REGISTRATION REPORT

Part A

Risk Management

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
August 2024	Section was updated due to comments on completeness check. Corrected information are highlighted in yellow.
February 2025	Version evaluated by zRMS PL
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.
November 2025	zRMS updated final version

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PART A
RISK MANAGEMENT

1 Details of the application

This application is submitted by XXXX. For the authorization of the product MATLAM in Poland. The product is a herbicide formulated as suspension concentrate [SC] containing 50 g/L of Florasulam. The product MATLAM was not a representative formulation during EU review of the active substance.

1.1 Application background

The application was for the first approval of MATLAM, SC formulation containing 50 g florasulam/L, to be used as herbicide applied maximum once a year in cereals against different weeds.

1.2 Letters of Access

The letter of access will be provided.

1.3 Justification for submission of tests and studies

All the tests and studies submitted with this application were considered necessary for the fulfilment of the dossier and risk assessment.

1.4 Data protection claims

The data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorization decision

2.1 Product identity

Product code	RNB 072 A
Product name in MS	MATLAM
Authorization number	Not allocated
Function	herbicide
Applicant	XXXX
Active substance(s) (incl. content)	Florasulam, 50 g/L
Formulation type	Suspension concentrate [SC]
Packaging	0.1, 0.25, 0.5 1.0 L round bottles HDPE; HDPE/PA; HDPE/F; HDPE EVOH 4.0, 5.0, 10.0, 20 L square barrels HDPE; HDPE/PA; HDPE/F; HDPE EVOH 200.0 L drum HDPE; HDPE/PA; HDPE/F; HDPE EVOH

Coformulants of concern for national authorizations	Not relevant
Restrictions related to identiy	Not relevant
Mandatory tank mixtures	Not relevant
Recommended tank mixtures	Not relevant

2.2 Conclusion

The evaluation of the application for MATLAM resulted in the decision to grant the authorization. All uses applied for were authorised (2.6 Intended uses).

Physicochemical properties:
From physicochemical perspective **MATLAM is not considered equivalent/ comparable to already registered Kantor 050 SC in Poland under Composition's comparison in accordance with Article 34 of Regulation 1107/2009.** So, unprotected physicochemical data taken from Kantor 050 SC cannot be used to support Matlam registration in Poland.

From physicochemical perspective **MATLAM is considered equivalent/ comparable to already registered Floras 50 SC in Poland** under Composition's comparison**.**
Applicant has provided the letter of access to the Floras 50 SC data. So, physicochemical data taken from Floras 50 SC can be used to support Matlam registration in Poland.

Efficacy:
The evaluation of the application for Matlam (RNB 072 A) (florasulam – 50 g/L), resulted in the decision to grant its authorization for broadleaved weeds control in cereal crops. The authorization covers the application of herbicide at the rate of 0.1 L/ha, at the crop growth stages BBCH 13-32, for weeds control in winter and spring wheat, winter wheat spelt, winter and spring barley, winter and spring triticale, winter rye, spring oat. Tested product was selective for all tested crops, did not cause phytotoxicity, and had no impact on the yield and its quality, succeeding and adjacent crops.
Data protection. The list of data considered to support the Matlam registration, presented in Part B3, Appendix 1, should be recognized as protected data unless the applicant decides otherwise.

Toxicology:
As it have been demonstrated in confidential part C of this report the composition of product MATLAM is considered equivalent/ comparable to already registered Floras 50 SC in Poland. Applicant has provided the letter of access to the Floras 50 SC data. So, toxicological data taken from Floras 50 SC can be used to support product MATLAM registration in Poland.

2.3 Substances of concern for national monitoring

Not applicable. The plant protection product code RNB 072 A does not contain any substance of concern for national monitoring.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Acute 1, H400 Aquatic Chronic 1, H410

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	GHS09
Signal word:	Warning
Hazard statement(s):	H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	~~P280 - Wear protective gloves/protective clothing/eye protection/face protection.~~ ~~P273 – Avoid release to the environment.~~ P391 – Collect spillage. P501 Dispose of contents/container to …in accordance with local/ regional/ national/international regulation
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	EUH208 - Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction.
	Other non-active hazardous substances: 1,2-Benzisothiazol-3(2H)-one

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR an unsprayed buffer zone of 1m to non-agricultural land with use 75% drift reducing nozzles
SPo5	Until spray has dried before re-entry.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	Workwear at mixing and loading and during application
Worker protection:	
	Arm, body and legs covered
Integrated pest management (IPM)/sustainable use:	
Environmental protection	
Spe3:	To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR an unsprayed buffer zone of 1m to non-agricultural land with use 75% drift reducing nozzles
Other specific restrictions	

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
Environmental protection:		Relevant for use no.

