **MATLAM**

Chemical active substance:

Florasulam, 50 g/L

Central Zone

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: June 2024

Evaluation date: February 2025

MS Finalisation date: October 2025

Version history

When	What
February 2025	Initial RR
October 2025	The amendment introduced by the evaluator, at the request of the MRiRW included in the email of Fri, 24 Oct 2025, of the submitted for the evaluation GAP, because in accordance with the Regulation of MRiRW of 18 September 2023 (JoL 2023, 2008) winter oats are not recognized as a minor crop in Poland.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation MATLAM 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.

Matlam is a water based suspension concentrate (SC) formulation.

For all necessary data to support this application reference is made to the unprotected data from the product KANTOR 050 SC (EF-1343).

The applicant proposes as a basis for its requested approval the residue data of the product KANTOR 050 SC. Unfortunately, no KANTOR 050 SC source data in its dossier thus, the applicant's references lead to nowhere. Moreover, the KANTOR 050 SC files provided seem to be from CIRCABC. The evaluator strongly draws attention to the fact that CIRCABC is not a database accessible to applicants.

In case of lack of own data and necessary LoAs, applicants are obliged to use publicly accessible unprotected data. In this case, EFSA (EFSA Journal 2012;10(3):2626) data and the EU GAP (SANTE/10542/2015 Rev 1) can be a basis for the requested approval. The proposed GAP is less critical.

Overall conclusion

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

Code	Products to which MRLs apply	Florasulam Reg. (EU) 2022/1363
		applicable
0500010	● Barley	0.01*
0500050	● Oat	0.01*
0500070	● Rye	0.01*
0500090	● Wheat	0.01*

The chronic and the short-term intakes of active substances residues are unlikely to present a public health concern. Cereals are not melliferous crops.

As far as consumer health protection is concerned, Poland agrees with the authorization of the intended uses.

Residues exceeding 0.01 mg/kg are not expected in rotational crops and specific plant-back restrictions related to the use of florasulam are not required (EJ 2012;10(3):2626). According to available data, no specific mitigation measures should apply.

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
Use-No. *	Member state(s)	Crop and/ or situation (crop destination / pur- pose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dos- e rate expres- sion, dose range (min- max)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. inter- val 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 Winter spelt, Winter barley, Winter triticale, Winter rye	F	dicotyledonous weeds (TTDS)	Broadcast spray	BBCH 12-33 (spring ap- plication)	1	-	a) 0.1	5.0	200- 400	60	
2	Poland	Spring barley Spring wheat Spring triticale, Spring oat	F	dicotyledonous weeds (TTDS)	Broadcast spray	BBCH 12-33 (spring ap- plication)	1	-	b) 0.1	5.0	200- 400	55	
Minor uses according to Article 51 (zonal uses)													
3	PL	Winter wheat durum	F	dicotyledonous weeds (TTDS)	Broadcast spray	BBCH 12-33 (spring ap- plication)	a) 1 b) 1	NA	a) 0.1 c) b) 0.1	a) 5.0 b) 5.0	200- 400	60	
4	PL	Winter oat	F	dicotyledonous weeds (TTDS)	Broadcast spray	BBCH 12-33 (spring ap- plication)	a) 1 b) 1	NA	a) 0.1 d) b) 0.1	a) 5.0 b) 5.0	200- 400	60	
5	PL	Spring wheat durum	F	dicotyledonous weeds (TTDS)	Broadcast spray	BBCH 12-33 (spring ap- plication)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200- 400	55	

* 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
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SANTE/10542/2015 Rev 1; 14 July 2015

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc of a.i. g/kg (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	g a.i./hl min max (g/hl)	Water L/ha min-max	g a.i./ha min max (g/ha)		
Winter cereals (wheat, barley, rye, triticale, oats, spelt)	EU	EF-1343	F	Broad leaved weeds	SC	50 g a.s./L	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 00-29 (1 st September to end of December)	1	N/A	0.94-5.36	70-400	3.75	N/A	Autumn uses Max autumn rate is 3.75 g a.s./ha and the total rate per season is 6.25 g a.s./ha)
Winter cereals (wheat, barley, rye, triticale, oats, spelt)	EU	EF-1343	F	Broad leaved weeds	SC	50 g a.s./L	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 13-45 (1 st January to early July)	1	N/A	1.56-8.93	70-400	6.25	N/A	Spring uses
Spring cereals (wheat, barley, rye, triticale, oats, spelt)	EU	EF-1343	F	Broad leaved weeds	SC	50 g a.s./L	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 12-45 (1 st February to 15 th July)	1	N/A	1.56-8.93	70-400	6.25	N/A	Spring uses

7.1.2 Summary of the evaluation

MATLAM 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 Florasulam

Table 7.1-3.1: 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 wheat	Yes	Yes	Yes	Yes	Yes	No	No
3	Winter wheat (durum or soft), Winter spelt, Winter barley, Winter triticale, Winter rye Winter oat	Yes	Yes	Yes	Yes	Yes	No	No
4	Spring wheat (durum and soft), Spring barley, Spring triticale, Spring oat	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 MATLAM

