

FINAL REGISTRATION REPORT

Part B

Section 5

Analytical Methods

Detailed summary of the risk assessment

Product code: CHR/H/FDF 574 SC

Product name(s): Cezaro 574 SC/Huron 574 SC

Chemical active substance(s):

Florasulam, 12 g/L

Diflufenican, 250 g/L

Flufenacet, 312 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: November 2021

MS Finalisation date: 21/11/2022

CHR/H/FDF 574 SC/Cezaro 574 Sc, Huron 574 SC
Part B – Section 5 - Core Assessment
zRMS version

Version history

When	What
March 2022	Dossier sent for evaluation
September 2022	zRMS evaluation of dRR
November 2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

5 Analytical methods

In the following document, data for active substances - diflufenican and flufenacet - was described during its inclusion on Annex 1 process in respectively 2009 and 2004 . Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.

Data matching studies for florasulam have been evaluated by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/H/FDF 574 SC INN VIGO is allowed to refer to EU approved reports

5.1 Conclusion and summary of assessment

Sufficiently sensitive and selective analytical methods are ~~not~~ available for the active substance(s) and relevant impurities in the plant protection product.

Noticed data gaps are: none

- data-gap-1
- data-gap-2
- data-gap-3

The document was not rewritten by the evaluator. The evaluator text is on grey background.

Sufficiently sensitive and selective analytical methods – in the context of the authorisation request - are available for all analytes included in the residue definitions. They were accepted previously on EU level.

Noticed data gaps in the context of the authorisation request are: none

Commodity/crop	Supported/ Not supported
Cereals	Supported

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)

An overview on the acceptable methods and possible data gaps for analysis of Florasulam, Diflufenican and Flufenacet in plant protection product is provided as follows:

Comments of zRMS:	The method is accepted and may be applied for analysing all the active substances in the PPP. Furthermore, its linearities ranges allow to use the method in the efficiency of the cleaning process and suspensibility testing in the physicochemical section as well.
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Reference:	KCP 5.1.1/01
Report	Validation of analytical method for CHR/H/FDF 574 SC for determination of florasulam, flufenacet and diflufenican and impurity 2,6-difluoroaniline.; Study code: ICB/109/2020, I. Knapik, 2021
Guideline(s):	SANCO/3030/99 rev.5 22/03/19
Deviations:	No
GLP:	Yes
Acceptability:	yes

Materials and methods

Validation - Results and discussions

Table 5.2-1: Methods suitable for the determination of active substances Florasulam, Diflufenican, Flufenacet in plant protection product CHR/H/PENDIF 599.5 SC

	Florasulam	Diflufnican	Flufenacet		
Author(s), year	I. Knapik , 2021				
Principle of method	HPLC-DAD				
Results for primary chromatographic system.					
Active ingredient		Linearity			
florasulam		R ² =0.9999650			
flufenacet		R ² =0.9999249			
diflufenican		R ² =0.9999731			
Validation level	Active ingredient	Precision [%]	Horwitz ratio	Recovery [%]	Standard addition [%]
100% without standard addition	florasulam	0.50	0.19	-	-
100% with standard addition (20-30%)	florasulam	-	-	96.88-107.47	25.52
LOQ	florasulam	1.08	0.33	100.6 (average)	-
ULOQ	florasulam	0.32	0.13	101.1 (average)	-
100% without standard addition	flufenacet	0.39	0.24	-	-
100% with standard addition (20-30%)	flufenacet	-	-	99.30-102.91	24.07
LOQ	flufenacet	2.12	0.64	106.9 (average)	-
ULOQ	flufenacet	1.10	0.47	102.3 (average)	-

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100% without standard addition	flufenacet	0.21	0.13	-	-
100% with standard addition (20-30%)	flufenacet	-	-	98.44-102.46	24.00
LOQ	flufenacet	0.63	0.19	104.3 (average)	-
ULOQ	flufenacet	0.49	0.21	102.4 (average)	-
100% without standard addition	diflufenican	1.24	0.73	-	-
100% with standard addition (20-30%)	diflufenican	-	-	97.14-102.30	20.35
LOQ	diflufenican	2.16	0.65	102.8 (average)	-
ULOQ	diflufenican	0.51	0.21	101.9 (average)	-

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100% without standard addition	diflufenican	1.17	0.69	-	-
100% with standard addition (20-30%)	diflufenican	-	-	97.56-101.62	20.48
LOQ	diflufenican	1.32	0.40	102.9 (average)	-
ULOQ	diflufenican	1.05	0.44	98.0 (average)	-

Results for secondary chromatographic system.

Active ingredient	Linearity
florasulam	$R^2=0.9998250$
flufenacet	$R^2=0.9999604$
diflufenican	$R^2=0.9999822$

Validation level	Active ingredient	Precision [%]	Horwitz ratio	Recovery [%]	Standard addition [%]
100% without standard addition	florasulam	0.65	0.24	-	-
100% with standard addition (20-30%)	florasulam	-	-	93.67-99.43	25.00
LOQ	florasulam	1.14	0.35	102.4 (average)	-
ULOQ	florasulam	0.33	0.13	104.1 (average)	-

Conclusion

It was confirmed that the method is specific. There were no peaks from placebo interfering with determined compounds. The validation parameters (specificity, linearity, instrument precision, re-peatability, accuracy and LOQ) are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev.5.

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

An overview on the acceptable methods and possible data gaps for analysis of relevant impurities in plant protection product is provided as follows:

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Comments of zRMS:	The method is accepted for analysing the impurity.
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Reference:	KCP 5.1.1/01
Report	Validation of analytical method for CHR/H/FDF 574 SC for determination of florasulam, flufenacet and diflufenican and impurity 2,6-difluoroaniline.; Study code: ICB/109/2020, I. Knapik, 2021
Guideline(s):	SANCO/3030/99 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Validation - Results and discussions

Table 5.2-2: Methods suitable for the determination of the relevant impurities in plant protection product (PPP) CHR/H/PENDIF 599.5 SC

	Bis-CHYMP max. 0.1 g/kg
Author(s), year	I. Knapik, 2021
Principle of method	HPLC-DAD

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Results for primary chromatographic system.					
Impurity			Linearity		
2,6-difluoroaniline			R ² =0.9995901		
Validation level	Impurity	Precision [%]	Horwitz ratio	Recovery [%]	Standard addition [%]
100% without standard addition	2,6-difluoroaniline	0.62	0.08	-	-
100% with standard addition (20-30%)	2,6-difluoroaniline	-	-	72.63-93.60	26.82
LOQ	2,6-difluoroaniline	1.58	0.19	98.6 (average)	-
Results for secondary chromatographic system.					
Impurity			Linearity		
2,6-difluoroaniline			R ² =0.9996292		
Validation level	Impurity	Precision [%]	Horwitz ratio	Recovery [%]	Standard addition [%]
100% without standard addition	2,6-difluoroaniline	1.65	0.21	-	-
100% with standard addition (20-30%)	2,6-difluoroaniline	-	-	76.49-97.60	26.30
LOQ	2,6-difluoroaniline	1.45	0.17	96.3 (average)	-

Conclusion

It was confirmed that the method is specific. There were no peaks from placebo interfering with determined compounds. The validation parameters (specificity, linearity, instrument precision, repeatability, accuracy and LOQ) are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev.5.