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0, date: 2024-06

PPP (product name/code):	MATLAM	Formulation type:	SC [a, b]
Active substance 1:	Florasulam	Conc. of as 1:	50 g/L [c]
Active substance 2:	-	Conc. of as 2:	- [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	XXXX	Professional use:	☒
Zone(s):	Central zone [d]	Non professional use:	☐
Verified by MS:	yes/no		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn 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 [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg 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.	PL	**Winter wheat Winter spelt, Winter barley, Winter triticale, Winter rye**	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	60	
2.	PL	**Spring barley Spring wheat Spring triticale, Spring oat**	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	55	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn 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 [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5	PL	Winter wheat durum	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	60	
~~6~~	~~PL~~	~~Winter oat~~	~~F~~	~~dicotyledonous weeds (TTTDS)~~	~~Broadcast spray~~	~~BBCH 12-33 (spring application)~~	~~a) 1~~ ~~b) 1~~	~~NA~~	~~a) 0.1~~ ~~b) 0.1~~	~~a) 5.0~~ ~~b) 5.0~~	~~200-400~~	~~60~~	
7	PL	Spring wheat durum	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	55	
Minor uses according to Article 51 (interzonal uses)													
7													
8													

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 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
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of white liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 495 °C. In aqueous solution, it has a pH value around 4.84 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE commercial packaging. Its technical characteristics are acceptable for a Suspension concentrate formulation.

3.2 Efficacy (Part B, Section 3)

Thirty efficacy trials and forty selectivity trials were conducted in 2022 and 2023. In North-east EPPO zone in Poland.

3.3 Efficacy data

Preliminary studies on product MATLAM were not carried out because this herbicide contains florasulam which is a well-known active substance that has been used for many years in agricultural practice.No specific studies were conducted to fill this data point. No specific studies were conducted to fill this data point.

Data from 30 efficacy trials conducted in the North-east EPPO zone (30; i.e. Poland have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone.

In the 30 trials, the level of control obtained by MATLAM was assessed on dicotyledonous weeds present in the trials.

The efficacy trials were conducted to prove the following label claims:

- Post-emergence application for control of **broadleaved weeds** in winter and spring cereals

Thirty efficacy trials and forty selectivity trials were conducted in 2022 and 2023.Thirty efficacy trials and forty selectivity trials were conducted in the 2022 and 2023 in North-east EPPO zone to support the proposed label claims of MATLAM. The trials were conducted in Poland.
In the 30 trials, the level of control obtained by MATLAM was assessed on dicotyledonous weeds present in the trials.
The efficacy trials were conducted to prove the following label claims:

- Post-emergence application for control of broadleaved weeds in winter and spring cereals

Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Based on the results of 30 field trials carried out in 2022, the following can be concluded for the intended use '*Control of broadleaved weeds*' from MATLAM applied post-emergence at the dose rate of 0,1 L/ha in winter wheat and spring cereals

- MATLAM provides a high level control of dicotyledonous weeds.

- As weeds often occur as a complex of several weeds with different susceptibility towards florasulam, one application of MATLAM at the recommended rate should be used to efficiently control all weeds claimed on the label.
- A high level of control may also be obtained against less susceptible weed species if treated with the recommended dose rate under optimal conditions, i.e. early growth stages and good weather conditions.
- Compared to the florasulam reference product, the efficacy obtained with MATLAM is comparable against all weed species.
- The trial results are considered valid for all intended EU Central zone countries.

MATLAM is suitable for the control of broadleaved weeds in winter and spring cereals

Based on results achieved in 30 trials, it can be concluded that the recommended dose rate of 0,1 L/ha MATLAM applied once post emergence is required for consistent control of the label claimed broadleaved weed species in winter and spring cereals, On the basis of information included the assessment of efficacy and phytotoxicity trials herbicide FLENPY in winter and spring cereals the minimum effective dose of product FLENPY used is: 0,1 L/ha once a season in winter and spring cereals which are corresponding to 5 g a.s./ha of florasulam.