Table 7.1-4: Information on MATLAM (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	60	Yes		
Spring wheat	55	Yes		

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 (durum or soft), Winter spelt, Winter barley, Winter triticale, Winter rye Winter oat	60	Yes		
Spring wheat (durum and soft), Spring barley, Spring triticale, Spring oat	55	Yes		

NR: not relevant

* Purpose of withholding period to be specified

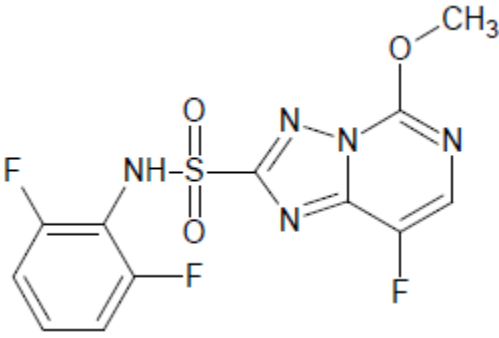
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Florasulam

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

Table 7.2-1.1: 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 ₈ O ₃ N ₅ F ₃ S
Molar mass	359,3
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 Agro
Rapporteur Member State (RMS)	Poland
Approval status	Approved Date: 01.01.2016
Restriction	Only uses as herbicide may be authorised.
Review Report	SANCO/1406/2001
Current MRL regulation	REGULATION (EU) No 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, 2015)
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.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No new residue trials have been performed.

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.

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.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No new data submitted in the framework of this application.

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 7.2.2.4. Summary from EFSA Conclusion.

Endpoints	
Plant groups covered	Cereal (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 applicable
Plant residue definition for monitoring	Florasulam (Reg EU 2022/1363)
Plant residue definition for risk assessment	Florasulam (Reg EU 2022/1363)
Conversion factor from enforcement to RA	Not applicable

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

Available data

No new data submitted in the framework of this application.

Table 7.2.2.5. Summary from EFSA Conclusion.

Florasulam	
Animals covered	Goat, laying hen
Animal residue definition for monitoring	Florasulam
Animal residue definition for risk assessment	Florasulam pending assessment with regard to 4-OH-phenyl-florasulam
Conversion factor (monitoring to risk assessment)	For milk, liver, kidney and eggs: 1
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. The data applied by the applicant is EFSA data from EFSA Journal 2012;10(3):2626



Review of the existing MRLs for florasulam

Table 3-2: Overview of the available residue trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (florasulam)	Risk assessment (florasulam)					
Barley grain/ Oat grain/ Rye grain/ Wheat grain	NEU	Outdoor	17 x <0.01	17 x <0.01	0.01	0.01	0.01*	1.00	Combined dataset on barley (6) and wheat (11) supporting the critical NEU GAP for small grain cereals.
	SEU	Outdoor	8 x <0.01	8 x <0.01	0.01	0.01	0.01*	1.00	Combined dataset on barley (6) and wheat (2) supporting the critical SEU GAP for small grain cereals.
Barley straw/ Oat straw / Rye straw / Wheat straw	NEU	Outdoor	17 x <0.05	17 x <0.05	0.05	0.05	0.05	1.00	Combined dataset on barley (6) and wheat (11) supporting the critical NEU GAP for small grain cereals.
	SEU	Outdoor	8 x <0.05	8 x <0.05	0.05	0.05	0.05	1.00	Combined dataset on barley (6) and wheat (2) supporting the critical SEU GAP for small grain cereals.

Table 7.2-2.1: Summary of EU reported and new data supporting the intended uses of MATLAM (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 cal- culator MRL (mg/kg)	Current EU MRL (mg/kg)	MRL com- pliance
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 – grains (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	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				

rye, oats and triticale	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
	Overall supporting data for cGAP	N-EU	4 x <0.05* mg/kg 8 x <0.01* mg/kg	0,01*	-	-	0,01*	Yes

*) – LOQ, Regulation (EU) No 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 outdoor uses.

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

EFSA Journal 2012;10(3):2626:

According to the RMS, the active substance florasulam is authorised under outdoor conditions in northern Europe for foliar application in cereals, maize, millet and grass and in southern Europe for foliar application in cereals, maize and grass (see Appendix A). To assess the magnitude of florasulam residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, and additional data submitted during the Member States consultation (France, 2011; Italy, 2011). All available residue trials that, according to the RMS, comply with the authorised GAPs are summarized in above Table 3-2.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment, except in the following cases:

- For the use on maize and millet, data on grain are not available; residue levels were only measured in cobs and in whole plants. Considering that in those trials cobs and whole plants were harvested at an early stage, that residues were below the LOQ in these commodities and that in metabolism studies TRR levels in cereal grain were well below 0.01 mg/kg, it is concluded that no residues are expected in maize grains. Further trials are therefore not required.

- For the use on grass, the number of residue trials is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were all below the LOQ of 0.05 mg/kg. However, an LOQ of 0.01 mg/kg could be achieved for enforcement purposes and it is not possible based on the metabolism studies that residue levels between 0.01 and 0.05 mg/kg will not occur. Trials carried out with the enforcement LOQ of 0.01 mg/kg are therefore desirable.