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

Please refer to PART C – Confidential data.

5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

Analytical methods for determination of florasulam impurities and relevance of CIPAC methods in CHR/H/PENDIF 599.5 SC were not evaluated as part of the EU review. Therefore, all relevant data are provided and are considered adequate.

5.2.2 Methods for the determination of residues (KCP 5.1.2)

An overview on the acceptable methods and possible data gaps for analysis of residues of florasulam, diflufenican and flufenacet for the generation of pre-authorization data is given in the following table.

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

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
Plants, plant products,... (Residues)	Primary	0.01 mg/kg	LC/MS/MS	Rodrigues Junior, A. (2011) B.5.2.1.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis Bacher, R.. (2011) B.5.2.1.1b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Foodstuff of animal origin (Residues)	Primary	0.01 mg/kg	LC/MS/MS	Bacher, R. (2011) B.5.2.2.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis Robaugh David A.. (2012) B.5.2.2.1b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis Lindner, M. (2011) B.5.2.2.1c, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Soil (Environmental fate)	Primary	0.05 µg/kg	LC/MS/MS	Bacher, R.. (2011) B.5.3.1.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Water (Surface Water,	Primary	0.05 mg/L	LC/MS/MS	Class, T.. (2011) B.5.3.2.1a, RAR, Florasulam -

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
Ground Water and Drinking Water)				Volume 3, Annex B.5: Methods of analysis Souza, N.. (2011) B.5.3.2.1b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Air (Exposure)	Primary	1.5 µg/m ³	LC/MS/MS	Class, T (2011) B.5.3.3.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Body fluids and tissue (Exposure)	Primary	0.05 mg/L	LC/MS/MS	Class, T., Gocer, M. (2011) B.5.4.2a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Soil, water (Ecotoxicology)	Primary	All data was evaluated during Annex I inclusion , and no new studies are necessary. All methods are described separately in RAR Vol3 B8 Ecotoxicology 2013. Please refer to the DAR 2013. No general analytical methods were developed for risk assessment apart those reported as specific in studies in support of ecotoxicological studies.		
	Confirmatory (if required)			

Table 5.2-4: Validated methods for the generation of pre-authorization data

Component of residue definition: diflufenican				
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,...	Primary	0.01 mg/kg		Bacher,R.. (2002)
	Confirmatory (if required)	Not required		
Animal products, food of animal origin,...	Primary	0.01 mg/kg	GC-MS	Klumpp M, 2002
	Confirmatory (if required)	Not required		
Soil	Primary	0.002 mg/kg	GC-MS	Doran A.M., McGuire G.M., 2002
	Confirmatory (if required)	Not required		

Component of residue definition: diflufenican				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
Water	Primary	0.05 mg/kg	LC-MS/MS	Bacher R. (2002)
	Confirmatory (if required)			
Air	Primary	0.04 µg/m ³	GC-MSD	Bacher R., 2002
	Confirmatory (if required)			
Body fluids,	Primary	Not required. The active ingredient is not classified as toxic or highly toxic.		
	Confirmatory (if required)			

Table 5.2-5: Validated methods for the generation of pre-authorization data

Component of residue definition: Flufenacet				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
Food/feed of plant origin (Residues)	Primary	0.05 mg/kg	GC-MS	Seym 1994 and 1995a, II A 4.2.1, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory	Not required		
Animal products, food of animal origin (Residues)	Primary	0.01 mg/kg-0.01 mg.kg	GC-MS	Seym 1994 and 1995a, II A 4.2.2, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory (if required)	Not required		
Soil (Environmental fate)	Primary	0.01 mg/kg	HPLC-MS-MS	Almendinger, H., Bachlechner, G.(1994) II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory (if required)	Not required		
Water (surface, ground and drinking water) (Environmental fate)	Primary	0.05 µg/L	GC-ECD	Konig, T 1996., II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory (if required)	0.04 µg/L	LC-ESI-MS-MS	Bethem, R.A., Peterson R.G., Leimkuhler, W., Mattern, G.C

Component of residue definition: Flufenacet				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
				1995., II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
Air (Environmental fate)	Primary	2.2µg/m ³	HPLC-UV	Riegner.K,1995 II A 4.2.2 to 4.2.4, IIIA 5.2 DAR DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory (if required)	N/A		
Feed, body fluids,... (Toxicology)	Primary	No data submitted or required as Flufenacet is not classified as toxic or very toxic		
	Confirmatory (if required)			
Body fluids, air, (Exposure)	Primary	No data submitted or required as flufenacet is not classified as toxic or very toxic		
	Confirmatory (if required)			
Soil, water. (Ecotoxicology)	Primary	All data was evaluated during Annex I inclusion , and no new studies are necessary. All methods are described separately in DAR Vol3 B8 Ecotoxicology 1997. Please refer to the DAR 1997. No general analytical methods were developed for risk assessment apart those reported as specific in studies in support of ecotoxicological studies.		
	Confirmatory (if required)			

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

Data provided on Annex I inclusion is sufficient for post-authorizations methods. All data is de-scribed in EU approved documents for :

- RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis (2013)
- - DAR, Diflufenican - Volume 3, Annex B.5: Methods of analysis
- DAR, Flufenacet - Volume 3, Annex B.5: Methods of analysis

Methods are described and presented in Table 5.2-3 in point KCP 5.1.2.

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 florasulam (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of relevant impurities in plant protection product is provided as follows:

Reference: KCP 5.2

Report Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100

	OD or FLOT 150 WG and Adjuvant Super in wheat at 4 sites in Northern Europe 2016, J. Semrau, EAS Study Code S16-02449,
Guideline(s):	SANCO /3029 /99 rev.4.
Deviations:	NO
GLP:	YES
Acceptability:	YES

Materials and methods

The analytical methods multi-residue QuEChERS for the determination of residues of florasulam in wheat (whole plant, grain and straw) was validated according to SANCO/3029/99, rev. 4 within this analytical phase of this study. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical methods was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at each 0.003 mg/kg (30 % of the LOQ). No residues above 30% of the LOQ were detected in the control (untreated) test portions used for recovery determination. All mean recovery values at fortification levels of 0.01 mg/kg (LOQ) and 0.1 mg/kg (10x LOQ) comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev 4, with the evaluation of two mass transitions.