MATLAM applied at the proposed dose rate in winter and spring cereals did not affect crop yield nor the quality of the crop yield significantly in any of the 40 trials conducted on cereals post -emergence. In all trials, MATLAM applied at 0,2 L/ha – representative for sprayer overlap – did not significantly affect the crop yield.

MATLAM was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with applied at 0.05, 0.08 , 0.1 L/ha in post-emergence application. . The dose rates tested reflects 50%, 80%, 100% of proposed dose rate. Minimum effective dose rate was evaluated in 30 trials for the control of the broadleaved and grass weeds present in the trials. in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The risk of resistance was analysed following the EPPO-Standard (2003), the classification of the Herbicide Resistance Action Committee (HRAC) and the international Survey of Herbicide Resistant Weeds (Heap, 2016). So far there are 33 reported cases of weed resistance to florasulam reported in EU.
Adverse effects on treated crops
Phytotoxcity
The selectivity trials were designed, conducted and reported according to the following EPPO guidelines:
- PP 1/135 (4) Phytotoxicity assessment
- PP 1/152 (4) Design and analysis of efficacy evaluation trials
- PP 1/181 (5) Conduct and reporting of efficacy evaluation trials including good experimental practice

They were carried out on the field in the conditions of natural agrofag infestation. The efficacy trials were concluded according to the EPPO standards:
Weeds in cereals crop phytotoxicity was evaluated in efficacy- and selectivity trials where MATLAM was applied post-emergence, when the majority of the crop was at growth stages ranging from BBCH 12-33 at the rate 0,1, and 0,2 Lha in winter and spring cereals. The 0,2 L/ha dose rate corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89). No adverse effects in regards to phytotoxicity and vigour were observed in any of the 30 efficacy trials as well as no adverse effects were observed in any of the 40 selectivity trial
Effects on yield and quality
40 selectivity trials treated with MATLAM were harvested and yields recorded. In these, assessments were conducted on the potential impact of treatment on protein content, Thousand Grain weight, HLW and

moisture content of the harvested crop. Furthermore, results from maize trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.
Adverse effects on beneficial organisms (other than bees)
From the experimentation carried out with in 2022 and 2023, no problems regarding ad-verse effects on beneficial organisms were reported.
The impact on succeeding crops is determined in accordance with guidance provided by EPPO standard PP 1/207(2) 'Effect on succeeding crops'.

Impact on other plants including adjacent crops During the conduct of efficacy trials and selectivity trials, no observations about negative or positive effects on other plants or neighbouring crops were reported.

No separate studies have been carried out concerning the influence of product MATLAM on adjacent plants. The owner of the product MATLAM and of its registration documentation is referring to available sources in literature treating on herbicide florasulam.

3.3.2 Observations on other undesirable or unintended side-effects

None

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Methods suitable for the determination of the relevant impurities in plant protection product (PPP) MATLAM/RNB 072 A

	Florasulam
Author(s), year	Kupiec J., 2022
Principle of method	HPLC-UV/VIS
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	0.3018 - 0.7545 mg/mL n = 5 y = 8365610.324x - 5909.439 R^2 = 0.999
Precision – Repeatability Mean n = 6 (%RSD)	Mean conc.: 4.83 % RSD = 0.61 % RSD_r = 2.11 % H_r = 0.29, $H_r \leq 1$
Accuracy n = 2 in in 6 repetitions (% Recovery)	Total recovery Average 101.92 %
Interference/ Specificity	No interferences between the analyte and other compounds, the method is specific.
Comment	-

Conclusion

According to SANCO/3030/99 rev. 5 the presented method was sufficiently validated and is suitable for determination of Florasulam content in the test item Florasulam 50 g/L SC.

