

# REGISTRATION REPORT

## **Part B**

### **Section 5**

#### **Analytical Methods**

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

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June 2024 (final Core Assessment)

### Version history

When	What
November 2023	Original version from applicant for submission to zRMS: Poland, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009.
April 2024	Applicants' update.
April 2024	Initial assessment by the zRMS 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 highlighted in grey. Not agreed or not relevant information are <del>struck through</del> and shaded 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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## Methods for the determination of residues

All analytical methods are active substance data and were evaluated during the EU review of Florasulam. They were considered adequate. No additional studies have been performed.

### Florasulam

EFSA Journal 2015; 13(1):3984

Residues of Florasulam in food and feed of plant origin can be monitored with LC-MS/MS method with LOQs of 0.01 mg/kg in all commodity groups. Florasulam can be monitored in food of animal origin with LC-MS/MS with LOQs of 0.01 mg/kg in meat, liver, fat, milk and eggs. Residues of Florasulam in soil can be monitored by LC-MS/MS with a LOQ of 0.05 µg/kg. Appropriate LC-MS/MS method with a LOQ of 0.05 µg/L exists for monitoring Florasulam in surface water and drinking water. Residues of Florasulam in air can be monitored by LC-MS/MS with a LOQ of 1.3 mg/m<sup>3</sup>. LC-MS/MS method with LOQs of 0.05 mg/L exists for the determination of Florasulam in body fluids.

Commodity/crop	Supported/ Not supported
Cereals	Supported

This document reviews the analytical methods for the product Floras 50 SC containing the active substance Florasulam.

Florasulam was reviewed as part of the renewal of approval procedure by the Member States and the Commission and the Commission review report finalised on 14.08.2015 approved Florasulam in accordance with Regulation (EC) No. 1107/2009 (Regulation 2015/1397).

The EFSA Report of Florasulam (EFSA Journal 2015; 13(1):3984) is considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Florasulam, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- ☐ the risk to aquatic organisms and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

## 5 Analytical methods

### 5.1 Conclusion and summary of assessment

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.

Sufficiently sensitive and selective analytical methods are available for the active substance(s) and relevant impurities in the plant protection product.

Noticed data gaps are: N/A

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- validated method for the determination of florasulam in body fluids with LOQ of 0.01 mg/L

zRMS-PL considers that this data gap is anticipated to be addressed at active substance level in context with the renewal of florasulam and will be subject of the art.43 re-authorisation process for the product.

Commodity/crop	Supported/ Not supported
Cereals	Supported

#### zRMS conclusions:

##### Florasulam

The analytical methods are active substance data and were provided in the EU review of florasulam and were considered adequate.

According to the EFSA Journal 2015; 13(1):3984: *Residues of florasulam in food and feed of plant origin can be monitored with LC-MS/MS method with LOQs of 0.01 mg/kg in all commodity groups. Florasulam can be monitored in food of animal origin with LC-MS/MS with LOQs of 0.01 mg/kg in meat, liver, fat, milk and eggs. Residues of florasulam in soil can be monitored by LC-MS/MS with a LOQ of 0.05 µg/kg. Appropriate LC-MS/MS method with a LOQ of 0.05 µg/L exists for monitoring florasulam in surface water and drinking water. Residues of florasulam in air can be monitored by LC-MS/MS with a LOQ of 1.3 mg/m³. LC-MS/MS method with LOQs of 0.05 mg/L exists for the determination of florasulam in body fluids.*

#### Analytical methods for residues (Annex IIA, point 5.2)

##### Residue definitions for monitoring purposes

Food of plant origin  
Food of animal origin  
Soil  
Water  
Air  
Body fluids and tissue

Florasulam
Florasulam
Florasulam
Florasulam
Florasulam
Florasulam

#### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

LC/MS/MS, LOQ = 0.01 mg/kg, recovery for  $m/z = 360/129$ : 84 – 100% for (acidic crops: orange fruit, apple fruit; dry crops: corn grain, wheat grain; oil crops: soybean grain, canola seed; wet crops: whole tomato, potato tuber).  
Confirmation: recovery for  $m/z = 360/109$ : 71 – 124% for (acidic crops: orange fruit, apple fruit; dry crops: corn grain, wheat grain; oil crops:

	soybean grain, canola seed; wet crops: whole tomato, potato tuber). Confirmation ILV method: recovery: 81% - 86% for tomato and orange fruit.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC/MS/MS, LOQ = 0.01 mg/kg, recovery for $m/z$ = 360/129: 72 – 102% for bovine liver, milk, bovine fat and eggs. Confirmation: recovery for $m/z$ = 360/109: 71 – 103% for bovine liver, milk, bovine fat and eggs. Confirmation: ILV for milk, bovine, eggs (recovery: 72-105%).
Soil (analytical technique and LOQ)	LC/MS/MS, LOQ = 0.05 µg/kg, recovery for Florasulam for $m/z$ = 358/167: 73 – 83% and for $m/z$ = 358/152 as a confirmation transition: 74% - 94%; recovery for 5-OH Florasulam for $m/z$ = 344/324: 86% - 99% and for $m/z$ = 344/104 as a confirmation transition: 86% - 100%.
Water (analytical technique and LOQ)	LC/MS/MS, LOQ = 0.05 µg/L, recovery for Florasulam $m/z$ = 358/167: 92 – 104% and recovery for $m/z$ = 358/152 as a confirmation transition: 92% - 104%; recovery for 5-OH Florasulam for $m/z$ = 344/324: 98% - 104% and for $m/z$ = 344/104 as a confirmation transition: 97% - 105% (surface water, ground water, drinking water). Confirmation: ILV for surface water, ground water, drinking water (Florasulam recovery for $m/z$ 358/167: 100 -104% and for $m/z$ 358/152: 94% - 104%, and for 5-OH Florasulam recovery for $m/z$ 344/324: 99 - 109% and for $m/z$ 344/104: 88% - 104%).
Air (analytical technique and LOQ)	LC/MS/MS, LOQ = 1.30 mg/m <sup>3</sup> , recovery for Florasulam for $m/z$ 360/129: 76 -110% and for $m/z$ 360/120: 75% – 109%.
Body fluids and tissues (analytical technique and LOQ)	LC/MS/MS, LOQ = 0.05 mg/L, Florasulam recovery for $m/z$ 360/129: 94 - 99% and for $m/z$ 360/109: 93 – 101% for body fluids.
For florasulam, sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions for plant commodities, commodities of animal origin, soil, drinking/surface water, air, body fluids and tissues.	
<p><u>Remark:</u></p> <p>According to the SANTE/2020/12830, Rev.2, 24. February 2023 an analytical method for the determination of residues in body fluids for enforcement/monitoring purposes is required with lower LOQ equals 0.01 mg/L. zRMS-PL considers that this data gap is anticipated to be addressed at active substance level in context with the renewal of florasulam and will be subject of the art.43 re-authorisation process for the product.</p>	
No additional data are required.	

## 5.2 Methods used for the generation of pre-authorization data (KCP 5.1)

### 5.2.1 Analysis of the plant protection product (KCP 5.1.1)

#### 5.2.1.1 Determination of active substance and/or variant in the plant protection product (KCP 5.1.1)

Comments of zRMS:	The method is sufficiently described and validated according to SANCO/3030/99 rev. 5 (22 March 2019) and is suitable for the determination of active substance in the plant protection product.
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An overview on the acceptable methods and possible data gaps for analysis of active substances, and in plant protection product is provided as follows:

Reference: 5.2.1.1/01, Kupiec J., 2022.

Report Floras 50 SC Stage I: Determination of physicochemical properties.  
Method development and validation for the determination of active substances and relevant impurities content in the formulation.  
No. of study: BF-21/22

Guideline(s): SANCO/3030/99 rev. 4 5 (22/03/19)

Deviations: No

GLP: Yes

Acceptability: Yes

#### Materials and methods

**Examined material:** Floras 50 SC

Batch no: RFEAR0501

Manufacturer: Elvita Sp. z o.o.

Active substance: Florasulam

**Reference material:** Florasulam, IPO, batch no 2A/21, purity 99.7%.

Determination method of Florasulam content is based on using HPLC with UV/Vis detection at wavelength of 280 nm and external standard.

#### Apparatus:

- Shimadzu liquid chromatograph equipped with UV/Vis detector, a thermostated column oven and autosampler
- Column: Arion Plus C18, 250x4.6mm, 5µm
- Analytical balance Mettler Toledo AT261, accuracy 0.01 mg

#### Reagents and materials:

- Water for HPLC, Millipore
- Acetonitrile for HPLC, POCh
- Analytical standards.

#### Chromatographic conditions:

- Oven temperature: 40 °C 30 °C
- Mobile phase A: Acetonitrile
- Mobile phase B: Water

Time [min]	A [%]	B [%]
0.01-2.30	70	30
2.31-5.00	28	72
5.01-8.00	70	30

- Wavelength:  $\lambda = 260$  nm
- Injected volume: 5  $\mu$ L
- Flow rate: 1.0 mL/min

Under the above conditions the retention time of Florasulam was 4,2 min  $\pm 0.3$ min. The total time of analysis was 8 min.

## Preparation of solutions

### Standard solutions

Florasulam standard was weighed (with the accuracy of 0.01 mg) into the 10 ml volumetric flask and acetonitrile was added. The flask was put into the ultrasonic bath for 5 min. After cooling, acetonitrile was added to the nominal volume and solution was diluted. Standards solutions of Florasulam was in the concentration range from 0.3018 mg/ml to 0.7545 mg/ml and analyzed.

### Specimen solutions

About 100 mg of examined specimen was weighed (with the accuracy of 0.01 mg) into the 10 ml volumetric flask. 2 ml water was added, stirred and the flask was put into the ultrasonic bath for 5 min. After cooling, acetonitrile was added to the nominal volume, solutions of examined specimen were passed through syringe filters and analyzed (exemplary chromatogram is presented in Appendix 4 – at the initial stage, Appendix 5 – after accelerate storage).