- In cereal straws, residues trials were also carried out with an LOQ of 0.05 mg/kg while an LOQ of 0.01 mg/kg could be achieved for enforcement purposes. It is not possible to conclude based on the metabolism studies that residue levels between 0.01 and 0.05 mg/kg will not occur and trials carried out with the enforcement LOQ of 0.01 mg/kg are desirable.

Two studies descriptions provided here by the applicant were moved to Appendix 2 and highlighted in grey

~~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 a.s./L. EF 1343 is a SC formulation that contains florasulam 50 g a.s./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.~~

7.2.4 Residues in livestock

Table 7.2-3: Residues from livestock feeding studies (Florasulam)

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

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 7.2-4: Results of the dietary burden calculation

New data requirements		Regulation (EU) No 283/2013								Column to be deleted if not relevant
Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment	
	mg/kg bw per day		mg/kg DM					0.004	Max burden	
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw	
Cattle (all diets)	0,002	0,002	0,05	0,05	Dairy cattle	Wheat	milled bypds	No		
Cattle (dairy only)	0,002	0,002	0,05	0,05	Dairy cattle	Wheat	milled bypds	No		
Sheep (all diets)	0,003	0,003	0,07	0,07	Lamb	Wheat	milled bypds	No		
Sheep (ewe only)	0,002	0,002	0,07	0,07	Ram/Ewe	Wheat	milled bypds	No		
Swine (all diets)	0,001	0,001	0,05	0,05	Swine (finishing)	Wheat	milled bypds	No		
Poultry (all diets)	0,002	0,002	0,03	0,03	Poultry layer	Wheat	milled bypds	No		
Poultry (layer only)	0,002	0,002	0,03	0,03	Poultry layer	Wheat	milled bypds	No		
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"										
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".										

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

EFSA Journal 2012;10(3):2626: According to the above mentioned metabolism studies, it is concluded that, after exposure to the maximum dietary burden (about 10-20 times lower than the dose level of the

metabolism studies; see also section 3.2.1), residue levels should not result in quantifiable residues in milk and tissues of ruminants. Hence, no livestock feeding study is needed; MRLs and risk assessment values for the relevant commodities in ruminants can be established at the LOQ level.

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

Since quantifiable residues of florasulam were not found in grains (cereals), there is no requirement to investigate the effect of industrial processing or household preparation. 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)

No new data submitted in the framework of this application.

No residues of florasulam in following crops are expected following the use of MATLAM in cereals, and supplementary studies are not required.

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.

No further studies are required to support the proposed uses.

For all necessary data to support this application reference is made to the unprotected data from the product KANTOR 050 SC (EF-1343).

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

No data are provided in support of the application for authorization of MATLAM (RNB 072 A). Reference is made to the unprotected data and dossier in support of KANTOR 050 SC authorization (Reg. No. EF-1343), in accordance with Article 34 of Regulation 1107/2009/EC.

No data on residues in honey was required since cereals are not melliferous crops.

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 7.2-12: Toxicological reference values

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				

Table 7.2-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Florasulam				
For all crops	Current MRL: Regulation (EU) No 2022/1363			

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-14: Consumer risk assessment – regarding Florasulam

TMDI (% ADI) according to EFSA PRIMo	Highest TMDI: 2% (NL toddler), highest contributor: milk cattle (1%)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% 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 rev 3.1

** if national model is available

The proposed uses of MATLAM 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.

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

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 Floroxypyr 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
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 Southern 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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Florasulam

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 plants

The data provided by the applicant and listed in the Appendix 1 were already **evaluated and accepted** by EFSA. The short applicant's descriptions of them are here for clarity.

Reference:	CA 6.3.1, Pronier, I. (2011)
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. Dow AgroSciences, European Development Centre
Report No.	14SRXIOR (Accession Number) 2009991; GHE-P-12647/14SRX10R05
GLP:	Yes
Acceptability:	Yes

Description:

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 a.s./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.

Reference:	CA 6.3.2, I. Pronier, 2012
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.
Report No.	GHE-P-12794.
Guideline(s):	Guidelines: Commission Working Documents 7029/VI/95 rev. 5 and 7035/VI/95 rev. 5
GLP:	Yes
Acceptability:	Yes

Description:

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.

A 2.1.4 Magnitude of residues in livestock

No study submitted by applicant.

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

No study submitted by applicant.

A 2.1.6 Magnitude of residues in representative succeeding crops

No study submitted by applicant.

A 2.1.7 Other/Special Studies

No additional studies.

Appendix 3 Pesticide Residue Intake Model (PRIMo Rev 3.1)



European Food Safety Authority

EFSA PRIMo revision 3.1: 2021/01/06

<h1 style="text-align: center;">FLORASULAM</h1>			
LOQs (mg/kg) range from:		0,01	to: 0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,05	ARID (mg/kg bw):	insert valid entry
Source of ADI:	EFSA	Source of ARID:	
Year of evaluation:	2015	Year of evaluation:	

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 under assessment (in % of ADI)
TMDI/NEDI 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	0,63	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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.											