Methods suitable for the determination of the relevant impurities in plant protection product (PPP) MATLAM/RNB 072 A

	2,6-DFA **max. 0.1 g/L in PPP**
Author(s), year	Kupiec J., 2022
Principle of method	UHPLC-MS/MS
Linearity **(linear between** **mg/L)** **(correlation coefficient, expressed as r)**	0.0002 - 0.01103 mg/mL n = 6 y = 2225855.9670x + 2962.9829 R^2 = 0.9994
Precision – Repeatability Mean **n = 6** **(%RSD)**	Mean conc.: < LOQ % In none of the examined samples, 2,6-DFA was detected above the LOQ. Therefore, for the determination of repeatability five portions of placebo were fortified with 2,6-DFA at one level 0.0029 mg/mL and analyzed. n = 1 Mean conc.: ~ 0.00029 % RSD = 0.87 % RSD_r = 9.13 % H_r = 0.09, $H_r \leq 1$
Accuracy **n = 2 in 5 replicates** **(% Recovery)**	Total recovery Average 108.9 %
Interference/ Specificity	No interferences between the analyte and other compounds, the method is specific.
LOQ	0.00020 mg/mL (0.00000010 g/kg of PPP)
Comment	-

Conclusion

According to SANCO/3030/99 rev. 5 the presented method was sufficiently validated and is suitable for determination of 2,6-DFA content in the test item Florasulam 50 g/L SC.

3.4.2 Analytical methods for residues

Validated methods for food and feed of plant origin (required for all matrix types, "difficult" matrix only when indicated by intended GAP)

Component of residue definition: Florasulam				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing / EU agreed**
High water content	Primary	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed

Component of residue definition: Florasulam				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing / EU agreed**
	ILV	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed
High acid content	Primary	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed
	ILV	-	-	Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed
High oil content	Primary	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed
	ILV	-	-	Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed
High protein/high starch content (dry)	Primary	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed
	ILV	-	-	Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed

Validated methods for food and feed of animal origin (if appropriate)

Component of residue definition: Florasulam				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (*i.e.* GC-MS or HPLC-UV)**	**Author(s), year / missing**
Milk	Primary	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
Eggs	Primary	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
Muscle	Primary	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
Fat	Primary	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
Kidney, liver	Primary	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	David Robaugh A., 2012 amended 2014, Report No.

Component of residue definition: Florasulam				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (*i.e.* GC-MS or HPLC-UV)**	**Author(s), year / missing**
				110541, Addendum to the RAR, Poland, 2014, EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed

Validated methods for soil (if appropriate)

Component of residue definition: Florasulam			
Method type	**Method LOQ**	**Principle of method (*i.e.* GC-MS or HPLC-UV)**	**Author(s), year / missing**
Primary	0.05 µg/kg (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Bacher R., 2011, Report No. 110537, RAR, Poland, 2013, EU agreed
Confirmatory	0.05 µg/kg (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Bacher R., 2011, Report No. 110537, RAR, Poland, 2013, EU agreed

Validated methods for water (if appropriate)

Component of residue definition: Florasulam				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing**
Drinking water	Primary	0.05 µg/L (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed
	ILV	0.05 µg/L (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Souza N., 2011, Report No. 110539, RAR, Poland, 2013 EU agreed
	Confirmatory	0.05 µg/L (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed
Surface water	Primary	0.05 µg/L (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed
	Confirmatory	0.05 µg/L (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed
Ground water	Primary	0.05 µg/L (for Florasulam and 5-OH	LC-MS/MS	Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed

Component of residue definition: Florasulam				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing**
		Florasulam)		
	Confirmatory	0.05 µg/L (for Florasulam and 5-OH Florasulam)	LC-MS/MS	Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed

Validated methods for air (if appropriate)

Component of residue definition: Florasulam			
Method type	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing**
Primary	1.5 µg/m^3	LC-MS/MS	Class T., 2011, Report No. 110282, RAR, Poland, 2013, EU agreed
Confirmatory	1.5 µg/m^3	LC-MS/MS	Class T., 2011, Report No. 110282, RAR, Poland, 2013, EU agreed

Methods for body fluids and tissues (if appropriate)

Component of residue definition: Florasulam			
Method type	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing**
Primary	0.05 mg/L(in blood, urine)	LC-MS/MS	Class T., Gocer M., 2011, Report No. 110283, RAR, Poland, 2013, EU agreed
Confirmatory	0.05 mg/L(in blood, urine)	LC-MS/MS	Class T., Gocer M., 2011, Report No. 110283, RAR, Poland, 2013, EU agreed

zRMS:
Accepted (see B5 for the zRMS short conclusion).