Validation - Results and discussions

Table 5.3-1: Methods suitable for the determination of the residues in plant protection product (PPP) CHR/H/FLO 100 SC

	Residues
Author(s), year	J.Semrau, 2016
Principle of method	LC MS/MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	The linearity of the detector response was demonstrated by single determination of matrix-matched and solvent calibration standards at a minimum of five concentration levels ranging from 0.30 ng/ml to 100 ng/ml for determination of all analytes in wheat (whole plant) and for the determination of florasulam in wheat (grain). This range corresponds to a fortification level of 0.003 mg/kg to 1.0 mg/kg and thus covers the range from no more than 30% of the LOQ and at least +20% of the highest analyte concentration detected in any (diluted) specimen extract. The calibration curves obtained for both mass transitions for each analyte were linear with coefficients of determination ($R^2 \geq 0.980$). Linear regression was performed without any weighting. Representative linear regression curve(s) are below.

	<div>Residues</div> <div></div>																		
Quantification	<p>Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The average response factor was used for calculation of the analyte concentrations. The relative standard deviation of the average re-sponse factor was lower or equal to 20 %.</p> <p>If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range. Diluted sample extracts (at least by a factor of 10) were quantified using solvent calibration standards instead of matrix-matched calibration standards.</p>																		
Selectivity	<p>The analytes were determined in the final specimen extracts by use of LC MS/MS detection.</p> <p>For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantifi-cation of specimens. Untreated samples for accompanying control sample work up, for determination of (procedural) recoveries and, if needed, for preparation of matrix-matched standards originated from the current study. At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention times of the analytes.</p> <p>Correction for blank values was not performed.</p>																		
Matrix Effects	<p>The effect of wheat (whole, plant, grain and straw) on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards with solvent standards at identical concentrations. During validation of the methods following matrix effects were determined:</p> <table><tr><th rowspan="2">Matrix / Com- modity</th><th rowspan="2">Stand- ard Con- centra- tion (ng/mL)</th><th colspan="2">Matrix Effect for Flo- rasulam (%)</th></tr><tr><th>Quantifi- cation (358→167 m/z)</th><th>Confir- mation (358→152 m/z)</th></tr><tr><td>Wheat (whole plant)</td><td>1 - 50</td><td>(+) 4.6</td><td>(+) 6.1</td></tr><tr><td>Wheat (grain)</td><td>1 - 50</td><td>(+) 2.1</td><td>(+) 1.7</td></tr><tr><td>Wheat (straw)</td><td>1 - 50</td><td>(-) 7.4</td><td>(-) 3.8</td></tr></table>	Matrix / Com- modity	Stand- ard Con- centra- tion (ng/mL)	Matrix Effect for Flo- rasulam (%)		Quantifi- cation (358→167 m/z)	Confir- mation (358→152 m/z)	Wheat (whole plant)	1 - 50	(+) 4.6	(+) 6.1	Wheat (grain)	1 - 50	(+) 2.1	(+) 1.7	Wheat (straw)	1 - 50	(-) 7.4	(-) 3.8
Matrix / Com- modity	Stand- ard Con- centra- tion (ng/mL)			Matrix Effect for Flo- rasulam (%)															
		Quantifi- cation (358→167 m/z)	Confir- mation (358→152 m/z)																
Wheat (whole plant)	1 - 50	(+) 4.6	(+) 6.1																
Wheat (grain)	1 - 50	(+) 2.1	(+) 1.7																
Wheat (straw)	1 - 50	(-) 7.4	(-) 3.8																

	Residues
	<p>Matrix effects were < 20 % for Florasulam in wheat (whole plant, grain and straw), the matrix effect were deemed insignificant. Therefore solvent standards were used for quantification.</p> <p>Matrix effects were once again tested during the analysis of the field samples to determine the actually conditions of mass spectrometer system. Matrix effects were < 20 % for Florasulam and in wheat (whole plant) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification of field samples.</p>
LOQ	The limit of quantification (LOQ) was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg
Comment	The validation parameters are within the acceptance range and fulfil EU requirements given in SANCO/3029/99 rev.4.

Conclusion

The method was successfully validated for determination of all analytes in all matrices with an LOQ of 0.01 mg/kg according to the guidance document(s) SANCO /3029 /99 rev.4. With regard to selectivity, accuracy and precision, the analytical methods were applied successfully for each analytical set when analysing the specimens of the study,

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 Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-2: 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 water content	Florasualm	LOQ 0.01 mg/kg	RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
Plant, high acid content		LOQ 0.01 mg/kg	
Plant, high protein/high starch content (dry commodities)		LOQ 0.01 mg/kg	
Plant, high oil content		LOQ 0.01 mg/kg	
Muscle	Florasulam	LOQ 0.01 mg/kg	RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
Milk		LOQ 0.01 mg/kg	
Eggs		LOQ 0.01 mg/kg	
Fat		LOQ 0.01 mg/kg	

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
			analysis
Liver, kidney		LOQ 0.01 mg/kg	RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
Soil (Ecotoxicology)	Florasulam, 5-OH Florasulam	0.05 µg/kg	RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
Drinking water (Human toxicology)	Florasulam, 5-OH Florasulam	0.1 µg/L	general limit for drinking water
Surface water (Ecotoxicology)	Florasulam, 5-OH Florasulam	1.18 µg a.s./L	EFSA Journal 2015; 13(1): 3984
Air	Florasulam	1.5 µg/m ³	AOEL sys/AOEL inhal: 0.05 mg/kg bw/d
Tissue (meat or liver)	Florasulam	LOQ 0.01 mg/kg	notclassified as T / T+
Body fluids		0.05 mg/L	notclassified as T / T+

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 and possible data gaps for analysis of Florasulam in plant matrices is given in the following tables.

Table 5.3-3: 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) B.5.2.1.1.a RAR Florasulam - Volume 3 Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Bacher R. (2011) B.5.2.1.1b RAR Florasulam - Volume 3 Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
High acid content	Primary	0.01 mg/kg	LC/MS/MS	Rodrigues Junior A. (2011) B.5.2.1.1.a RAR Florasulam - Volume 3 Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Bacher R. (2011) B.5.2.1.1b RAR Florasulam -

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
				Volume 3 Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
High oil content	Primary	0.01 mg/kg	LC/MS/MS	Rodrigues Junior A. (2011) B.5.2.1.1.a RAR Florasulam - Volume 3 Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Bacher, R. (2011) B.5.2.1.1b RAR Florasulam - Volume 3 Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
High protein/high starch content (dry)	Primary	0.01 mg/kg	LC/MS/MS	Rodrigues Junior A. (2011) B.5.2.1.1.a RAR Florasulam - Volume 3 Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Bacher R. (2011) B.5.2.1.1b RAR Florasulam - Volume 3 Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Difficult (if required, depends on intended use)	Primary	Not required		
	ILV			
	Confirmatory (if required)			

Table 5.3-4: Statement on extraction efficiency

	Method for products of plant origin
Not required, because:	Residues below LOQ

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 and possible data gaps for analysis of Florasulam in animal matrices is given in the following tables.

Table 5.3-5: 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) B.5.2.2.1.a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Robaugh David A.. (2012) B.5.2.2.1.b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Eggs	Primary	0.01 mg/kg	LC/MS/MS	Bacher, R. (2011) B.5.2.2.1.a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Robaugh David A.. (2012) B.5.2.2.1.b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Muscle	Primary	0.01 mg/kg	LC/MS/MS	Bacher, R. (2011) B.5.2.2.1.a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Robaugh David A.. (2012) B.5.2.2.1.b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Fat	Primary	0.01 mg/kg	LC/MS/MS	Bacher, R. (2011) B.5.2.2.1.a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Robaugh David A.. (2012) B.5.2.2.1.b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		
Kidney, liver	Primary	0.01 mg/kg	LC/MS/MS	Bacher, R. (2011) B.5.2.2.1.a, RAR, Florasulam - Volume 3, Annex B.5: Methods

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
				of analysis
	ILV	0.01 mg/kg	LC/MS/MS	Robaugh David A.. (2012) B.5.2.2.1.b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory (if required)	Not required		

Table 5.3-6: Statement on extraction efficiency

	Method for products of animal origin
Not required, because:	Residues below LOQ

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

An overview on the acceptable methods and possible data gaps for analysis of Florasulam in soil is given in the following tables.

Table 5.3-7: 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	LC/MS/MS	Bacher, R.. (2011) B.5.3.1.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
Confirmatory	Not required		

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

An overview on the acceptable methods and possible data gaps for analysis of Florasulam in surface and drinking water is given in the following tables.

Table 5.3-8: 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		Class, T.. (2011) B.5.3.2.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis

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
	ILV	0.05 µg/L		Souza, N.. (2011) B.5.3.2.1b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory	Not required		
Surface water	Primary	0.05 µg/L		Class, T.. (2011) B.5.3.2.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis Souza, N.. (2011) B.5.3.2.1b, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
	Confirmatory	Not required		

5.3.2.6 Description of methods for the analysis of air (KCP 5.2) Florasulam in air is given in the following tables.

Table 5.3-9: 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) B.5.3.3.1a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis
Confirmatory	Not required		

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

An overview on the acceptable methods and possible data gaps for analysis of Florasulam in body fluids and tissues is given in the following table.

Table 5.3-10: 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	LC/MS/MS	Class, T., Gocer, M. (2011) B.5.4.2a, RAR, Florasulam - Volume 3, Annex B.5: Methods of analysis

Component of residue definition: Florasulam			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Confirmatory	Not required		

5.3.2.8 Other studies/ information

Not required

5.3.3 Description of analytical methods for the determination of residues of diflufenican (KCP 5.2)

5.3.3.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is not identical.

Table 5.3-11: 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 water content	Diflufenican	0.01 mg/kg	Reg. (EU) 2017/623
Plant, high acid content		0.01 mg/kg	Reg. (EU) 2017/623
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	Reg. (EU) 2017/623
Plant, high oil content		0.01	Reg. (EU) 2017/623
Plant, difficult matrices (hops, spices, tea)		0.05 mg/kg	Reg. (EU) 2017/623
Muscle	Diflufenican	0.02 mg/kg	Reg. (EU) 2017/623
Milk		0.01 mg/kg	Reg. (EU) 2017/623
Eggs		0.02 mg/kg	Reg. (EU) 2017/623
Fat		0.02 mg/kg	Reg. (EU) 2017/623
Liver, kidney		0.02 mg/kg	Reg. (EU) 2017/623
Soil (Ecotoxicology)	Diflufenican	0.11 mg/kg	AOEL
Drinking water (Human toxicology)	Diflufenican	0.1 µg/L	general limit for drinking water
Surface water (Ecotoxicology)	Diflufenican	0.015 mg/L	lowest NOEC [EFSA Scientific Report (2007) 122]
Air	Diflufeniacn	0.051 µg/m ³	AOEL sys/AOEL inhal: 0.017 mg/kg bw/d
Tissue (meat or liver)	Diflufenican	Not required	notclassified as T / T+
Body fluids		Not required	notclassified as T / T+

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

An overview on the acceptable methods and possible data gaps for analysis of diflufenican in plant matrices is given in the following tables.

Table 5.3-12: 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: diflufenican				
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	GC-ECD	Bacher R. 2002
	ILV	0.01 mg/kg	GC-ECD	Thom M. 2003a
	Confirmatory (if required)	0.01 mg/kg	GC-MS	Bacher R. 2002g
High acid content	Primary	0.01 mg/kg	GC-ECD	Bacher R. 2002g
	ILV	0.01 mg/kg	GC-ECD	Thom M. 2003a
	Confirmatory (if required)	0.01 mg/kg	GC-MS	Bacher R. 2002g
High oil content	Primary	0.01 mg/kg	GC-ECD	Bacher R. 2002g
	ILV	0.01 mg/kg	GC-ECD	Thom M. 2003a
	Confirmatory (if required)	0.01 mg/kg	GC-MS	Bacher R. 2002g
High protein/high starch content (dry)	Primary	0.02 mg/kg	GC-ECD	Sharpe J.P. 1984b
	ILV	0.01 mg/kg	GC-ECD	Klumpp M. 2001a
	Confirmatory (if required)	0.01 mg/kg	GC-MS	Class T. 2001b

For any special comments or remarkable points concerning the analytical methods for the determination of residues in plant matrices, please refer to Appendix 2.

Table 5.3-13: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	DAR Diflufenican, Volume 3, Annex B.5
Not required, because:	

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

An overview on the acceptable methods and possible data gaps for analysis of diflufenican in animal matrices is given in the following tables.

Table 5.3-14: Validated methods for food and feed of animal origin (if appropriate)

Component of residue definition: diflufenican				
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	GC-MS	(Class T. 1999c)
	ILV	0.01 mg/kg	GC-MS	Klumpp, M. 2002a
	Confirmatory (if required)	Not required		
Eggs	Primary	0.02 mg/kg	GC-ECD	Guillet, M; Simonin, B. 1996
	ILV	0.02 mg/kg	GC-MS	Klumpp, M. 2002
	Confirmatory (if required)	Not required		
Muscle	Primary	0.02 mg/kg	GC-ECD	Guillet, M; Simonin, B. 1996
	ILV	0.02 mg/kg	GC-MS	Klumpp, M. 2002
	Confirmatory (if required)	0.02 mg/kg	GC-MS	Class T. 1999
Fat	Primary	0.02 mg/kg	GC-ECD	Guillet, M; Simonin, B. 1996
	ILV	0.02 mg/kg	GC-MS	Klumpp, M. 2002
	Confirmatory (if required)	Not required		
Kidney, liver	Primary	0.02 mg/kg	GC-ECD	Guillet, M; Simonin, B. 1996
	ILV	0.02 mg/kg	GC-MS	Klumpp, M. 2002
	Confirmatory (if required)	Not required		

For any special comments or remarkable points concerning the analytical methods for the determination of residues in animal matrices, please refer to Appendix 2.

Table 5.3-15: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	DAR Diflufenican, Volume 3, Annex B.5
Not required, because:	-

5.3.3.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of diflufenican in soil is given in the following tables.