## Validation - Results and discussions

**Table 5.2-1: Methods suitable for the determination of active substances in plant protection product Floras 50 SC.**

	Florasulam
<b>Author(s), year</b>	Kupiec J., 2022
<b>Principle of method</b>	The content of active substance in the examined sample was determined by high performance liquid chromatography (HPLC) using reverse phase column, UV/Vis detection (wavelength 260 nm) and external standard. Chromatographic conditions: Column temperature: 40°C 30 °C Mobile phase flow rate: $v = 1.0$ mL/min Wavelength: $\lambda = 260$ nm Injected volume: 5 $\mu$ L Mobile phase: Acetonitrile + Water
<b>Linearity</b> <b>Equation for Florasulam:</b> <b><math>y = 8365610x - 5909,439</math></b> <b>Correlation coefficient:</b> <b><math>R^2 = 0,999</math></b>	The linearity of the detector response was assessed using five standards solutions of Florasulam in the concentration range from 0.3018 mg/ml to 0.7545 mg/ml. To prepare the calibration curve volumes of: 0.60 ml, 0.80 ml, 1.00 ml, 1.20 ml and 1.50 ml of standard solution (5.0299 mg/ml) were pipetted to 10 ml flasks and acetonitrile was added up to the nominal volume.
<b>Precision – Repeatability Mean Florasulam:</b> <b><math>n=6</math>; 0,61 % RSD, <math>RSDr \leq 2.11</math></b>	The content of Florasulam in the Floras 50 SC preparation was determined by analysis of six - about 100 mg - portions of the specimen solution.  Horrat value calculated with the equation:  $Hr = \%RSD / \%RSDr,$



	Florasulam
	where: %RSD is obtained repeatability; %RSDr is expected repeatability obtained with modified Horwitz equation; is 0.22 and fulfils acceptance criterion $Hr \leq 1$ .
<b>Accuracy</b> <b>Florasulam:</b> <b>n = 12</b> <b>101,92 % Recovery</b>	Recovery of the method for determination of Florasulam content in Floras 50 SC preparation was assessed by total recovery. To twelve 5 ml flasks 1 ml placebo solution in acetonitrile (concentration 50.212 mg/mL) was added. To six of them 0.60 ml standard solutions of Florasulam concentration– 5.030 mg/ml and to other six 0.90 ml standard solution of Florasulam concentration– 3.240 mg/ml, were added. Acetonitrile was added up to the nominal volume. Solutions were analyzed.
<b>Interference/ Specificity</b>	It was confirmed that the method is specific. There were no peaks from placebo interfering with determined compound.
<b>Comment</b>	-

### Conclusion

The validation parameters (specificity, linearity, instrument precision, repeatability and accuracy) are within the acceptance range and fulfil EU requirements given in SANCO/3030/99 rev.4 SANCO/3030/99 rev. 5 (22/03/19).

### 5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)

Comments of zRMS:	The method is sufficiently described and validated according to SANCO/3030/99 rev. 5 (22 March 2019) and is suitable for the determination of 2,6-difluoroaniline in plant protection product (PPP) Floras 50 SC.
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An overview on the acceptable methods and possible data gaps for analysis of relevant impurities in plant protection product is provided as follows:

Reference:	5.2.1.1/02, Kupiec J., 2022.
Report	Floras 50 SC Stage I: Determination of physicochemical properties. Method development and validation for the determination of active substances and relevant impurities content in the formulation. No. of study: BF-21/22
Guideline(s):	SANCO/3030/99 rev. 4 5 (22/03/19)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Determination of 2,6-difluoroaniline

#### Materials and methods

**Examined material:** Floras 50 SC

Batch no: RFEAR0501

Manufacturer: Elvita Sp. z o.o.

Active substance: Florasulam

**Reference material:** 2,6-difluoroaniline (2,6-DFA), 97 %, Sigma-Aldrich, Batch no. STBH3159.

The content of relevant impurity in the examined specimen was determined by high

performance liquid chromatography HPLC with UV/Vis detector using reversed phase column.  
External standard method was used.

#### Apparatus and materials

- Sciex QTRAP 4500 mass spectrometer with UHPLC
- Column: Luna Omega Polar PS C18, 100 × 2,1 mm, Phenomenex
- Analytical balance RADWAG
- Glass pipettes
- Glass graduated flasks
- Ultrasonic bath
- Typical laboratory equipment

#### Reagents

- Deionized water, ultra-pure, Millipore
- Acetonitrile hypergrade for LC-MS, J.T. Baker
- Formic acid > 95%, Sigma-Aldrich
- Ammonium formate ≥ 99.995%, Sigma-Aldrich
- Chromatographic conditions
- Column temperature: 30 °C
- Mobile phase: 5 mmol aqueous solution of ammonium formate + 0,1% aqueous solution of formic acid (A) + 5 mmol acetonitrile solution of ammonium formate + 0,1% acetonitrile solution of formic acid (B) (A+B; v/v)
- Flow rate: 0.4 ml/min
- Volume of sample injected: 10 µl

Time [min]	A [%]	B [%]
0,00	95	5
1,00	95	5
5,00	5	95
9,00	5	95
10,00	95	5
12,00	95	5

#### Preparation of the solutions

##### Preparation of the specimen solution

About 100 mg of examined specimen was weighted into a 10 ml volumetric flask, then mobile phase A was added up to the mark. The content was mixed and the flask was put into the ultrasonic bath for 2 minutes. After cooling, the solution was analysed.

##### Preparation of the standard solution

About 10 mg of 2.6-DFA standard was weighted into a 10 ml volumetric flask. Acetonitrile was added up to the mark and the flask was put into the ultrasonic bath for 2 minutes. The solution was adjusted to the room temperature and appropriate diluted.

In the examined sample Floras 50 SC preparation 2.6-DFA was detected below LOQ.

It means below 0.00000010 g/kg of preparation. The determined value is below maximum permitted level 0.2 % (2 g/kg) of technical Florasulam so 0.101 g/kg of the preparation.

#### Validation - Results and discussions

**Table 5.2-2: Methods suitable for the determination of 2,6-difluoroaniline in plant protection product (PPP) Floras 50 SC.**

<b>Specificity</b>	It was confirmed that the method is specific. There were no peaks from placebo interfering with determined compound.
<b>Linearity</b> <b>Equation:</b> <b>Y=2225855.9670x+2962.98.29</b> <b>R<sup>2</sup> = 0,9994</b>	The linearity of the detector response was assessed using six standards solutions at the concentration range from 0.00020 mg/ml to 0.01103 mg/ml of 2.6 – difluoroaniline which corresponds to the concentration range of 20.05 % to 1102.64 % of maximum acceptable limit (FAO) for 2.6 - difluoroaniline content

	in the preparation. For this purpose, appropriate volumes of standard solution were added to the flasks and mobile phase A was added up to the mark. Each of the solutions were analysed twice (two replicates), except the lowest level which was analysed six times (six replicates) to determine limit of quantification (LOQ) of the method.
<b>Precision</b> <b>n=5; RSD=0,87</b>	<p>The method repeatability was assessed on the basis of six independent determinations of 2.6 - difluoroaniline content in Floras 50 SC preparation. In none of the examined samples 2.6 - difluoroaniline was detected above the LOQ. Therefore, for the determination of repeatability five portions of placebo were fortified with 2.6 - difluoroaniline at I level 0.0029 mg/ml and analyzed. For this purpose, 0.10 ml of placebo solution at concentration 10 mg/ml (500 mg / 50 ml) was added into five 10 ml flasks and 0.30 ml of (A2) 2.6 - difluoroaniline standard solution was placed.</p> <p>Horrat value calculated with the equation:</p> $H_r = \frac{\%RSD}{\%RSD_r}$ $H_r = \frac{0.87 \%}{9.13 \%} = 0.09 \leq 1$ <p>where: %RSD is obtained repeatability; %RSDr is expected repeatability obtained with modified Horwitz equation; is 0.09 and fulfils acceptance criterion <math>H_r \leq 1</math>.</p>
<b>Accuracy</b> <b>n = 11</b> <b>108,9 % Recovery</b>	<p>Recovery of the method for determination of 2.6 - difluoroaniline in Floras 50 SC preparation was assessed by at two levels of concentration.</p> <p>Level I – 0.10 ml of placebo solution at concentration 10 mg/ml (500 mg / 50 ml) was added into five 10 ml flasks, next 0.30 ml of (A2) 2.6 - difluoroaniline solution was placed, and mobile phase A was added up to the volume.</p> <p>Level II – 0.10 ml of placebo solution at concentration 10 mg/ml (500 mg / 50 ml) was added into five 10 ml flasks and 0.70 ml of (A2) 2.6 - difluoroaniline solution was placed, and mobile phase A was added up to the volume. The flasks were put into the ultrasonic bath for 2 min. The concentration of analytes in each solution was calculated from the equation of the calibration curve.</p> <p>Obtained final concentrations were examined and the theoretical and calculated contents were compared.</p> <p>For the ingredients at concentration &lt; 0.01% the average recovery value should be 100 ± 30%. The obtained result of 108.9% is acceptable.</p>
<b>LOQ</b>	Limit of quantification (LOQ) of 2.6 - difluoroaniline in Floras 50 SC preparation was defined as the lowest concentration of injected standard that gave precise and accurate measurements. Limit of quantification is 0.00020 mg/ml what corresponds to 0.00000010 g/kg of Floras 50 SC preparation and 0.0000020 g/kg of Florasulam.

### 5.2.1.3 Description of analytical methods for the determination of formulants (KCP 5.1.1)

With respect to toxicological, eco-toxicological or environmental aspects Floras 50 SC does not contain any relevant formulants. Therefore, a special analytical method and validation isn't needed.

### 5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

CIPAC method no. 616 is available for Florasulam.

### 5.2.2 Methods for the determination of residues (KCP 5.1.2)

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.

**Table 5.2-3: Validated methods for the generation of pre-authorization data.**

Component of residue definition: Florasulam only (provisionally) <sup>(a)</sup>				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
Plants, plant products. (Residues)	Primary	0.01 mg/kg	LC/MS/MS Recovery for m/z=360/129:84-100% for acidic crops (orange fruit, apple fruit), dry crops (corn grain, wheat grain), oil crops (soybean grain, canola seed), wet crops (whole tomato, potato tuber)	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Rodrigues Junior, A./2011+2014/110535
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS Recovery for m/z=360/109: 71-124% for acidic crops (orange fruit, apple fruit), dry crops (corn grain, wheat grain), oil crops (soybean grain, canola seed), wet crops (whole tomato, potato tuber)	
	Confirmatory ILV	0.01 mg/kg	LC/MS/MS Recovery: 81-86% for tomato and orange fruit	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Bacher, R./2011/110536
Animal products, food of animal origin. (Residues)	Primary	0.01 mg/kg	LC/MS/MS Recovery for m/z=360/129: 72-102% for bovine liver, milk, bovine fat and eggs.	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Bacher, R./2011/110540
	Confirmatory (if required)	0.01 mg/kg	Recovery for m/z=360/109 : 71-103% for bovine liver, milk, bovine fat and eggs.	
	Confirmatory ILV	0.01 mg/kg	LC/MS/MS Recovery: 81-86% for milk, bovine, eggs (recovery: 72-105%)	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Robaugh, D. A./2011+2014/110541
Soil. (Environmental fate)	Primary	0.05 µg/kg	LC/MS/MS Recovery for florasulam for m/z=358/167: 73-83% and for m/z=358/152 as a confirmation transition: 74-94% Recovery for 5-OH florasulam for m/z=344/324: 86-99% and for m/z= 344/104 as a confirmation transition: 86-100%	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Bacher, R./2011/110537
	Confirmatory (if required)			
Water (drinking water, ground water, surface water)	Primary	0.05 µg/L	LC/MS/MS Recovery for florasulam m/z=358/167: 92-104% and recovery for m/z=358/152 as a confirmation transition: 92-104%. Recovery for 5-OH florasulam for	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Class, T./2011/110538
	Confirmatory (if required)			

Component of residue definition: Florasulam only (provisionally) <sup>(a)</sup>				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
			m/z=344/324: 98-104% and for m/z=344/104 as a confirmation transition: 97-105% (surface water, ground water, drinking water)	
	Confirmatory ILV	0.05 µg/L	LC/MS/MS For surface water, ground water, drinking water (florasulam recovery for m/z 358/167: 100-104% and for m/z 358/152: 94-104%, and for 5-OH florasulam recovery for m/z 344/324: 99-109% and for m/z 344/104: 88-104%)	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Souza, N./2011/110539
Body fluids. (Toxicology)	Primary	0.05 mg/L	LC/MS/MS Florasulam recovery for m/z 360/129: 94-99% and for m/z 360/109: 93-101% for body fluids	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Class, T./2011/110283
	Confirmatory (if required)			
Air. (Exposure)	Primary	1.3 µg/m <sup>3</sup>	LC/MS/MS Recovery for florasulam for m/z 360/129: 76-110% and for m/z 360/120: 75-109%	EFSA Conclusion 2015; 13(1):3984 + RAR florasulam Class, T./2011/110282
	Confirmatory (if required)			

(a) The EFSA conclusion (EFSA, 2015) on the plant and animal residue definitions for risk assessment are given as data gaps as it was not possible to conclude if a metabolite detected in some livestock feed items could present a risk to consumers via transfer through animal commodities. Until this data gap has been further evaluated, the definition of residue in plants and animals for risk assessment agreed in the original DAR (Belgium, 1999) remains applicable.

## 5.3 Methods for post-authorization control and monitoring purposes (KCP 5.2)

### 5.3.1 Analysis of the plant protection product (KCP 5.2)

Analytical methods for the determination of the active substance and relevant impurities in the plant protection product shall be submitted, unless the applicant shows that these methods already submitted in accordance with the requirements set out in point 5.2.1 can be applied.

### 5.3.2 Description of analytical methods for the determination of residues of Active substances (KCP 5.2).

#### 5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Reports (incl. its addenda) the current legal residue definition is identical.

**Table 5.3-1: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required**

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high protein/high starch content (dry commodities)  Wheat Barley	Florasulam	0.01 mg/kg 0.01 mg/kg	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
Plant, high water content	Florasulam	0.01 mg/kg	Reg. (EU) 2022/1363
Plant, high acid content		0.01 mg/kg	
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	
Plant, high oil content		0.01 mg/kg	
Plant, difficult matrices (hops, spices, tea)		0.01 mg/kg	
Muscle	Florasulam	0.01 mg/kg	Reg. (EU) 2022/1363
Milk		0.01 mg/kg	
Eggs		0.01 mg/kg	
Fat		0.01 mg/kg	
Liver, kidney		0.01 mg/kg	
Soil (Ecotoxicology)	Florasulam	0.05 mg/kg bw/day	AOEL
Drinking water (Human toxicology)	Florasulam	0.1 µg/L	general limit for drinking water SANTE/2020/12830, Rev.2 14. February 2023
Surface water (Ecotoxicology)	Florasulam	0.05 mg/L	DAR
Air	Florasulam	1.3 mg/m <sup>3</sup>	DAR
Tissue (meat or liver) Body fluids	Florasulam	0.05 mg/L	SANCO/825/00 rev. 8.1
		0.01 mg/L (body fluids)	SANTE/2020/12830, Rev.2 14. February 2023
		0.01 mg/kg (body tissues)	

### 5.3.2.2 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

An overview on the acceptable methods for analysis of Florasulam in plant matrices is given in the following tables. For more details please refer to the RAR of florasulam or to the EFSA conclusion of florasulam.

**Table 5.3-2. 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	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110536
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535
High acid content	Primary	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110536
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535
High oil content	Primary	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110536
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535
High protein/high starch content (dry)	Primary	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110536
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 + RAR of florasulam Rodrigues Junior, A./2011+2014/110535

**Table 5.3-3: Statement on extraction efficiency**

	Method for products of plant origin
Required, available from:	For the studies N° 110535 and N°110536 (RAR volume 4 of florasulam p.8), it is written: “For this method, no new extraction efficiency studies were conducted. Extraction was performed as previously reported in the two most recent methods developed for extraction of florasulam which both used a solution of acetone/water/acetic acid (80:19:1) for extraction. The data was described in 2 unpublished residue method of Dow AgroSciences LLC, 2000 and 2004”. Thanks to the findings of the recovery experiments for the method used in the Rodrigues study, it’s confirmed that the efficiency of extraction of florasulam from agricultural commodities is high.
Not required, because:	-

**zRMS comments:**

Analytical methods for monitoring of residues of florasulam in relevant plant matrices have previously been evaluated during evaluation of the active for approval.

In RAR (2013) RMS concluded that *Residues of florasulam are extracted from the sample matrices by homogenizing and shaking with an acetone:water:acetic acid (80:19:1) solution. The sample was analyzed by liquid chromatography with positive-ion electrospray ionization tandem mass spectrometry (LC-MS/MS). The method was validated over the concentration range of 0.01-1.0 mg/kg with a limit of quantification (LOQ) of 0.01 mg/kg, limit of determination (LOD) 0.003 mg/kg and with adequate recovery, linearity, specificity, repeatability. The analytical method was independently validated for the determination of florasulam in agricultural commodities.*

No further data are required for Floras 50 SC.

### 5.3.2.3 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

An overview on the acceptable methods for active substances in animal matrices is given in the following table.

**Table 5.3-4: Validated methods for food and feed of animal origin**

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	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Robaugh, D. A./2011+2014/110541
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
Eggs	Primary	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Robaugh, D. A./2011+2014/110541
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
Muscle	Primary	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Robaugh, D. A./2011+2014/110541
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
Fat	Primary	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Robaugh, D. A./2011+2014/110541
	Confirmatory (if required)	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
Kidney, liver	Primary	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Bacher, R./2011/110540
	ILV	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Robaugh, D. A./2011+2014/110541
	Confirmatory	0.01 mg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984



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
	(if required)			Bacher, R./2011/110540

**Table 5.3-5: Statement on extraction efficiency**

	Method for products of animal origin
Required, available from:	<p>RAR of florasulam volume 4</p> <p>For the study N°110540:</p> <p>Florasulam was extracted from samples of egg, bovine meat, liver and kidney by ethyl acetate then transferred into dilute acid after drying and cleaned-up.</p> <p>Florasulam is extracted from rendered bovine fat by ethyl acetate, transferred to hexane after evaporating off the ethyl acetate and partitioned into acetonitrile.</p> <p>For the study N°110541:</p> <p>Florasulam was extracted from samples of egg, bovine meat, liver and kidney by homogenizing with ethyl acetate/ethanol (v/v). The samples was then centrifuged, evaporated and reconstituted with hydrochloric acid and cleaned-up.</p> <p>Florasulam is extracted from rendered bovine fat by homogenizing with ethyl acetate/ethanol (v/v), centrifuged and transferred to hexane after evaporating off the ethyl acetate and partitioned into acetonitrile</p>
Not required, because:	-

**zRMS comments:**

Analytical methods for monitoring of residues of florasulam in relevant animal matrices have previously been evaluated during evaluation of the active for approval.

In RAR (2013) RMS concluded that *The analytical methods were developed and validated for the determination of florasulam in animal matrices (exemplified by milk, egg, bovine meat, liver, kidney and fat) using liquid chromatography with mass selective detection (LC/MS/MS) and they have been demonstrated to be suitable for their intended purpose. The methods were validated with adequate recovery, linearity, specificity, repeatability, and with a limit of quantitation (LOQ) of 0.01 mg/kg and limit of detection (LOD) 0.003 mg/kg.*

No further data are required for Floras 50 SC.

#### 5.3.2.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods for active substances in animal matrices is given in the following table.

**Table 5.3-6: Validated methods for soil**

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	LC/MS/MS	EFSA Conclusion 2015;
Confirmatory			13(1):3984 Bacher, R./2011/110537

For any special comments or remarkable points concerning the analytical methods for soil please refer to Appendix 2.

**zRMS comments:**

Analytical methods for monitoring of residues of florasulam in soil matrices have previously been evaluated during evaluation of the active for approval.

In RAR (2013) RMS concluded that *The residue definition for monitoring purposes and risk assessment for*

*florasulam in soil has been established as a florasulam. The analytical methods described in this document determine residues of florasulam and its 5-OH metabolite in soil.*

*The principle of the method was based on the chemical analysis methods for determination of florasulam and its metabolite 5-OH using LC/MS/MS described in the DAR. The method has been modified and validated to meet the new requirements from the EC Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1.*

*The analytical method was independently successfully validated for the determination of florasulam and its metabolite 5-OH florasulam in soil using liquid chromatography with mass selective detection (LC/MS/MS) and it has been demonstrated to be suitable for its intended purpose. The method was validated with adequate recovery, linearity, specificity, repeatability, and with a limit of quantitation (LOQ) of 0.05 µg/kg and an estimated limit of detection (LOD) of at least 0.015 µg/kg per analyte.*

No further data are required for Floras 50 SC.

### 5.3.2.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods for active substances in animal matrices is given in the following table.

**Table 5.3-7: Validated methods for water**

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/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Class, T./2011/110538
	Confirmatory			
	ILV	0.05 µg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Souza, N./2011/110539
Surface water	Primary	0.05 µg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Class, T./2011/110538
	Confirmatory			
	ILV	0.05 µg/kg	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Souza, N./2011/110539

For any special comments or remarkable points concerning the analytical methods for water please refer to Appendix 2.

#### **zRMS comments:**

Analytical methods for monitoring of residues of florasulam in water have previously been evaluated during evaluation of the active for approval.

In RAR (2013) RMS concluded that *The residue definition for monitoring purposes and risk assessment for florasulam in water has been established as a florasulam. The analytical methods described in this document determine residues of florasulam and its 5-OH metabolite in surface water, ground water and drinking water.*

*The principle of this method was based on the chemical analysis methods for determination of florasulam and its metabolite 5-OH using HPLC with UV detection (260 nm) described in the DAR. The method has been modified, ia by using new equipment – LC/MS/MS, and validated to meet the new requirements from the EC Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1.*

*The revised analytical method for drinking water, ground water and surface water was validated at the levels of 0.05 µg/L (LOQ) and 0.50 µg/L (10xLOQ) for determination of florasulam and its 5-OH metabolite. The limit of quantification (LOQ) of the method was 0.05 µg/L per analyte and the limit of detection (LOD) is estimated (based on the lowest calibration concentration) to be about 0.015 µg/L (about 30 % of the LOQ). The method was successfully validated and thus demonstrated to be applicable for enforcement and monitoring purposes. This method for drinking water, ground water and surface water was also successfully validated by the independent laboratory.*

No further data are required for Floras 50 SC.

### 5.3.2.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods for active substances in animal matrices is given in the following table.

**Table 5.3-8: Validated methods for air**

Component of residue definition: Florasulam			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	1.3 µg/m <sup>3</sup>	LC/MS/MS	EFSA Conclusion 2015; 13(1):3984 Class, T./2011/110282
Confirmatory			

For any special comments or remarkable points concerning the analytical methods for air it is referred to Appendix 2.

**zRMS comments:**

Analytical methods for monitoring of residues of florasulam in air have previously been evaluated during evaluation of the active for approval.

In RAR (2013) RMS concluded that *The residue definition for monitoring purposes and risk assessment for florasulam in air has been established as florasulam only.*

*Air sampling used adsorption tubes and final determination of florasulam was performed by LC-MS/MS. The analytical method was developed and validated for the determination of florasulam in air with a limit of quantitation (LOQ) of 1.5 µg/m<sup>3</sup>. The limit of detection (LOD) was demonstrated on ≤ 0.3 µg/m<sup>3</sup> (i.e. ≤ 20% of the LOQ).*

EFSA w EFSA Journal 2015; 13(1):3984 provides different a limit of quantitation (LOQ) of 1.3 µg/m<sup>3</sup> for air.

No further data are required for Floras 50 SC.

### 5.3.2.7 Description of methods for the analysis of body fluids and tissues (KCP 5.2)

An overview on the acceptable methods for active substances in animal matrices is given in the following table.

**Table 5.3-9: Methods for body fluids and tissues**

Substance	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Florasulam	0.05 mg/L	LC/MS/MS	Class, T., 2011 / EU Agreed

For any special comments or remarkable points concerning the analytical methods for body fluids and tissues please refer to Appendix 2.

**zRMS comments:**

Analytical methods for monitoring of residues of florasulam in body fluids have previously been evaluated during evaluation of the active for approval.

In RAR (2013) RMS concluded that *The residue definition for determination of florasulam residues in body fluids and tissues is as florasulam only.*

*For analysis of florasulam in extracts from body fluids by LC/MS/MS, calibration functions were established by injecting calibration solutions (ranging from 0.020 to 0.125 ng/mL, minimum 5 levels) interspersed with final specimen extracts. Analytical methods were developed and validated for the determination of florasulam in body fluids (whole blood and urine) with a limit of quantitation (LOQ) of 0.05 mg/L.*

**Remark:**

According to the SANTE/2020/12830, Rev.2, 24. February 2023 an analytical method for the determination of residues in body fluids for enforcement/monitoring purposes is required with lower LOQ equals 0.01 mg/L. RMS-PL considers that this data gap is anticipated to be addressed at active substance level in context with the renewal of florasulam and will be subject of the art.43 re-authorisation process for the product.

### **5.3.2.8 Other studies/ information**

No other studies or information.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
5.2.1.1/01 5.2.1.1/02	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.

### 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 4.2.3_1	Cathie, C.	2009	Analytical Method and Validation for the Determination of Florasulam in Florasulam Technical Grade Active Ingredient Dow AgroSciences DAS Report No.: DAS-AM-G-09-16 (Accession Number) 2002576 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.2.3_2	Knowles, S.	1997	Development and Validation of Analytical Method EU-AM-97-001 for the Determination of the Active Ingredient Content in Technical Grade XDE-570 Dow AgroSciences DAS Report No.: GHE-P-6651 (Accession Number) 62227 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.3_1	Rodrigues Junior, A.	2011 Amended 2014	Residue Method Validation for the Determination of Florasulam in Agricultural Commodities Dow AgroSciences DAS Report No.: 110535 (Accession Number) 2009969 GLP/GEP (Y/N): Y	N	DAS

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
			Published (Y/N): N		
CA 4.3_2	Bacher, R.	2011a	Florasulam: Independent Laboratory Validation of a Residue Method for the Determination of Florasulam in Agricultural Commodities PTRL Europe GmbH DAS Report No.: 110536 (Accession Number) 2011200 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.3_3	Lindner, M.	2011	Examination of the Applicability of the Modular Analytical Method L 00.00-34 for the Determination of Residues of Florasulam Eurofins Agrosciences Services Chem GmbH DAS Report No.: 110671 (Accession Number) 2011133 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.4	Bacher, R.	2011b	Method Validation Study for the Determination of Residues of Florasulam and its 5-OH Metabolite in Soil by Liquid Chromatography with Tandem Mass Spectrometry PTRL Europe GmbH DAS Report No.: 110537 (Accession Number) 2011131 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.5_1	Class, T.	2011a	Method Validation Study for the Determination of Residues of Florasulam and its 5 OH Metabolite in Surface Water, Ground Water and Drinking Water by Liquid Chromatography with Tandem Mass Spectrometry PTRL Europe GmbH DAS Report No.: 110538 (Accession Number) 2011132 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.5_2	Souza, N.	2011	Independent Laboratory Validation of Dow AgroSciences LLC Method - Determination of Residues of Florasulam and its 5 OH Metabolite in Drinking Water, Ground Water and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection Dow AgroSciences DAS Report No.: 110539 (Accession Number) 2010315 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.7	Class, T.	2011b	Development and Validation of a Method for the Analysis of Florasulam in Air PTRL Europe GmbH	N	DAS

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			DAS Report No.: 110282 (Accession Number) 2011198 GLP/GEP (Y/N): Y Published (Y/N): N		
CA 4.8_1	Bacher, R.	2011c	Method Validation Study for the Determination of Residues of Florasulam in Foodstuffs of Animal Origin by Liquid Chromatography with Tandem Mass Spectrometry PTRL Europe GmbH, Helmholtzstr DAS Report No.: 110540 (Accession Number) 2009882 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.8_2	Robaugh, D. A.	2011	Independent Laboratory Validation Study for the determination of Residues of Florasulam in Bovine and Poultry Tissues by Liquid Chromatography with Tandem Mass Spectrometry Pyxant Labs Inc DAS Report No.: 110541 (Accession Number) 2011453 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CA 4.8_3	Class, T., Göcer, M.	2011	Florasulam: Development of an Analytical Method for the Determination of Florasulam in Body Fluid(s) PTRL Europe GmbH DAS Report No.: 110283 (Accession Number) 2011127 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS

## **Appendix 2 Detailed evaluation of submitted analytical methods**

### **A 2.1 Analytical methods for active substances.**

#### **A 2.1.1 Methods used for the generation of pre-authorization data (KCP 5.1)**

No new study have been submitted.

#### **A 2.1.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)**

##### **A 2.1.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)**

New study have been submitted.

##### **A 2.1.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)**

No new or additional studies have been submitted.

##### **A 2.1.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)**

No new or additional studies have been submitted.

##### **A 2.1.2.4 Description of Methods for the Analysis of Water (KCP 5.2)**

No new or additional studies have been submitted.

##### **A 2.1.2.5 Description of Methods for the Analysis of Air (KCP 5.2)**

No new or additional studies have been submitted.

##### **A 2.1.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)**

No new or additional studies have been submitted.

##### **A 2.1.2.7 A.2.A.9 Other Studies/ Information**

No new or additional studies have been submitted.