3.5 Mammalian toxicology (Part B, Section 6)

zRMS PL:
As it have been demonstrated in confidential part C of this report the composition of product **MATLAM** is considered equivalent/ comparable to already registered Floras 50 SC in Poland. Applicant has provided the letter of access to the Floras 50 SC data. So, toxicological data taken from Floras 50 SC can be used to support product **MATLAM** registration in Poland.

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Hazard class(es), categories:	None
Hazard pictograms or Code(s) for hazard pictogram(s):	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	None

3.5.1 Acute toxicity

All acute toxicity studies are acceptable.

RNB 072 A is not classified in any of toxicological hazard class.

zRMS:
The product MATLAM (formulation RNB 072 A) does not require classification for health hazards.

3.5.2 Operator exposure

Operator exposure was assessed using the OPEX and considering the AOEL level agreed in the Review Report for florasulam.
No unacceptable risk for operators was identified when the product is used as intended and PPE (workwear at mixing and loading and during application) are applied.

zRMS:
The potential exposure of operator as well as the exposure of operator not wearing PPE, but wearing a work clothing (long sleeved shirt, long trousers) and applying product MATLAM (formulation RNB 072 A) on low crops (cereals) at maximal dose of 0.1 L/ha, using tractor-mounted/trailed sprayer (downward spraying, calculated with the EFSA AOEM 2022 are both below of 100% of AOEL for Florasulam, an active substance of the product, therefore it is concluded that operator is not at unacceptable risk if applying MATLAM (formulation RNB 072 A) according to its intended use.

3.5.3 Worker exposure

Worker exposure was assessed using the OPEX and considering the AOEL level agreed in the Review Report for florasulam.
No unacceptable risk for workers was identified when the product is used as intended and PPE (workwear) is applied.

zRMS:
The potential systemic exposure of worker as well as exposure of worker not wearing PPE, but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection afield of cereals sprayed with product MATLAM (formulation RNB 072 A) calculated using acceptable model (EFSA 2022 AOEM model) demonstrates that such exposures are below of 100% of AOEL for Florasulam, an active substance of the product. Thus it is concluded that the application of a product MATLAM (formulation RNB 072 A) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice.

3.5.4 Bystander and resident exposure

Resident and bystander exposure was assessed using the OPEX and considering the AOEL level agreed in the Review Report for florasulam.
No unacceptable risk for bystander and resident was identified when the product is used as intended.

zRMS:
The exposure estimation of residents (adult and child) to Florasulam, an active substance of a product MATLAM (formulation RNB 072 A) applied on cereals in line with GAP at dose of 0.1 L/ha calculated with the EFSA AOEM 2022 demonstrates that such a exposure in all cases is well below AOEL, therefore the application of product MATLAM (formulation RNB 072 A) does not pose an unacceptable risk to the health of adult and child residents for its intended use within good agricultural practice.

No bystander acute exposure estimation for to Florasulam, an active substance of a product MATLAM (formulation RNB 072 A) is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Florasulam as a result of application of a product MATLAM (formulation RNB 072 A) ALLY with accordance with intended use within good agricultural practice.

3.6 Residues and consumer exposure (Part B, Section 7)

zRMS:
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. In case of lack of own data and necessary LoAs, applicants are obliged to use publicly accessible unprotected data. In this case, 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.
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.
The chronic and the short-term intakes of active substances residues are unlikely to present a public health concern. Moreover cereals are not melliferous crops.
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).
The approval for the intended Matlam GAP can be granted.
The below considerations of the applicant are not necessary.

Toxicological reference values for the dietary risk assessment of Florasulam

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				

3.6.1 Residues

Summary of the nature of residues in commodities of plant origin

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

Summary on the nature of residues in commodities of animal origin

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	Yse
Fat soluble residue	no

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:

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 of200 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.

3.6.2 Consumer exposure

Chronic consumer risk assessment was performed with EFSA PRIMo model rev. 3.1 for all com-modities; the current MRLs for Florasulam (Regulation (EU) 2022/1363), were used as input values.
For acute risk assessment only the crop of interest was used for the assessment.