Table 5.3-16: Validated methods for soil (if appropriate)

Component of residue definition: diflufenican			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.002 mg/kg	GC-MS	Doran A.M.; McGuire G.M. 2002
Confirmatory	0.002 mg/kg	LC-MS/MS	Bacher R. 2002

Table 5.3-17: Validated methods for soil (if appropriate)

Component of residue definition: AE B107137			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.002 mg/kg	GC-MS	Doran A.M.; McGuire G.M. 2002
Confirmatory	0.002 mg/kg	LC-MS/MS	Bacher R. 2002

Table 5.3-18: Validated methods for soil (if appropriate)

Component of residue definition: AE 0542291			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.002 mg/kg	GC-MS	Doran A.M.; McGuire G.M. 2002
Confirmatory	0.002 mg/kg	LC-MS/MS	Bacher R. 2002

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

5.3.3.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of diflufenican in surface and drinking water is given in the following tables.

Table 5.3-19: Validated methods for water (if appropriate)

Component of residue definition: diflufenican				
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	LC-MS-MS	Bacher, R. 2002
	ILV	-		
	Confirmatory	-		
Surface water	Primary	0.05 µg/L	LC-MS-MS	Bacher, R. 2002
	Confirmatory			

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

5.3.3.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of diflufenican in air is given in the following tables.

Table 5.3-20: Validated methods for air (if appropriate)

Component of residue definition: diflufenican			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.4 µg/m ³	LC-MS-MS	Bacher, R., 2002
Confirmatory			

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

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

Not required. The active substance is not classification like as toxic or very toxic.

5.3.3.8 Other studies/ information

Not required

5.3.4 Description of analytical methods for the determination of residues of flufenacet (KCP 5.2)

5.3.4.1 Overview of residue definitions and levels for which compliance is required

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

Table 5.3-21: 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) –cereals, maize	Flufenacet	LOQ 0.05 mg/kg	DAR (1997) Flufenacet Vol 3 B4
Muscle	Flufenacet	LOQ 0.05 mg/kg	DAR (1997) Flufenacet Vol 3 B4
Milk		LOQ 0.01 mg/kg	
Eggs		LOQ 0.05 mg/kg	
Fat, kidney		LOQ 0.05 mg/kg	
Liver,		LOQ 0.02 mg/kg	
Soil	Flufenacet, FOE 5043 alcohol, FOE 5043 oxalate, FOE 5043-sulfonic acid	LOQ 0.01 mg/kg	DAR (1997) Flufenacet Vol 3 B4
Water (drinking)	Flufenacet,	0.1 µg/L	general limit for drinking water

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Water (Surface) Ecotox	Flufenacet	2.04 µg/L (lowest endpoint from algae study)	7469/VI/98-Final 3 July 2003
Air	Flufenacet	2.2 µg/m ³	AOEL sys/AOEL inhal: 0.0032 mg/kg bw/d
Tissue (meat or liver)	Flufenacet	Not required	notclassified as T / T+
Body fluids		Not required	notclassified as T / T+

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

An overview on the acceptable methods and possible data gaps for analysis of Flufenacet in plant matrices is given in the following tables. For the detailed evaluation of additional studies it is referred to Appendix 2.

Table 5.3-22: 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: Flufenacet				
Matrix type	Method type	Method LOQ	Principle of method	Author(s), year / missing / EU agreed
High protein/high starch content (dry) High oil content High water content	Primary	0.02 mg/kg	GC-MS	Gould, T.J., Lemke V.J 1995 and Seym 1995a DAR (1997) Flufenacet Vol 3 B4
	ILV	0.02mg/kg	GC MS	Seym M 1994 DAR (1997) Flufenacet Vol 3 B4
	Confirmatory (if required)		Not required	

Table 5.3-23: Statement on extraction efficiency

	Method for products of plant origin
Not required,	Oxidation and hydrolysis

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

An overview on the acceptable methods and possible data gaps for analysis of Flufenacet in animal matrices is given in the following tables. For the detailed evaluation of additional studies it is re-ferred to Appendix 2.

Component of residue definition: Flufenacet				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Milk	Primary	LOQ 0.01 mg/kg		Gould, T.J., Zemke, V.J, K.L (1995) DAR (1997) Flufenacet Vol 3 B4

Component of residue definition: Flufenacet				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
	ILV	LOQ 0.05 mg/kg		Bajzik, M.E 1995 DAR (1997) Flufenacet Vol 3 B4
	Confirmatory (if required)	Not required		
Eggs	Primary	LOQ 0.05 mg/kg		Seym M. (1995) DAR (1997) Flufenacet Vol 3 B4
	ILV	LOQ 0.05 mg/kg		Bajzik, M.E 1995 DAR (1997) Flufenacet Vol 3 B4
	Confirmatory (if required)	Not required		
Muscle	Primary	LOQ 0.05 mg/kg		Gould, T.J., Zemke, V.J, K.L (1995) DAR (1997) Flufenacet Vol 3 B4
	ILV	LOQ 0.05 mg/kg		Bajzik, M.E 1995 DAR (1997) Flufenacet Vol 3 B4
	Confirmatory (if required)	Not required		
Fat	Primary	LOQ 0.05 mg/kg		Gould, T.J., Zemke, V.J, K.L (1995) DAR (1997) Flufenacet Vol 3 B4
	ILV	LOQ 0.05 mg/kg		Bajzik, M.E 1995 DAR (1997) Flufenacet Vol 3 B4
	Confirmatory (if required)	Not required		
Kidney	Primary	LOQ 0.05 mg/kg		Gould, T.J., Zemke, V.J, K.L (1995) DAR (1997) Flufenacet Vol 3 B4
	ILV	LOQ 0.05 mg/kg		Bajzik, M.E 1995 DAR (1997) Flufenacet Vol 3 B4
	Confirmatory (if required)	Not required		
Liver	Primary	LOQ 0.02 mg/kg		Gould, T.J., Zemke, V.J, K.L (1995) DAR (1997) Flufenacet Vol 3 B4
	ILV	LOQ 0.05 mg/kg		Bajzik, M.E 1995 DAR (1997) Flufenacet Vol 3 B4
	Confirmatory (if required)	Not required		

Table 5.3-24: Statement on extraction efficiency

	Method for products of animal origin
Not required, because:	Residues below LOQ

5.3.4.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Flufenacet in soil is given in the following tables. No new methods are necessary.

Table 5.3-4: Validated methods for soil (if appropriate)

Component of residue definition: Flufenacet, FOE 5043 alcohol, FOE 5043 oxalate, FOE 5043-sulfonic acid			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	LOQ=0.01 mg/kg	LC MS/MS	Allmendinger, H., Bachlechner, G. 1994
Confirmatory	Not required		

5.3.4.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Flufenacet in drinking water is given in the following tables. No new method is necessary.

Table 5.3-5: Validated methods for water (if appropriate)

Component of residue definition: Flufenacet				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Drinking water	Primary	LOQ=0.05 µg/L	LC-ESI-MS/MS	DAR of flufenacet 1997 Konig T. 1996: Method for the determination of FOE 5043 in drinking water by gas chromatography. Doc No: MR-894/95
	ILV		Not available	
	Confirmatory	Not required		
Surface water	Primary	0.04 µg/L	HPLC- ESI/MS/MS	Bethem, R.A., Peterson R.G., Leimkuhler, W., Mattern, G.C 1995., II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory	Not required		

Table 5.3-5: Validated methods for water (if appropriate)

Component of residue definition: FOE 5043 sulfonic acid				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Surface water	Primary	0.02 μ g/L	HPLC- ESI/MS/MS	Bethem, R.A., Peterson R.G., Leimkuhler, W., Mattern, G.C 1995., II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory	Not required		

Table 5.3-5: Validated methods for water (if appropriate)

Component of residue definition: FOE 5043 alcohol				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Surface water	Primary	0.04 μ g/L	HPLC- ESI/MS/MS	Bethem, R.A., Peterson R.G., Leimkuhler, W., Mattern, G.C 1995., II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory	Not required		

Table 5.3-5: Validated methods for water (if appropriate)

Component of residue definition: FOE 5043 oxalate				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Surface water	Primary	0.05 μ g/L	HPLC- ESI/MS/MS	Bethem, R.A., Peterson R.G., Leimkuhler, W., Mattern, G.C 1995., II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory	Not required		

Table 5.3-5: Validated methods for water (if appropriate)

Component of residue definition: FOE 5043 thiadone				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Surface water	Primary	0.08 μ g/L	HPLC- ESI/MS/MS	Bethem, R.A., Peterson R.G., Leimkuhler, W., Mattern, G.C

Component of residue definition: FOE 5043 thiadone				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
				1995., II A 4.2.2 to 4.2.4, IIIA 5.2 DAR Flufenacet , B.4: Methods of analysis 1997
	Confirmatory	Not required		

5.3.4.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Flufenacet in air is given in the following tables. No new method necessary.

Table 5.3-6: Validated methods for air (if appropriate)

Component of residue definition: flufenacet			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	2.2 µg/m ³	HPLC-UV	Riegner, K (1995)
Confirmatory		Not required	

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

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

An overview on the acceptable methods and possible data gaps for analysis of Flufenacet in body fluids and tissues is given in the following table. No new methods are necessary.

No methods are necessary, since no MRLs for animal tissues have not been set. No data submitted or required as Flufennacet is not classified as toxic or very toxic.

5.3.4.8 Other studies/ information

No other studies are provided.

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
KCP 5.1.1/01	I. Knapik	2021	Validation of analytical method for CHR/H/FDF 574 SC for determination of florasulam, flufenacet and diflufenican and impurity 2,6-difluoroaniline ICB/109/2020 ICB Pharma, Lema 10 Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 5.2	J.Semrau	2016	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuvant Super in wheat at 4 sites in Northern Europe 2016 EAS Study Code S16-02449 Eurofins Agroscience Services GmbH, Stade, Germany GLP yes Unpublished	N	PUH Chemiroł 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
KCP 5.1.2/01	Rodrigues Junior A.	2011	Residue Metod Validation for the Determination of Florasulam in Agricultural Commodities Das Report No. 110535	N	DAS

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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
			Mogi Mirim Reg. Lab., Brazil GLP yes Unpublished		
KCP 5.1.2/02	Bacher R.	2011	Florasulam: Independet Laboratory Validation of Residue Method for the Determination of Florasulam in Agricultural Commodities. DAS Report No. 110536 PTRL EUROPE Gmbh, Ulm, Germany GLP yes Unpublished	N	DAS
KCP 5.1.2/03	Bacher R.	2011	Method Validation Study for the Determination of Residues of Forasulam in Foodstaff and Animal Origin bt Liquid Chromatography with Tandem Mass Spectrometry DAS Report No. 110540 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished	N	DAS
KCP 5.1.2/04	Robaugh David A.	2012	Independet Laboratory Validation Study for the determination of Residues of Florasulam in Bolvine and Poultry Tissues by Liquid Chromatography with Tandem Mass Spectrometry DAS Report No. 110541 Pyxant Labs Inc., Colorado Srings, USA GLP yes Unpublished	N	DAS
KCP 5.1.2/05	Lindner M.	2011	Examination of the Applicability of the Modular Analytical Method L 00.00-34 for the Determination of Residues of Florasulam DAS Report No. 110671 Eurofins Agrosiences Services Chem Gmbh, Hamburg, Germany GLP yes Unpublished	N	DAS
KCP 5.1.2/06	Bacher R.	2011	Method Validation Study for the Determination of Residues of Florasulam and its 5-OH Metabolite	N	DAS

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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
			in Soil by Liquid Chromatography with Tandem Mass Spectrometry DAS Report No. 110537 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished		
KCP 5.1.2/07	Class T.	2011	Method Validation Study for the Determination of Residues of Florasulam and its 5-0h Metabolite in Surface Water, Ground Water and Drinking Water by Liquid Chromatography with Tandem Mass Spectrometry DAS Report No. 110538 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished	N	DAS
KCP 5.1.2/08	Souza N.	2011	Independet Laboratory Validation of Dow AgroSciences LLC Method – Determination of Residues of Florasulam and its 5-OH Metabolite in Surface Water, Ground Water and Drinking Water ny Liquid Chromatography with Tandem Mass Spectrometry Detection DAS Report No. 110539 Dow AgroSciences Ind., Mogi Mirim, Brazil GLP yes Unpublished	N	DAS
KCP 5.1.2/09	Class T.	2011	The Development and Validationof a Method for the Analysis of Florasulam in Air DAS Report No. 110282 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished	N	DAS
KCP 5.1.2./10	Class T, Göcer M.	2011	Florasulam: Develpoment of an Analytical Method for the Determination of Florasulam in Body Fluid(s) DAS Report No. 110283 PTRL Europe Gmbh, Ulm, Germany	N	DAS

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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
			GLP yes Unpublished		
KCP 5.1/04	Sharpe, J.P.	1984	Herbicides: Diflufenican (M&B 38544) – Analytical procedure for the determination of residues in cereal grain, straw and silage. Generated by: Rhone-Poulenc; May & Baker Ltd., Essex; Environmental Science Department Document No: R000944 GLP / GEP unpublished	N	BCS
KCP 5.1/05	Maycey P.A., Outram J.R.	1987	Herbicides: Diflufenican - Analytical method for the determination residues in cereal leaves, grain and straw Generated by: Rhone-Poulenc; May & Baker Ltd., England; Analytical Chemistry Document No: R001011 GLP / GEP unpublished	N	BCS
KCP 5.1/06	Class, T.	2001	Validation of the DFG S19 multi-residue enforcement method for the determination of diflufenican in wheat Generated by: PTRL Europe, Ulm, DEU; PTRL Europe, Ulm, DEU; Aventis CropScience GmbH, DEU; Residues and Human Exposure, Frankfurt Document No: C013331 GLP / GEP Yes Unpublished	N	BCS
KCP 5.1/07	Bacher R.	2002	Assessment and validation of the multi-residue enforcement method DFG S19 for the determination of diflufenican in plant material Generated by: PTRL Europe, Germany; PTRL Europe, Germany; BCS GmbH, DEU; Residues and Human Exposure, Frankfurt Document No: C028188	N	BCS

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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
			GLP / GEP Yes unpublished		
KCP 5.2/05	Klumpp, M.	2001	Independent laboratory validation of the German multiresidue enforcement method DFG S19 for the determination of diflufenican in wheat green plant, grain and straw Generated by: Arbeitsgemeinschaft. GAB GmbH & IFU GmbH; Aventis CropScience GmbH, DEU; Document No: C018307 GLP / GEP Yes unpublished	N	BCS
KCP 5.2/06	Thom, M.	2003	Independent laboratory validation of the German multiresidue enforcement method DFG S19 for the determination of diflufenican in plant material Generated by: BCS GmbH, DEU; Arbeitsgemeinschaft. GAB GmbH & IFU GmbH,DEU; BCS GmbH, DEU; Industriepark Hoechst, Frankfurt Document No: C031483 GLP / GEP Yes unpublished	N	BCS
KCP 5.2/07	Guillet M., Simonin B.	1996	Diflufenican: Analytical method for the determination of residues in animal products Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon; Centre de Recherche de la Dargoire Rhone-Poulenc Agro; Document No: R002767 GLP / GEP Yes unpublished	N	BCS
KCP 5.2/08	Class, T.	1999	Multi-residue enforcement method for the determination of diflufenican in foodstuff of animal origin Generated by: Rhone-Poulenc; Rhone-Poulenc Agro, Lyon; PTRL Europe,Labor f.Umwelt-und Pestizidchemie, DEU; Rhone-Poulenc Agro, Lyon; Document No: R004321 GLP / GEP Yes	N	BCS

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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
			unpublished		
KCP 5.1/08	Klumpp, M.	2002	Validation of the German multiresidue enforcement method DFG S19 (modified) for the determination of diflufenican in animal tissues (muscle, milk, eggs, fat and liver) Generated by: Arbeitsgemeinschaft. GAB GmbH & IFU GmbH, DEU; Aventis CropScience GmbH, DEU; Document No: C022357 GLP / GEP Yes unpublished	N	BCS
KCP 5.2/09	Sharpe J.P., Hill W.S.	1984	Herbicides: Diflufenican - Analytical procedure for the determination of residues in soil Generated by: Rhone-Poulenc; May & Baker Ltd., Essex, GBR; Environmental Chemistry Department, Ongar Document No: R006375 GLP / GEP unpublished	N	BCS
KCP 5.2/10	Maycey P.A., Outram J.R.	1987	Herbicides: Diflufenican - Analytical method for the determination of residues in dried soil Generated by: Rhone-Poulenc; May & Baker Ltd., England; Analytical Chemistry Document No: R001052 GLP / GEP unpublished	N	BCS
KCP 5.2/11	Brockelsby C.H., Maycey P.A., Savage E.A.	1991	Herbicides: M&B 38181: Analytical method for the determination of residues in soil Generated by: Rhone-Poulenc Agriculture Ltd., Ongar, GBR; Analytical Chemistry Department Document No: C022101 GLP / GEP Yes unpublished	N	BCS
KCP 5.2/12	Doran A.M., McGuire G.M.	2002	Validation of an analytical method to determine residues of Diflufenican and its metabolites M & B 38181 and M & B 43625 in soil Generated by: Inveresk Research International Ltd; Inveresk Research International Ltd; Aventis CropScience GmbH, DEU;	N	BCS

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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
			Document No: C025222 GLP / GEP Yes		
KCP 5.2/13	Bacher R.	2002	Development and validation of an analytical method for the determination of diflufenican in soil Generated by: PTRL Europe, Ulm, DEU; PTRL Europe, Ulm, DEU; BCS GmbH, DEU; Residues and Human Exposure, Frankfurt Document No: C025918 GLP / GEP Yes unpublished	N	BCS
KCP 5.2/14	Bacher, R.	2002	Development and validation of an analytical method for the determination of diflufenican and its metabolites in water Generated by: PTRL Europe GmbH, Ulm, DEU; PTRL Europe GmbH, Ulm, DEU; BCS GmbH, DEU; Residues and Human Exposure, Frankfurt Document No: C026100 GLP / GEP Yes unpublished	N	BCS
KCP 5.2/15	Bacher R.	2002	Analytical method for the determination of Diflufenican in air Generated by: PTRL Europe, Labor f. Umwelt-und Pestizidchemie, DEU; BCS GmbH, DEU; PTRL Europe, Labor f. Umwelt-und Pestizidchemie, DEU; Document No: C025825 GLP / GEP Yes unpublished	N	BCS
KCP 5.1/09	Seym. M	1994	Independent laboratory validation of the residue analytical method for FOE 5043 residues in plant. Bayer AG, Report No.106907, (RA - 352-94) GLP, Unpublished	N	Bayer

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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
KCP 5.1/10	Bajzik, M.E	1995	Independent laboratory validation of the analytical method for the determination of FOE 5043 residues in animal matrices. Source: Huntingdon Analytical Services Bayer AG, Report No. 106913 GLP, Unpublished	N	Bayer
KCP 5.1/11	Gould, T.J., Lemke, V.J., Zoloty, K.L	1995	An analytical method for the determination of FOE 5043 residues in animal matrices. Source: Bayer Corp. Bayer AG, Report No. 106773, method 00418 GLP, Unpublished	N	Bayer
KCP 5.1/12	Seym, M.	1995b	Modification M001 for eggs. Source: Bayer Corp. Bayer AG, Report No. MR-118/95, method 00418/M001 GLP, Unpublished	N	Bayer
KCP 5.1/13	Gould, T.J. Lemke, V.J.	1995	An analytical method for the determination of FOE 5043 residues in plant matrices. Source: Bayer Corp. Bayer AG, Report No. 106406 GLP, Unpublished	N	Bayer

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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
KCP 5.1/14	Seym, M.	1995	Analytical method for the determination of the total residue of FOE 5043 in plant materials. Bayer AG, Report No. MR-981/95, method 00346, Date: 22.09.1995 a) amended: M. Seym, 20.10.1995 GLP, Unpublished	N	Bayer
KCP 5.2/16	Allmendinger, H., Bachlechner G.	1994	Validated method for the determination of the herbicide FOE 5043 and its metabolites FOE 5043 alcohol, FOE 5043 oxalate and FOE 5043 sulfonic acid in soil using HPLC-MS-MS. Bayer AG, Report No. RA-399/94, method 00359 GLP, Unpublished	N	Bayer
KCP 5.2/17	Bethem, R.A., Peterson, R.G., Leimuhler W., Mattern, G.C	1995	Determination of FOE 5043 and the alcohol, oxalate, thiadone and sulfonic acid metabolites in groundwater by high performance liquid chromatography electrospray tandem mass spectrometry (LC-ESI/MS/MS). Source: ALTA Analytical Laboratory Bayer AG, Report No. 107138 (ALTA file No.: AMFOE3) GLP, Unpublished	N	Bayer

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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
KCP 5.2/18	Konig, T.	1996	Method for the determination of FOE 5043 in drinking water by gas chromatography Bayer AG, Report No.: MR-894/95, method No. 00412 GLP, Unpublished	N	Bayer
KCP 5.2/19	Riegner, K.	1995	Method for the determination of FOE 5043 in air. Bayer AG, Report No. MR-798/95, method 00410 GLP, Unpublished	N	Bayer

Appendix 2 Detailed evaluation of submitted analytical methods

No new or additional studies have been submitted

A 2.1 Analytical methods for florasulam

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

No new or additional studies have been submitted

The method has been accepted with the study (see section 7)

Reference:	KCP 5.2
Report	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuvant Super in wheat at 4 sites in Northern Europe 2016, J. Semrau, EAS Study Code S16-02449,
Guideline(s):	SANCO /3029 /99 rev.4.
Deviations:	NO
GLP:	YES
Acceptability:	YES

Materials and methods

The analytical methods multi-residue QuEChERS for the determination of residues of florasulam in wheat (whole plant, grain and straw) was validated according to SANCO/3029/99, rev. 4 within this analytical phase of this study. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical methods was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at each 0.003 mg/kg (30 % of the LOQ). No residues above 30% of the LOQ were detected in the control (untreated) test portions used for recovery determination. All mean recovery values at fortification levels of 0.01 mg/kg (LOQ) and 0.1 mg/kg (10x LOQ) comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev 4, with the evaluation of two mass transitions.

Validation - Results and discussions

Table 5.3-1: Methods suitable for the determination of the residues in plant protection product (PPP) CHR/H/FLO 100 SC

	Residues
Author(s), year	J.Semrau, 2016
Principle of method	LC MS/MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	The linearity of the detector response was demonstrated by single determination of matrix-matched and solvent calibration standards at a minimum of five concentration levels ranging from 0.30 ng/ml to 100 ng/ml for determination of all analytes in wheat (whole plant) and for the determination of florasulam in wheat (grain). This range corresponds to a fortification level of 0.003 mg/kg to 1.0 mg/kg and thus covers the range from no more than 30% of the LOQ and at least +20% of the highest analyte concentration detected in any (diluted) specimen extract. The calibration curves obtained for both mass transitions for each analyte were linear with coefficients of determination (R^2) ≥ 0.980 . Linear regression was performed without any weighting. Representative linear regression curve(s) are below.

	<div>Residues</div> <div></div>														
Quantification	<p>Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The average response factor was used for calculation of the analyte concentrations. The relative standard deviation of the average re-sponse factor was lower or equal to 20 %.</p> <p>If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range. Diluted sample extracts (at least by a factor of 10) were quantified using solvent calibration standards instead of matrix-matched calibration standards.</p>														
Selectivity	<p>The analytes were determined in the final specimen extracts by use of LC MS/MS detection.</p> <p>For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantifi-cation of specimens. Untreated samples for accompanying control sample work up, for determination of (procedural) recoveries and, if needed, for preparation of matrix-matched standards originated from the current study. At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention times of the analytes.</p> <p>Correction for blank values was not performed.</p>														
Matrix Effects	<p>The effect of wheat (whole, plant, grain and straw) on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards with solvent standards at identical concentrations. During validation of the methods following matrix effects were determined:</p> <table><tr><th rowspan="2">Matrix / Com- modity</th><th rowspan="2">Stand- ard Con- centra- tion (ng/mL)</th><th colspan="2">Matrix Effect for Flo- rasulam (%)</th></tr><tr><th>Quantifi- cation (358→167 m/z)</th><th>Confir- mation (358→152 m/z)</th></tr><tr><td>Wheat (whole plant)</td><td>1 - 50</td><td>(+) 4.6</td><td>(+) 6.1</td></tr><tr><td>Wheat (grain)</td><td>1 - 50</td><td>(+) 2.1</td><td>(+) 1.7</td></tr></table>	Matrix / Com- modity	Stand- ard Con- centra- tion (ng/mL)	Matrix Effect for Flo- rasulam (%)		Quantifi- cation (358→167 m/z)	Confir- mation (358→152 m/z)	Wheat (whole plant)	1 - 50	(+) 4.6	(+) 6.1	Wheat (grain)	1 - 50	(+) 2.1	(+) 1.7
Matrix / Com- modity	Stand- ard Con- centra- tion (ng/mL)			Matrix Effect for Flo- rasulam (%)											
		Quantifi- cation (358→167 m/z)	Confir- mation (358→152 m/z)												
Wheat (whole plant)	1 - 50	(+) 4.6	(+) 6.1												
Wheat (grain)	1 - 50	(+) 2.1	(+) 1.7												

	Residues				
	<table><tr><td>Wheat (straw)</td><td>1 - 50</td><td>(-) 7.4</td><td>(-) 3.8</td></tr></table> <p>Matrix effects were < 20 % for Florasulam in wheat (whole plant, grain and straw), the matrix effect were deemed insignificant. Therefore solvent standards were used for quantification.</p> <p>Matrix effects were once again tested during the analysis of the field samples to determine the actually conditions of mass spectrometer system. Matrix effects were < 20 % for Florasulam and in wheat (whole plant) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification of field samples.</p>	Wheat (straw)	1 - 50	(-) 7.4	(-) 3.8
Wheat (straw)	1 - 50	(-) 7.4	(-) 3.8		
LOQ	The limit of quantification (LOQ) was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg				
Comment	The validation parameters are within the acceptance range and fulfil EU requirements given in SANCO/3029/99 rev.4.				

Conclusion

The method was successfully validated for determination of all analytes in all matrices with an LOQ of 0.01 mg/kg according to the guidance document(s) SANCO /3029 /99 rev.4. With regard to selectivity, accuracy and precision, the analytical methods were applied successfully for each analytical set when analysing the specimens of the study,

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)

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

A 2.2 Analytical methods for Diflufenican

A 2.2.1 Methods used for the generation of pre-authorization data (KCP 5.1)

No new or additional studies have been submitted

A 2.2.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)

A 2.2.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.4 Description of Methods for the Analysis of Water (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.5 Description of Methods for the Analysis of Air (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.7 A.2.A.9 Other Studies/ Information

No new or additional studies have been submitted

A 2.3 Analytical methods for Flufenacet

A 2.3.1 Methods used for the generation of pre-authorization data (KCP 5.1)

No new or additional studies have been submitted

A 2.3.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)

A 2.3.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.3.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.3.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)

No new or additional studies have been submitted

A 2.3.2.4 Description of Methods for the Analysis of Water (KCP 5.2)

No new or additional studies have been submitted

A 2.3.2.5 Description of Methods for the Analysis of Air (KCP 5.2)

No new or additional studies have been submitted

A 2.3.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)

No new or additional studies have been submitted

A 2.3.2.7 A.2.A.9 Other Studies/ Information

No new or additional studies have been submitted