TMDI (% ADI) according to EFSA PRIMo	Highest TMDI: 2% (NL toodler), 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.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PECsoil calculations have been conducted with Florasulam and its relevant metabolites 5-OH Florasulam, DFP-ASTCA, ASTCA and TSA using the EU agreed endpoints (EFSA Journal 2015;13(1):3984).

~~Maximum PECsoil value for Florasulam was 0.007 mg/kg, 0.005 mg/kg for 5-OH Florasulam, 0.001 for DFP-ASTCA, 0.001 for ASTCA and 0.001 mg/kg for TSA, following the highest application rate of 5 g Florasulam/ha.~~

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PECgw have been realised for Florasulam and its relevant metabolites 5-OH Florasulam, DFP-ASTCA, ASTCA and TSA.

PECgw values were below 0.1 µg/L for Florasulam, 5-OH Florasulam and DFP-ASTCA, for ASTCA the maximum PECgw is 0.336 µg/L for Hamburg FOCUS PEARL scenario and for TSA the maximum PECgw is 0.320 µg/L for Hamburg FOCUS PEARL scenario. Therefore assessment of the relevance of these two metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is provided.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PECsw/sed of Florasulam and their relevant metabolites 5-OH Florasulam, DFP-ASTCA, ASTCA, TSA, TPSA, 5-OH ASTP and ASTP have been assessed with the models FOCUS STEP 1, 2, 3 ~~and 4 (when necessary)~~. Please refer to Part B, Section 9, Point 8.9 for more details about the results obtained.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapor pressure at 20 °C of the active substance Florasulam is < 10-5 Pa. Hence the active substance Florasulam is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Florasulam due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds
According to the screening assessments, all the TER_a and TER_{lt} values for Florasulam are greater than the Annex VI trigger of 10 and 5, respectively, indicating that MATLAM presents no unacceptable acute and long-term risk to birds according to the intended uses.

Mammals
According to the screening assessments for cereals, all the TER_a and TER_{lt} values for active substance are greater than the Annex VI trigger of 10 and 5, respectively, indicating that MATLAM presents no unacceptable acute and long-term risk to mammals according to the intended uses.

3.8.2 Effects on aquatic species

Florasulam
For the active substance Florasulam, calculated PEC/RAC ratios for spring and winter cereals, spring application, did indicate an acceptable risk in all FOCUS Steps 3 scenarios relevant for Poland.

Metabolites of Florasulam
Regarding the metabolites, calculated PEC/RAC ratios did indicate an acceptable risk in all FOCUS Step 1-2 scenarios for spring application.

3.8.3 Effects on bees

Use of MATLAM indicate low risk for bees.
The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled. Nevertheless, it should be noted that for larvae the single exposure test was submitted.

3.8.4 Effects on other arthropod species other than bees

Use of MATLAM indicate low risk for non-target arthropods other than bees.

3.8.5 Effects on soil organisms

Use of MATLAM indicate low risk for soil meso- and macrofauna and soil microbial activity.

3.8.6 Effects on non-target terrestrial plants

No potential risk to non-target plants located outside the treated area after application of MATLAM according to the GAP table is expected when the following risk mitigation measures are considered:

SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR an unsprayed buffer zone of 1m to non-agricultural land with 75% drift reducing nozzles.*

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No studies submitted.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites ASTCA and TSA are predicted to occur in groundwater at concentrations above 0.1 µg/L, therefore aassessment of the relevance of these two metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is provided.

According to this assessment, both metabolites are not considered to exceed the toxicological threshold of concern (all PEC_{gw} was < 0.75 µg/L), therefore ASTCA and TSA are considered as non-relevant in groundwater.

zRMS:
The metabolites ASTCA and TSA are not considered toxicologically relevant. Since their concentrations

in the ground water is < 0.75 µg/L in line with guidance SANCO/221/2000 – rev.11/ 21 October 2021 they do not pose an unacceptable risk for consumers

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant, florasulam is not a candidate for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

None

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Appendix 3 Letter of Access

Please refer to administrative documents.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
XXXX	XXXX	XXX	XXXX	XX	XX	XXXX	XXXX

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
XXXX	XXXX	XXX	XXXX	XX	XX	XXXX	XXXX

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner